Proposed Preferred Drug List

with

Prior Authorization Criteria

Proposal for TennCare

November 7, 2024

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TennCare Pharmacy Advisory Committee Meeting

November 7th, 2024 9:30 AM - 3:30 PM CST

Microsoft Teams Meeting: Click here to join the meeting
Meeting ID: 243 787 331 651
Meeting Phone Number: +1 (952)-222-7450; Phone Conference ID: 544 252 803#

Welcome and Introduction of Members
Approval of Minutes from Previous Meeting
Auto-Exempt Subcommittee Updates
Follow-up Items from Previous Meeting
TennCare Update
TennCare Pharmacy Update
Public Testimony
New Drug Approvals and Drug Class Reviews

New Drug Approvals (in presenting order)

- LYBALVI **(RE-REVIEW)**
- MIRCERA
- OHTUVAYRE
- TRYVIO
- VOQUEZNA TABLETS
- VORANIGO
- XOLREMDI

Note: The following new drug will be reviewed in their respective drug class review: EBGLYSS, RINVOQ LQ

TennCare Pharmacy Initiatives (Drug Class Reviews)

Standard Reviews

- Dermatologics
  - Antipsoriatics, Topical
  - Antifungals, Topical
  - Atopic Dermatitis Agents, Topical
- Immunologic
  - Immunomodulators
    - TNF Inhibitors
    - Interleukin Inhibitors
    - Miscellaneous
  - Anti-Rheumatic: Kinase Inhibitors
  - Anti-inflammatory: Immunoglobulins
- Central Nervous System
  - Sedative Hypnotic Agents

Abbreviated Reviews *

- Dermatologics
  - Acne Agents, Topical
  - Agents for Burns, Topical
  - Agents for Rosacea, Topical
  - Anesthetics, Topical
  - Antibiotics, Topical
  - Antineoplastics, Topical
  - Antipruritics/Antihistamines, Topical
  - Pediculocides/Scabicides
  - Retinoids, Oral
  - Retinoids, Topical
  - Topical Steroids: Least Potent
  - Topical Steroids: Mild
  - Topical Steroids: Lower Mid-Strength
  - Topical Steroids: Mid-Strength
  - Topical Steroids: Upper Mid-Strength
  - Topical Steroids: Potent
  - Topical Steroids: Super Potent
- Central Nervous System
  - Agents for Neuropathic Pain and Fibromyalgia
  - Agents for Restless Leg Syndrome
  - Alzheimer's: NMDA Receptor Antagonists
  - Cholinergic Muscle Stimulants
  - Movement Disorders
  - Skeletal Muscle Relaxants
- Endocrine and Metabolic
  - Disease Modifying Anti-Rheumatic Drugs (DMARDs)

Low Utilization Classes *

- Dermatologics
  - Antipsoriatics, Oral
  - Anti-seborrheic Agents
  - Emollients
  - Genital Warts
  - Keratolytic Agents
  - Topical Antivirals
- Central Nervous System
  - Alzheimer's: Cholinesterase Inhibitors
  - Analeptics
  - Miscellaneous CNS Agents

Review of Grayed Out Packet from Previous Meeting

Adjournment

Responsibilities of the TennCare Pharmacy Advisory Committee

Source: Tennessee Code/Title 71 Welfare/Chapter 5 Programs and Services for Poor Persons/Part 24 Tennessee TennCare Pharmacy Advisory Committee/71-5-2401 through 71-5-2404.

Make recommendations regarding a preferred drug list (PDL) to govern all state expenditures for prescription drugs for the TennCare program.

The TennCare Pharmacy Advisory Committee shall submit to the bureau of TennCare both specific and general recommendations for drugs to be included on any state PDL adopted by the bureau. In making its recommendations, the committee shall consider factors including, but not limited to, efficacy, the use of generic drugs and therapeutic equivalent drugs, and cost information related to each drug. The committee shall also submit recommendations to the bureau regarding computerized, voice, and written prior authorization, including prior authorization criteria and step therapy.

The state TennCare pharmacy advisory committee shall include evidence-based research in making its recommendations for drugs to be included on the PDL.

The TennCare bureau shall consider the recommendations of the state TennCare pharmacy advisory committee in amending or revising any PDL adopted by the bureau to apply to pharmacy expenditures within the TennCare program. The recommendations of the committee are advisory only and the bureau may adopt or amend a PDL regardless of whether it has received any recommendations from the committee. It isthe legislative intent that, insofar as practical, the TennCare bureau shall have the benefit of the committee's recommendations prior to implementing a PDL or portions thereof.

Keep minutes of all meetings including votes on all recommendations regarding drugs to be included on the state preferred drug list

The chair may request that other physicians, pharmacists, faculty members of institutions of higher learning, or medical experts who participate in various subspecialties act as consultants to the committee as needed.

PDL Decision Process

- The primary clinical decision that needs to be made is determining if the drugs within the therapeutic class of interest can be considered therapeutic alternatives.
- A **Therapeutic Alternative** is defined by the AMA as: "drug products with different chemical structures but which are of the same pharmacological and/or therapeutic class, and usually can be expected to have similar therapeutic effects and adverse reaction profiles when administered to patients in therapeutically equivalent doses"[1].
- The Committee should not feel obligated to decide if every drug within the therapeutic class is exactly equal to all other drugs within the class, nor should they feel obligated to decide if every drug within the therapeutic class works equally well in every special patient population or in every disease.
- In special situations (e.g., presence of comorbid conditions) and in special populations (e.g., pediatrics) use of a non- preferred drug might be the most appropriate therapy. These cases can be handled through prior authorization (PA). PA serves as a "safety valve" in that it facilitates use of the most appropriate agent regardless of PDLstatus.

[1] AMA Policy H-125.991 Drug Formularies and Therapeutic Interchange

LENGTH OF AUTHORIZATIONS: Dependent upon diagnosis and length of therapy needed to treat. (Most medications are used chronically, and thus would be approved for 1 year.)

- Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class?

  Acceptable reasons include:

  - **Allergy** to medications not requiring prior approval
  - **Contraindication** to or drug-to-drug interaction with medications not requiring prior approval
  - **History** of unacceptable/toxic side effects to medications not requiring prior approval

- The requested medication may be approved if both of the following are true:

  - If there has been a therapeutic failure of at least two medications within the same class not requiring prior approval (unless otherwise specified)

  - Approval of a branded product when a generic is available requires documentation of a serious adverse reaction from the generic via a FDA MedWatch form **OR** contraindication to an inactive ingredient in the AB-rated generic equivalent. Therapeutic Failure of an AB-rated generic equivalent may be considered for approval of branded products in the following high-risk medication classes: Anticonvulsants, Atypical Antipsychotics, HIV antivirals, Immunosuppressants, and Oncology Agents.

- The requested medication may be approved if the following is true:

  - An indication which is unique to a non-preferred agent and is supported by peer-reviewed literature or an FDA approved indication exists.

The information provided for each drug class is organized into the following sections, when applicable:

BACKGROUND:

1. General overview
2. Pharmacology
3. Therapeutic effect(s)
4. Adverse reactions
5. Outcome's data
6. Place in therapy according to current Treatment Guidelines

New Drug Reviews

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LYBALVI

Re-Review: New Drug Review

PDL Placement:

Antipsychotics: Atypical

Preferred		Non-Preferred	
ABILIFY ASIMTUFII PA, QL (aripiprazole)	lurasidone PA, QL	ABILIFY tabs PA, QL (aripiprazole)	RISPERDAL CONSTA PA, QL (risperidone)
ABILIFY MAINTENA PA, QL (aripiprazole)	olanzapine tabs QL	ABILIFY MYCITE PA, QL (aripiprazole)	risperidone ER injection PA, QL
aripiprazole ODT QL	olanzapine injection PA, QL	asenapine PA, QL	RYKINDO PA, QL (risperidone)
aripiprazole soln QL	olanzapine ODT PA, QL	CAPLYTA PA, QL (lumateperone)	SECUADO PA, QL (asenapine)
aripiprazole tabs QL	paliperidone tabs QL	clozapine ODT PA, QL	SEROQUEL PA, QL (quetiapine)
ARISTADA PA, QL (aripiprazole lauroxil)	PERSERIS PA, QL (risperidone)	CLOZARIL PA, QL (clozapine)	SEROQUEL XR PA, QL (quetiapine)
ARISTADA INITIO PA, QL (aripiprazole lauroxil)	quetiapine QL	FANAPT PA, QL (iloperidone)	VERSACLOZ PA (clozapine)
clozapine QL	quetiapine ER PA, QL	GEODON caps & injection PA, QL (ziprasidone)	ZYPREXA tabs PA, QL (olanzapine)
INVEGA HAFYERA PA, QL (paliperidone)	risperidone tabs QL	INVEGA PA, QL (paliperidone)	ZYPREXA IM PA, QL (olanzapine)
INVEGA SUSTENNA PA, QL (paliperidone)	risperidone ODT PA, QL	LATUDA PA, QL (lurasidone)	ZYPREXA RELPREVV PA, QL (olanzapine)
INVEGA TRINZA PA, QL (paliperidone)	risperidone soln PA, QL	LYBALVI PA, QL (olanzapine/ samidorphan)	ZYPREXA ZYDIS PA, QL (olanzapine)
	SAPHRIS PA, QL (asenapine)	NUPLAZID PA, QL (pimavanserin)	
	UZEDY PA, QL (risperidone)	REXULTI PA, QL (brexpiprazole)	
	VRAYLAR PA, QL (cariprazine)	RISPERDAL PA, QL (risperidone)	
	ziprasidone injection PA, QL		
	ziprasidone caps QL		

Background

LYBALVI (olanzapine/samidorphan) is a combination therapy agent approved in adults for the treatment of schizophrenia, for the acute treatment of manic or mixed episodes of bipolar I disorder as monotherapy or adjunct to lithium or valproate, and for the maintenance treatment of bipolar I disorder as monotherapy. Olanzapine is an atypical antipsychotic and samidorphan is an opioid antagonist. Samidorphan decreases olanzapine-associated changes in fat mass via blockade of adipose glucose uptake and/or by preventing olanzapine-induced insulin resistance. This combination agent offers an additional option for treatment of these conditions and has demonstrated less weight gain as compared to other antipsychotic agents.

Antipsychotic drugs can cause metabolic changes, including hyperglycemia, diabetes mellitus, dyslipidemia, and weight gain. Although all of the drugs in the class have been shown to produce some metabolic changes, each drug has its own specific risk profile. Clozapine and olanzapine have been associated with the highest risks. Aripiprazole, lurasidone, and ziprasidone have been associated with lower risks. Despite the stratified risks, routine monitoring of metabolic measures is recommended for patients on all antipsychotics.

LYBALVI is available as 5 mg/10mg, 10 mg/10 mg, 15 mg/10 mg, and 20 mg/10 mg tablets and dosed once daily. LYBALVI carries a boxed warning for increased mortality in elderly patients with dementia-related psychosis. LYBALVI is contraindicated in patients using opioids and in patients undergoing acute opioid withdrawal. Adverse reactions to LYBALVI varied between each indication but the most common between them were dry mouth, weight increase, and somnolence.

Class Recommendation

In order to best meet patient and prescriber needs, several oral and long-acting injectable agents representing a variety of side effect profiles should be available for use. It is recommended that clozapine should be available for use due to its unique indication for treatment resistant schizophrenia and patients at high risk of suicidality.

The above class has been previously presented in its entirety to the PAC Committee and is being provided for reference purposes only.

Prior Authorization criteria for LYBALVI

Current Criteria:

- Patient is ≥18 years of age; **AND**
- One of the following:
  - Diagnosis of schizophrenia
  - Diagnosis of Bipolar I disorder and will be used for the acute treatment of manic or mixed episodes
  - Diagnosis of Bipolar I disorder and will be used as maintenance monotherapy treatment
- Prescriber must attest that patient does not meet any of the following:
  - Patient is using opioids or has used a short-acting opioid in the last 7 days or a long-acting opioid in the last 14 days
  - Patient is undergoing acute opioid withdrawal; **AND**
- Clinically valid reason why preferred olanzapine formulations cannot be used

Proposed Criteria:

- Patient is ≥18 years of age; **AND**
- One of the following:
  - Diagnosis of schizophrenia
  - Diagnosis of Bipolar I disorder and will be used for the acute treatment of manic or mixed episodes
  - Diagnosis of Bipolar I disorder and will be used as maintenance monotherapy treatment; **AND**
- Prescriber must attest that patient does not meet any of the following:
  - Patient is using opioids or has used a short-acting opioid in the last 7 days or a long-acting opioid in the last 14 days
  - Patient is undergoing acute opioid withdrawal; **AND**
- ~~Clinically valid reason why preferred olanzapine formulations cannot be used~~
- *Approval of non-preferred atypical antipsychotics requires trial and failure of ONE preferred agent;* ***AND***
- *Submission of medical records (e.g. chart notes) documenting ONE of the following:*
  - *Patient has a BMI of 30 kg/m2 or greater*
  - *Patient has a BMI of 27 kg/m2 or greater with a weight-related comorbidity (e.g., dyslipidemia, hypertension, type 2 diabetes, sleep apnea)*
  - *Patient has a documented history of weight gain of greater than or equal to 10% of their baseline weight after trial and failure of a preferred atypical antipsychotic*
  - *Patient is stable on* Lybalvi *(minimum trial duration 4 weeks) and the request is for continuation of therapy*

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• LYBALVI	1/day

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- Correll CU, Newcomer JW, Silverman B, et al. Effects of olanzapine combined with samidorphan on weight gain in schizophrenia: a 24-week phase 3 study. Am J Psychiatry. 2020;177(12):1168-1178.
- Jibson MD. Second-generation antipsychotic medications: pharmacology, administration, and side effects. UpToDate Web site. Updated September 08, 2021. www.uptodate.com. Accessed November 29, 2021.
- Lybalvi (olanzapine and samidorphan) [prescribing information]. Waltham, MA: Alkermes Inc; January 2024.
- Martin, William F et al. "Mitigation of Olanzapine-Induced Weight Gain With Samidorphan, an Opioid Antagonist: A Randomized Double-Blind Phase 2 Study in Patients With Schizophrenia." *The American journal of psychiatry* vol. 176,6 (2019): 457-467. doi:10.1176/appi.ajp.2018.18030280

MIRCERA

New Drug Review

PDL Placement:

	Preferred	Non-Preferred	
Hematopoietic Agents	RETACRIT PA (epoetin alfa)	ARANESP PA (darbepoetin alfa) EPOGEN PA (epoetin alfa) JESDUVROQ PA (daprodustat)	MIRCERA PA (methoxy polyethylene glycol-epoetin beta) PROCRIT PA (erythropoietin)

Background

MIRCERA (methoxy polyethylene glycol-epoetin beta) is an erythropoiesis-stimulating agent (ESA) indicated for the treatment of anemia associated with chronic kidney disease (CKD) in adult patients and for pediatric patients 3 months to 17 years of age who are converting from another ESA after their hemoglobin level was stabilized with an ESA. Erythropoietin is a naturally occurring glycoprotein hormone that stimulates the production and maturation of red blood cells in the bone marrow. MIRCERA, a modified recombinant human erythropoietin, has a considerably longer half-life than other ESAs and should be dosed once every 2 weeks for anemia correction and once every 4 weeks for maintenance of hemoglobin (Hb) levels.

In June 2011, the FDA released more conservative recommendations for using the ESAs in patients with anemia of CKD resulting from data showing that using ESAs to target a Hb level of > 11 g/dL increased the risk of cardiovascular events, without providing any additional benefit to patients. For patients with anemia of CKD who are not on dialysis, ESA treatment can be considered when the Hb level is < 10 g/dL, and the dose should be reduced or interrupted when Hb exceeds 10 g/dL. For patients with anemia of CKD currently on dialysis, ESA treatment should be initiated when the Hb level is < 10 g/dL and the dose should be reduced or interrupted when Hb approaches or exceeds 11 g/dL. The Kidney Disease Improving Global Outcomes (KDIGO) do not specify a preferred agent for anemia of CKD. The iron status in all patients should be evaluated before and during treatment, and iron repletion maintained.

MIRCERA is available for intravenous or subcutaneous injection. Recommended dosing is weight based, dependent on dialysis status, and current treatment with an ESA. MIRCERA is not recommended in the treatment of anemia due to cancer chemotherapy or as a substitute for red blood cell transfusions in patients who require immediate correction of anemia. MIRCERA is contraindicated in patients with uncontrolled hypertension or pure red cell aplasia (PRCA) that begins after treatment with MIRCERA or other erythropoietin protein drugs. The most common adverse reactions are hypertension, diarrhea, and nasopharyngitis.

Class Recommendation

In order to ensure provider choice, it is recommended that at least one distinct erythropoietin agent be available for use. Due to the significant risks associated with use of the ESAs, it is recommended that all agents in the class be subject to clinical criteria.

The above class has been previously presented in its entirety to the PAC Committee and is being provided for reference purposes only.

Prior Authorization criteria for MIRCERA

Interim Criteria:

Initial Criteria

- Lab values obtained within 30 days of the date of administration; **AND**
- Adequate iron stores demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20%; **AND**
- One of the following:
  - Diagnosis of anemia secondary to chronic kidney disease (CKD) in adult patients and BOTH of the following:

        - Patient is 18 years of age or older
        - Hemoglobin (Hb) is < 10 g/dL
    - Diagnosis of anemia secondary to CKD in pediatric patients and BOTH of the following:
        - Patient is between 3 months and 17 years of age
        - Patient's hemoglobin stabilized following administration of another erythropoietin stimulating agent (ESA) (e.g., Retacrit, Aranesp, Procrit, Epogen); **AND**
- Patient will not use Mircera in combination with another ESA agent; **AND**
- Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out

Renewal Criteria

- Last dose < 60 days ago; **AND**
- Patient will not use Mircera in combination with another ESA agent; **AND**
- Lab values obtained within 30 days of the date of administration demonstrating BOTH of the following:
    - Adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% measured within the previous 3 months;
    - Increase or stabilization of hemoglobin from baseline

Proposed Criteria:

Initial Criteria

- Lab values obtained within 30 days of the date of administration; **AND**
- Adequate iron stores demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20%; **AND**
- One of the following:
    - Diagnosis of anemia secondary to chronic kidney disease (CKD) in adult patients and BOTH of the following:
        - Patient is 18 years of age or older
        - *Baseline* Hemoglobin (Hb) is < 10 g/dL
    - Diagnosis of anemia secondary to CKD in pediatric patients and BOTH of the following:
        - Patient is between 3 months and 17 years of age
        - Patient's hemoglobin stabilized following administration of another erythropoietin stimulating agent (ESA) (e.g., Retacrit, Aranesp, Procrit, Epogen); **AND**
- Patient will not use Mircera in combination with another ESA agent; **AND**
- Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out

Renewal Criteria

- Last dose < 60 days ago; **AND**
- Patient will not use Mircera in combination with another ESA agent; **AND**
- Lab values obtained within 30 days of the date of administration demonstrating BOTH of the following:
    - Adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% measured within the previous 3 months;
    - Increase or stabilization of hemoglobin from baseline

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- Food and Drug Administration Drug Safety Communication. Modified dosing recommendations to improve the safe use of erythropoiesis-stimulating agents (ESAs) in chronic kidney disease. FDA Web site. June 24, 2011. . Accessed February 14, 2024
- Hörl WH. Differentiating factors between erythropoiesis-stimulating agents: an update to selection for anaemia of chronic kidney disease. Drugs. 2013;73(2):117-130. doi: 10.1007/s40265-012-0002-2.
- Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO clinical practice guideline for anemia in chronic kidney disease. Kidney Int Suppl. 2012;2(4):279-335. https://kdigo.org/guidelines/anemia-in-ckd/. Accessed February 14, 2024.
- Mircera (methoxy polyethylene glycol-epoetin beta) [prescribing information]. Gallen, Switzerland: Vifor (International) Inc; June 2024.

OHTUVAYRE

New Drug Review

PDL Placement:

	Preferred	Non-Preferred
Phosphodiesterase 4 Inhibitors	roflumilast PA, QL	DALIRESP PA, QL (roflumilast) *OHTUVAYRE PA, QL (ensifentrine)*

Background

OHTUVAYRE (ensifentrine) is a phosphodiesterase 3 (PDE3) inhibitor and phosphodiesterase 4 (PDE4) inhibitor indicated for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients. This a first-in-class selective dual inhibition of both enzymes is believed to have a bronchodilator and non-steroidal anti-inflammatory effect.

The main treatment goals in COPD are to reduce symptoms and the risk of future exacerbations. The primary initial maintenance treatments are long-acting muscarinic antagonist (LAMA) or long-acting beta-agonist (LABA) monotherapy or combination LAMA + LABA. In patients with a higher risk of exacerbations, an inhaled corticosteroid may be added; however, this is primarily recommended in patients with a blood eosinophil level of ≥ 300 cells/µL as these are the patients most likely to benefit. Additional treatments appropriate for some patients include roflumilast, an oral PDE 4 inhibitor indicated to decrease the risk of COPD exacerbations in patients with chronic bronchitis and a history of exacerbations, and azithromycin, an oral macrolide antibiotic.

OHTUVAYRE is available as 3 mg/2.5 mL aqueous suspension in unit-dose ampules. The recommended dose is 3 mg (one ampule) twice daily administered by oral inhalation using a standard jet nebulizer with a mouthpiece. The most common adverse reactions are back pain, hypertension, urinary tract infection, and diarrhea.

Class Recommendation

This class of drugs is indicated for a targeted patient population for COPD; therefore, it is recommended roflumilast be subject to clinical criteria.

The above class has been previously presented in its entirety to the PAC Committee and is being provided for reference purposes only.

Prior Authorization criteria for OHTUVAYRE

Interim Criteria:

- Patient must be ≥ 18 years of age; **AND**
- Diagnosis of Chronic Obstructive Pulmonary Disorder (COPD); **AND**
- Trial and failure (as defined by continued symptoms, including exacerbations) of adequate treatment with a long-acting beta-agonist + long-acting antimuscarinic; **AND**
- Must be used as maintenance therapy only

Proposed Criteria:

- Patient must be ≥ 18 years of age; **AND**
- Diagnosis of Chronic Obstructive Pulmonary Disorder (COPD); **AND**
- *Submission of medical records (e.g. chart notes) that patient meets ALL the following:*
  - *Bronchodilator FEV1/FVC ratio of <0.7*
  - *FEV1 % predicted of ≤ 79%*
  - *modified Medical Research Council (mMRC) dyspnea scale score of ≥ 2; **AND***
- *One of the following:*

- *Trial and failure (as defined by continued symptoms, including exacerbations) of adequate treatment concomitantly with a long-acting beta-agonist (LABA) + long-acting antimuscarinic (LAMA) + inhaled corticosteroid;* ***OR***
- Trial and failure (as defined by continued symptoms, including exacerbations) of adequate treatment concomitantly with a long-acting beta-agonist *(LABA) and* long-acting antimuscarinic *(LAMA)*; **AND**

- *Medication* must be used as maintenance therapy only

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• OHTUVAYRE	2 ampules/day

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. 2024. https://goldcopd.org/2024-gold-report/. Accessed July 15, 2024.
- OHTUVAYRE(TM) oral inhalation, ensifentrine oral inhalation. Verona Pharma (Per Manufacturer), Raleigh, NC, 2024.
- "Verona Pharma Announces US FDA Approval of Ohtuvayre (ensifentrine)". Verona Pharm. June 26, 2024. https://www.veronapharma.com/news/verona-pharma-announces-us-fda-approval-of-ohtuvayre-ensifentrine/.

TRYVIO

New Drug Review

PDL Placement:

	Preferred	Non-Preferred	
Cardiac Agents, Miscellaneous	ranolazine ER [QL]	ASPRUZYO SPRINKLE [PA, QL] (ranolazine) CAMZYOS [PA, QL] (mavacamten) CORLANOR [PA, QL] (ivabradine)	RANEXA [PA, QL] (ranolazine) *TRYVIO [PA, QL] (aprocitentan)* VERQUVO [PA, QL] (vericiguat)

Background

TRYVIO (aprocitentan) is indicated for the treatment of hypertension in combination with other antihypertensive drugs, to lower blood pressure in adult patients who are not adequately controlled on other drugs. TRYVIO is the first dual endothelin receptor antagonist (ERA) FDA approved for the treatment of hypertension. TRYVIO lowers blood pressure primarily by inhibiting aldosterone production.

According to guidelines from the American College of Cardiology (ACC) and the American Heart Association (AHA), hypertension is defined as systolic blood pressure (SBP) ≥ 130 millimeters of mercury (mmHg) and/or diastolic blood pressure (DBP) ≥ 80 mmHg. Combination pharmacotherapy using agents from different pharmacologic classes is often needed to achieve BP goals. The primary agents used in the treatment of hypertension include thiazide diuretics, angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), and calcium channel blockers (CCBs). The diagnosis of resistant hypertension is made when a patient takes 3 antihypertensive medications with complementary mechanisms of action (of which a diuretic should be a component) but does not achieve control, or when BP control is achieved but requires ≥ 4 medications. Guidelines recommend a mineralocorticoid receptor antagonist (MRA) or beta blockers for patients with resistant hypertension.

TRYVIO is available as 12.5 mg tablets. The recommended dosage is 12.5 mg orally once daily. TRYVIO carries a boxed warning for embryo-fetal toxicity. Therefore, TRYVIO is only available through a restricted distribution program called TRYVIO REMS for patients who can become pregnant. The most common adverse reactions are edema, fluid retention, and anemia.

Class Recommendation

It is recommended that vericiguat is available and subject to prior authorization criteria.

The above class has been previously presented in its entirety to the PAC Committee and is being provided for reference purposes only.

Prior Authorization criteria for TRYVIO

Interim Criteria:

Initial Criteria: (6-month duration)

- Patient is 18 years of age or older; **AND**
- Diagnosis of resistant hypertension; **AND**
- Submission of medical records (e.g. chart notes) documenting patient has not achieved target blood pressure (e.g. systolic <130) following concurrent treatment with at least THREE of the following antihypertensive classes unless contraindicated or intolerance:
  - ACE inhibitors or Angiotensin II receptor blockers (ARBs)
  - Beta blockers
  - Calcium channel blockers
  - Mineralocorticoid Receptor Antagonists
  - Thiazide diuretics; **AND**
- Tryvio will be used in combination with at least one other hypertensive drug

Renewal Criteria

- Submission of medical records (e.g. chart notes) documenting a positive clinical response to therapy (e.g. decrease of systolic blood pressure from baseline); **AND**
- Patient is receiving concomitant therapy with other hypertensive drugs (documented by claims or medical records)

Proposed Criteria:

Initial Criteria: (6-month duration)

- Patient is 18 years of age or older; **AND**
- Diagnosis of resistant hypertension; **AND**
- Submission of medical records (e.g. chart notes) documenting patient has not achieved target blood pressure (e.g. systolic <130/*80*) following concurrent *maximumly tolerated* treatment with at least THREE of the following antihypertensive classes unless contraindicated or intolerance:
  - ACE inhibitors or Angiotensin II receptor blockers (ARBs)
  - Beta blockers
  - Calcium channel blockers
  - Mineralocorticoid Receptor Antagonists
  - Thiazide diuretics; **AND**
- Tryvio will be used in combination with at least one other hypertensive drug

Renewal Criteria

- Submission of medical records (e.g. chart notes) documenting a positive clinical response to therapy (e.g. decrease of systolic blood pressure from baseline); **AND**
- Patient is receiving concomitant therapy with other hypertensive drugs (documented by claims or medical records)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• TRYVIO	1/day

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- Tryvio (aprocitentan) [prescribing information]. Radnor, PA: Idorsia Pharmaceuticals US Inc; March 2024.
- "US FDA approves Idorsia's once-daily TRYVIO (aprocitentan) – the first and only endothelin receptor antagonist for the treatment of high blood pressure not adequately controlled in combination with other antihypertensives". Idorsia Pharmaceuticals. March 20, 2024. https://www.idorsia.com/media/news/news-archive/media-release-details?id=3195250
- Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: A report of the American College of Cardiology/American Heart Association task force on clinical practice guidelines. J Am Coll Cardiol. 2018;71(19):e127-e248.

VOQUEZNA TABLETS

New Drug Review

PDL Placement:

	Preferred	Non-Preferred	
Proton Pump Inhibitors	DEXILANT [QL] (dexlansoprazole) esomeprazole [QL] lansoprazole [QL] NEXIUM packs [PA, QL] (esomeprazole) omeprazole caps, ODT, and tabs [QL] omeprazole/sodium bicarbonate [QL] pantoprazole [QL] PROTONIX PACKS [QL] (pantoprazole)	ACIPHEX [QL] (rabeprazole) dexlansoprazole [QL] esomeprazole susp packs [QL] FIRST-LANSOPRAZOLE [PA ≥ 6 yr old] KONVOMEP [PA ≥ 6 yr old, QL] (omeprazole/sodium bicarbonate) lansoprazole ODT [PA, QL] NEXIUM [QL] (esomeprazole) pantoprazole pack	PREVACID [QL] (lansoprazole) PREVACID SOLUTAB [PA, QL] (lansoprazole) PRILOSEC [QL] (omeprazole) PROTONIX tabs [QL] (pantoprazole) rabeprazole [QL] *VOQUEZNA (vonoprazan)* ZEGERID [QL] (omeprazole/sodium bicarbonate)

Background

VOQUEZNA tablet (vonoprazan) is a potassium-competitive acid blocker (PCAB). VOQUEZNA suppresses basal and stimulated gastric acid secretion at the secretory surface of the gastric parietal cell through inhibition of the H+K+-ATPase enzyme system in a potassium competitive manner. Because this enzyme is regarded as the acid (proton) pump within the parietal cell, vonoprazan has been characterized as a type of gastric proton-pump inhibitor, in that it blocks the final step of acid production. VOQUEZNA is approved for the following indications: for healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults, to maintain healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults, and for the relief of heartburn associated with non-erosive gastroesophageal reflux disease (GERD) in adults.

The American College of Gastroenterology (ACG) clinical guideline for the diagnosis and management of GERD and the American Gastroenterological Association (AGA) clinical guidelines on evaluation of management of GERD recommend an 8-week trial of a proton pump inhibitor (PPI) for patients with classic GERD symptoms. For patients with an inadequate response, dosing can be increased to twice daily or switched to a more effective acid suppressive agent once daily. For switch therapy, a more potent PPI, one that is less metabolized through the CYP2C19 pathway (e.g., rabeprazole, esomeprazole), or available in an extended-release formulation (e.g., dexlansoprazole), as well as PCABs can be considered.

VOQUEZNA is available as 10 mg and 20 mg oral tablets dosed once daily. The higher dose is reserved for active treatment of erosive esophagitis. VOQUEZNA is contraindicated in patients with a known hypersensitivity to vonoprazan or any component and with rilpivirine-containing products. The most common adverse reactions are abdominal pain, constipation, diarrhea, nausea, and urinary tract infections. VOQUEZNA is also available in combination with amoxicillin and clarithromycin as a Triple & Dual pack for the treatment of *H. pylori* infection.

Class Recommendation

It is recommended that at least two agents be available for use. In addition, it is recommended that at least one liquid or dispersible tablet formulation, along with at least one compoundable dosage form, be available

The above class has been previously presented in its entirety to the PAC Committee and is being provided for reference purposes only.

Prior Authorization criteria for VOQUEZNA TABLETS

Interim Criteria:

- Patient is 18 years of age or older; **AND**
- One of the following diagnoses:
  - Active treatment of erosive esophagitis **(2- month approval duration); OR**

- Maintenance treatment of healed erosive esophagitis **(6- month approval duration); AND**
  - Request is for Voquezna 10 mg tablets; **OR**
- Non-erosive gastroesophageal reflux disease (GERD) **(1- month approval duration); AND**
  - Request is for Voquezna 10 mg tablets; **AND**

- Trial and failure, contraindication, or intolerance to TWO preferred proton pump inhibitors (e.g. Dexilant, esomeprazole, lansoprazole, omeprazole, and pantoprazole)

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

- VOQUEZNA TABLETS
  - 20 MG: 1/day; 2 months (60 days) per year
  - 10 MG: 1/day; 6 months (180 days) per year

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

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- "Phathom Pharmaceuticals Announces FDA Approval of VOQUEZNA (vonoprazan) Tablets for the Relief of Heartburn Associated with Non-Erosive GERD in Adults". Phathom Pharmaceuticals. July 18, 2024. https://investors.phathompharma.com/news-releases/news-release-details/phathom-pharmaceuticals-announces-fda-approval-voqueznar-0
- Voquezna (vonoprazan) [prescribing information]. Buffalo Grove, IL: Phathom Pharmaceuticals Inc; July 2024.
- Voquezna Triple-Pak and Voquezna Dual-Pak [package insert], Buffalo Grove, IL: Phathom Pharmaceuticals, Inc.; November 2023.
- Yadlapati R, Gyawali CP, Pandolfino JE on behalf of the CGIT GERD Consensus Conference Participants. AGA clinical practice update on the personalized approach to the evaluation and management of GERD: Expert review. Clin Gastroenterol Hepatol. 2022;20:984-994.

VORANIGO

New Drug Review

PDL Placement:

	Preferred	Non-Preferred
Isocitrate Dehydrogenase (IDH)	IDHIFA (enasidenib) TIBSOVO QL (ivosidenib)	REZLIDHIA PA, QL (olutasidenib) *VORANIGO PA, QL (vorasidenib)*

Background

VORANIGO (vorasidenib) is indicated for the treatment of adult and pediatric patients 12 years of age and older with Grade 2 astrocytoma or oligodendroglioma with a susceptible IDH1 or IDH2 mutation following surgery including biopsy, sub-total resection, or gross total resection.

VORANIGO is available as 10 mg and 40 mg tablets. In adults and pediatric patients 12 years of age and older weighing at least 40 kg, the recommended dosage is 40 mg orally once daily. In pediatric patients 12 years of age and older weighing less than 40 kg, the recommended dose is 20 mg orally once daily. Treatment should be continued until disease progression or unacceptable toxicity. The most common adverse reactions include fatigue, headache, COVID-19, musculoskeletal pain, diarrhea, nausea, and seizure. The most common laboratory abnormalities include increased ALT, AST, and GGT and decreased neutrophil count.

Class Recommendation

Any new oncology agents with clinical efficacy or authoritative guidelines supporting their use will be available for use with prior authorization criteria until brought back to PAC for review.

The above class has been previously presented in its entirety to the PAC Committee and is being provided for reference purposes only.

Prior Authorization criteria for VORANIGO

Interim Criteria:

Initial Criteria:

- Diagnosis of grade 2 astrocytoma or oligodendroglioma; **AND**
- Tumor has susceptible isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) mutation; **AND**
- Patient has had prior surgery including biopsy, sub-total resection, or gross total resection; **AND**
- Prescribed by, or in consultation with, an oncologist

Renewal Criteria:

- Patient continues to meet initial criteria; **AND**
- Patient does not show evidence of progressive disease or unacceptable toxicity (e.g., hepatoxicity)

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• VORANIGO 40 MG	1/day
• VORANIGO 10 MG	2/day

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- "Servier's VORANIGO (vorasidenib) tablets receives FDA approval as first targeted therapy for Grade 2 IDH-mutant glioma". Servier Pharmaceuticals. August 6, 2024. https://servier.us/blog/serviers-voranigo-vorasidenib-tablets-receives-fda-approval-as-first-targeted-therapy-for-grade-2-idh-mutant-glioma/?utm_campaign=vora_ann_webbanner_popup
- Voranigo (vorasidenib) [prescribing information]. Boston, MA: Servier Pharmaceuticals LLC; August 2024.

XOLREMDI

New Drug Review

PDL Placement:

	Preferred	Non-Preferred
WHIM Syndrome	N/A	*XOLREMDI* [PA, QL] *(mavorixafor)*

Background

XOLREMDI (mavorixafor) is indicated in patients 12 years of age and older with WHIM syndrome (warts, hypogammaglobulinemia, infections, and myelokathexis). WHIM syndrome is a rare primary immunodeficiency disorder most often due to pathogenic variants in the CXC chemokine receptor 4 gene (CXCR4) leading to a reduction in the number of circulating mature neutrophils and lymphocytes. Patients with WHIM are typically identified in early childhood, with recurrent bacterial infections, commonly of the respiratory tract or middle ear, being the first sign of disease. Neutropenia is a near-universal finding in patients with WHIM. Hypogammaglobulinemia is present in 30% to 80% of patients. Immunoglobulin (Ig) deficiencies have been associated with poor vaccine durability in this population. Warts (due to human papilloma virus [HPV] infection) are also common.

Treatment goals for WHIM are to reduce the risk of infection, prevent secondary complications, and improve quality of life. Chronic Ig replacement is indicated regardless of the presence/absence of hypogammaglobulinemia, as clinical data suggest early therapy significantly reduces the risk of respiratory infection. Granulocyte colony stimulating factors may be used to improve absolute neutrophil count (ANC) and down regulate CXCR4. Allogeneic HSC transplant (HSCT) is a curative option that may be feasible for patients with matched donors.

XOLREMDI is a CXCR4 antagonist that promotes neutrophil and lymphocyte mobilization, increasing their circulation in peripheral blood. XOLREMDI is available as 100 mg capsules. For patients that weigh more than 50 kg, the recommended dose is 400 mg orally once daily. For patients that weigh less than or equal to 50 kg, the recommended dose is 300 mg orally once daily. The most common adverse reactions are thrombocytopenia, pityriasis, rash, rhinitis, epistaxis, vomiting, and dizziness.

Class Recommendation

No recommendation available. This is a new drug class and will be reviewed at a future PAC meeting.

Prior Authorization criteria for Xolremdi

Interim Criteria:

Initial Criteria:

- Patient is 12 years of age or older; **AND**
- Diagnosis of WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis) confirmed by **ONE** of the following:
  - Genetic testing confirming variants of CXCR4 consistent with WHIM syndrome; **OR**
  - Bone marrow biopsy confirming myelokathexis; **AND**
- Submission of medical records (e.g., chart notes, labs) confirming absolute neutrophil count (ANC) ≤ 500 cells/uL; **AND**
- Prescribed by or in consultation with an immunologist, hematologist, geneticist, or allergist

Renewal Criteria

- Patient has positive clinical response to therapy (e.g., increase ANC from baseline, increase absolute lymphocyte counts (ALC), and reduction in infections)

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• XOLREMDI	4/day

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- Badolato R, Alsina L, Azar A, et al. Phase 3 randomized trial of mavorixafor, CXCR4 antagonist, in WHIM syndrome. Blood. 2024. doi:10.1182/blood.2023022658
- Badolato R, Donadieu J; WHIM Research Group. How I treat warts, hypogammaglobulinemia, infections, and myelokathexis syndrome. Blood. 2017;130(2):2491-2498. doi:10.1182/blood-2017-02-708552
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STANDARD DRUG CLASS REVIEWS

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ANTIPSORIATICS, TOPICAL

Re-Review: Pharmacy Initiatives

PDL Placement:

Topical Antipsoriatics		
Preferred	**Non-Preferred**	
calcipotriene cream PA, QL	calcipotriene foam PA, QL	ENSTILAR PA, QL (calcipotriene/ betamethasone foam)
calcipotriene scalp soln PA	calcipotriene ointment PA, QL	SORILUX PA, QL (calcipotriene, foam)
TACLONEX PA (calcipotriene/ betamethasone)	CALCITRENE ointment PA, QL (calcipotriene)	tazarotene 0.1% gel PA, QL
tazarotene 0.1% cream PA, QL	calcitriol ointment PA, QL	VTAMA PA, QL (tapinarof cream)
	calcipotriene/betamethasone PA, QL	ZORYVE CREAM PA, QL (roflumilast)
	DUOBRII PA, QL (halobetasol /tazarotene lotion)	

Last Review Date: November 2022

Recent Significant Changes

- Drug Discontinuation: DOVONEX, 2023

Background

The goal of treatment for patients with psoriasis is to control the disease. There are 3 main treatment modalities available for the treatment of psoriasis including topical agents, phototherapy, and systemic agents. Topical therapies are the mainstay for mild or moderate disease, and are frequently used in conjunction with phototherapy, traditional systemic agents, or biologic agents. Phototherapy, photochemotherapy, and traditional systemic agents are generally used for moderate or severe disease and in situations in which topical therapy is ineffective or otherwise contraindicated.

Topical corticosteroids (e.g., betamethasone, clobetasol, triamcinolone, etc.) are the cornerstone of treatment for the majority of patients with psoriasis. Their effectiveness in treating psoriasis is due to anti-inflammatory, antiproliferative, immunosuppressive, and vasoconstrictive effects. Drawbacks associated with topical corticosteroid treatment are local cutaneous side effects and more serious systemic side effects that are associated with long-term use over a large body surface area. Due to these side effects, several agents have been developed and tested as monotherapy or in combination with topical corticosteroids in the hopes of reducing the duration of corticosteroid treatment.

Other topical antipsoriatic agents include anthralin, calcitriol, calcipotriene, and tazarotene. These agents are available in a variety of vehicles. A topical phosphodiesterase 4 inhibitor, roflumilast cream, is approved for treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older. Tapinarof, a topical aryl hydrocarbon receptor agonist, was approved for the treatment of psoriasis in adults in 2022.

Table 1. Medications Included Within Class Review

Drug	Generic Availability
calcipotriene cream, topical scalp solution	✔
calcitriol ointment	✔
CALCITRENE (calcipotriene) ointment	✔
DUOBRII (tazarotene/ halobetasol propionate) lotion	-
ENSTILAR (calcipotriene/betamethasone dipropionate) foam	✔
SORILUX (calcipotriene) foam	✔
TACLONEX (calcipotriene/betamethasone dipropionate) ointment and suspension	✔
tazarotene cream and gel	✔
VTAMA (tapinarof) cream	-
ZORYVE (roflumilast) cream §	-

§ Only the 0.3% cream is approved for plaque psoriasis.

Table 2. FDA-Approved Indications

Drugs	Plaque Psoriasis	Acne Vulgaris	Atopic Dermatitis
Calcipotriene (calcipotriene cream, ointment, scalp solution; SORILUX; CALCITRENE) *	✔ *		
Calcitriol	✔		
Roflumilast (ZORYVE cream) ^	✔ ^		✔
Tapinarof (VTAMA)	✔		
Tazarotene (TAZORAC)	✔	✔	
Calcipotriene/ betamethasone dipropionate (ENSTILAR foam, TACLONEX suspension and ointment)	✔		
Tazarotene/ halobetasol propionate (DUOBRII)	✔		

*Sorilux is indicated for plaque psoriasis of scalp and body in adults and pediatric patients 4 years or older; calcipotriene topical solution, 0.005% (Scalp Solution) is indicated for the treatment of chronic, moderately severe psoriasis of the scalp.
^ Only the 0.3% cream indicated for plaque psoriasis; 0.15% cream is indicated for mild to moderate atopic dermatitis

Joint guidelines for the management of psoriasis from the American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) recommend topical agents for mild to moderate psoriasis. Topical agents are also used adjunctively with ultraviolet light or systemic medications for resistant lesions or more severe disease. Topical corticosteroids are recommended as first-line treatment for most patients. Other topical agents included in the guidelines are vitamin D analogues (calcipotriene and calcitriol), topical retinoids (tazarotene), calcineurin inhibitors (tacrolimus and pimecrolimus), anthralin, emollients, salicylic acid, and coal tar. The guideline recommends use of calcipotriene, calcitriol, or tazarotene for treatment of mild to moderate psoriasis. The guideline also recommends use of calcipotriene or tazarotene in combination with corticosteroids. Topical steroids alone or in combination with vitamin D analogues may be used with various biologic agents for treatment of moderate to severe plaque psoriasis.

Table 3. Safety Information

Drug	Contraindications	Warnings/Precautions	Adverse Events
Calcipotriene *	Vitamin D toxicity or hypercalcemia; Acute psoriatic eruptions (scalp solution only)	Should not be used for the treatment of the face	Local effects (burning, pruritic, dryness, skin irritation, rash, erythema), contact dermatitis
Calcitriol	N/A	Hypercalcemia	Hypercalciuria, skin discomfort
Calcipotriene/ Betamethasone	N/A	Caution in patients with elevated serum calcium levels; Increased risk of cataracts and glaucoma; Avoid exposure of treated areas to sunlight	Local reactions (allergic contact dermatitis), pruritus, worsening of psoriasis, erythema, burning sensation
Roflumilast (ZORYVE)	Individuals with moderate to severe liver impairment (Child-Pugh Class B or C)	Coadministration with systemic CYP3A4 inhibitors	Diarrhea, headache, insomnia, nausea, application site pain, upper respiratory tract infection, urinary tract infection
Tapinarof (VTAMA)	N/A	Not to be used in patients under 18 years of age	Folliculitis, nasopharyngitis, contact dermatitis, headache, pruritus
Tazarotene *	Pregnancy	Use on eczematous skin; Increased photosensitivity with coadministration of fluoroquinolones, sulfonamides, tetracyclines, and thiazides	Burning, erythema, pruritus, peeling, skin redness
Tazarotene/Halobetasol (DUOBRII)	Pregnancy	Hypothalamic-pituitary-adrenal axis suppression; Photosensitivity; Risk of cataracts and glaucoma	Contact dermatitis, application site pain, folliculitis, skin atrophy, excoriation

Clinical Rationale

Numerous topical and systemic therapies are available for the treatment of psoriasis. Topical treatment is considered to be the safest option and is widely used for mild or moderate psoriasis, followed by systemic and phototherapies, which are used for moderate to severe psoriasis. Selection of medication must take into account severity of disease, thickness and scaling of the lesions, relevant comorbidities, patient preference, efficacy, and evaluation of individual patient response.

Recommendation

~~Given their similar clinical profile,~~ It is recommended at least one topical anti-psoriatic agent should be available for use. It is also recommended all agents in this class should be subject to step therapy to reserve their use for second line therapy behind the topical steroids.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for calcipotriene foam, calcipotriene ointment, CALCITRENE, calcitriol ointment, calcipotriene/betamethasone, SORILUX, ENSTILAR

Current Criteria:

- Trial and failure, contraindication, or intolerance to a least one topical steroid

Proposed Criteria:

- Trial and failure, contraindication, or intolerance to a least one topical steroid; **AND**
- *Trial and failure, contraindication, or intolerance to a preferred topical antipsoriatic agent*

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for DUOBRII

Current Criteria:

Initial Criteria:

- Patient has a diagnosis of plaque psoriasis; **AND**
- Trial and failure, contraindication, or intolerance to at least one topical steroid; **AND**
- Clinically valid reason why the preferred individual components cannot be taken concomitantly

Renewal Criteria:

- Patient continues to meet the initial criteria; **AND**
- Documented clinical improvement in response to treatment

Proposed Criteria:

Initial Criteria:

- Patient has a diagnosis of plaque psoriasis; **AND**
- Trial and failure, contraindication, or intolerance to at least one topical steroid; **AND**
- Clinically valid reason why the preferred individual components cannot be taken *separately* ~~concomitantly~~

~~**Renewal Criteria:**~~

- ~~Patient continues to meet the initial criteria; **AND**~~
- ~~Documented clinical improvement in response to treatment~~

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for tazarotene 1% gel

Current Criteria:

- Diagnosis of psoriasis; **AND**
  - Trial and failure, contraindication, or intolerance to at least one topical steroid; **OR**
- Diagnosis of acne in patients less than 21 years of age

Proposed Criteria:

- Diagnosis of psoriasis *AND Both of the following:* ~~; **AND**~~
  - Trial and failure, contraindication, or intolerance to at least one topical steroid;
  - *Trial and failure, contraindication, or intolerance to a preferred topical antipsoriatic agent*; **OR**
- Diagnosis of acne in patients less than 21 years of age; ***AND***
  - *Trial and failure, contraindication, or intolerance to TWO preferred topical retinoids*

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for calcipotriene cream, calcipotriene scalp solution, TACLONEX

Current Criteria:

- Trial and failure, contraindication, or intolerance to ≥ 1 topical steroid

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for tazarotene 1% cream

Current Criteria:

- Diagnosis of psoriasis; **AND**
  - Trial and failure, contraindication, or intolerance to at least one topical steroid; **OR**
- Diagnosis of acne in patients less than 21 years of age

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for VTAMA

Current Criteria:

Initial Criteria:

- Diagnosis of plaque psoriasis; **AND**
- Prescribed by, or in consultation with, a dermatologist; **AND**
- Minimum duration of a 4-week trial and failure, contraindication, or intolerance to at least two of the following:
  - Corticosteroids (e.g., betamethasone, clobetasol)
  - Vitamin D analogs (e.g., calcitriol, calcipotriene)
  - Tazarotene
  - Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

Renewal Criteria:

- Documentation of positive clinical response to therapy as evidenced by one of the following:
  - Reduction in the body surface area (BSA) involvement from baseline
  - Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• calcipotriene cream, ointment, foam	1 package/Rx
• calcipotriene/betamethasone	1 package/Rx
• CALCITRENE (calcitriol ointment)	1 package/Rx
• DUOBRII	200 mg/30 days
• ENSTILAR	1 package/Rx
• SORILUX	1 package/Rx
• tazarotene gel and cream	1 package/Rx
• VTAMA	60 grams/28 days
• ZORYVE CREAM	60 grams/28 days

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

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ANTIFUNGAL AGENTS, TOPICAL

Re-Review: Pharmacy Initiatives

PDL Placement:

Topical Antifungal Agents

Preferred	Non-Preferred	
ciclopirox cream QL	CICLODAN (ciclopirox, soln)	luliconazole QL
ciclopirox soln 8% ~~PA, QL~~	ciclopirox gel and susp QL	LUZU QL (luliconazole)
clotrimazole 1% cream & soln (OTC) QL	ciclopirox nail kit PA	miconazole/zinc/petrolatum PA, QL
clotrimazole 1% cream (Rx) QL	clotrimazole 1% shampoo (Rx) QL	naftifine QL
clotrimazole/betamethasone QL	econazole QL	oxiconazole QL
ketoconazole cream and shampoo QL	ERTACZO QL (sertaconazole)	OXISTAT QL (oxiconazole)
nystatin/triamcinolone QL	JUBLIA PA (efinaconazole)	tavaborole soln PA, QL
nystatin cream, ointment, powder QL	ketoconazole foam	
NYSTOP QL (nystatin, powder)	KETODAN foam (ketoconazole)	
VUSION ~~PA~~ (miconazole/zinc/petrolatum)	KLAYESTA QL (nystatin powder)	

Last Review Date: November 2022

Recent Significant Changes

- American Academy of Pediatrics, Report of the Committee on Infectious Disease, 2024
- Drug Discontinuations
  - EXTINA, 2024; KERYDIN, 2024; KETODAN KIT, 2024; LOPROX, 2025; MENTAX, 2023; NAFTIN, 2024

Background

The topical antifungals are available in multiple dosage forms and are indicated for a number of fungal infections and related conditions. In general, these agents are FDA approved for the treatment of cutaneous candidiasis, onychomycosis, seborrheic dermatitis, tinea corporis, tinea cruris, tinea pedis, and tinea versicolor.

The topical antifungals are available as single entity and/or combination products. Two combination products, nystatin/triamcinolone and clotrimazole/betamethasone, contain an antifungal and a corticosteroid preparation. The corticosteroid helps to decrease inflammation and indirectly hasten healing time. The other combination product, Vusion (miconazole/zinc oxide/white petrolatum), contains an antifungal and zinc oxide. Zinc oxide acts as a skin protectant and mild astringent with weak antiseptic properties and helps to promote healing.

Table 1. Medications Included Within Class Review

Drug	Generic Availability
Single entity products	
CICLODAN (ciclopirox solution)	✔
ciclopirox shampoo 1%, suspension 0.77%, cream 0.77%, gel 0.77%	✔
clotrimazole cream, solution	✔
econazole cream	✔
ERTACZO (sertaconazole)	-
ketoconazole cream, shampoo 2%	✔
KETODAN foam (ketoconazole) 2%	✔
KLAYESTA (nystatin powder)	✔
JUBLIA (efinaconazole) solution 10%	-
LUZU (luliconazole) cream 1%	✔
naftifine cream 1%, 2%	✔
NYAMYC (nystatin powder)	✔

Drug	Generic Availability
Nystatin cream, ointment	✔
NYSTOP (nystatin powder)	✔
OXISTAT (oxiconazole) cream 1%	✔
OXISTAT (oxiconazole) lotion 1%	-
tavaborole solution 5%	✔
Combination products	
clotrimazole/betamethasone cream, lotion	✔
nystatin/triamcinolone cream, ointment	✔
VUSION (miconazole/zinc oxide/white petrolatum)	✔

Table 2. FDA-Approved Indications for Single Entity Products

Indication	Tinea corporis	Tinea cruris	Tinea pedis	Tinea versicolor	Seborrheic dermatitis	Cutaneous candidiasis	Onychomycosis
ciclopirox§	✔	✔	✔	✔	✔	✔	
clotrimazole				✔		✔	
ciclopirox solution							✔ **
econazole (cream)	✔	✔	✔	✔		✔	
ERTACZO (sertaconazole)			✔ ††				
KETODAN (ketoconazole) foam					✔ ††		
JUBLIA (efinaconazole)							✔
ketoconazole cream	✔	✔	✔	✔	✔	✔	
ketoconazole shampoo				✔ ‡			
LUZU (luliconazole)	✔	✔	✔				
naftifine	✔	✔	✔				
nystatin						✔	
OXISTAT (oxiconazole)¶	✔	✔	✔	✔ #			
tavaborole solution							✔ †

* The cream is indicated for all tinea infections, but the solution is not indicated for tinea pedis.
† Safety and efficacy have been established in patients ≥ 6 years of age.
‡ Shampoo 2%.
§ Refer to package inserts of individual formulations for specific indications for use.
¶ The cream is approved for pediatric patients for all indications.
# Cream only.
** Indicated as a component of a comprehensive management program, as topical treatment in immunocompetent patients with mild to moderate onychomycosis of fingernails and toenails without lunula involvement.
†† Indicated in immunocompetent adults and children ≥ 12 years of age.

Table 3. FDA-Approved Indications for Combination Products

Indication	Tinea corporis	Tinea cruris	Tinea pedis	Diaper dermatitis	Cutaneous candidiasis
clotrimazole/betamethasone*	✔	✔	✔		
nystatin/triamcinolone					✔
VUSION (miconazole/zinc oxide/white petrolatum)				✔ †	

* Indicated for ≥ 17 years of age for inflammatory conditions.
† For the adjunctive treatment of diaper dermatitis only when complicated by documented candidiasis (microscopic evidence of pseudohyphae and/or budding yeast), in immunocompetent pediatric patients 4 weeks and older.

National and international recommendations which discuss the management of fungal infections focus primarily on superficial mycotic infections. Several recommendations list topical antifungal agents or subclasses, and generally do not give preference to one agent vs another. According to these guidelines, mycological and clinical cure of noninvasive fungal infections are often achieved with topical therapy alone. Oral therapy is preferred for the treatment of extensive or severe infection and those with tinea capitis or onychomycosis.

The American Academy of Pediatrics (AAP) discusses treatments for various fungal infections in children. For tinea capitis, systemic antifungal agents are recommended since topical agents do not reach infection within the hair follicles. Topical treatments (such as selenium sulfide, ketoconazole, or ciclopirox shampoo) may be useful as an adjunctive therapy to decrease carriage of viable conidia. For tinea cruris or tinea corporis, if appropriate for age, reasonable first-line agents include miconazole, clotrimazole, tolnaftate, or ciclopirox; if appropriate for age, ketoconazole, terbinafine, econazole, naftifine, luliconazole, butenafine, oxiconazole, or sulconazole can also be used. Topical steroids are not recommended for treatment of tinea cruris/corporis. For tinea pedis, a myriad of topical antifungal agents is available, and treatment for 2 weeks is typically sufficient for milder cases. Oral therapy can be used for cases that are severe, chronic, or refractory to topical therapy.

Newer topical antifungal agents Jublia (efinaconazole) and tavaborole are recommended along with ciclopirox for toenail fungal infections. Despite lower cure rates and longer treatment duration compared to oral agents, the topical agents are preferred because of lower risk of adverse events, fewer drug-drug interactions, and no need for laboratory monitoring.

The most common adverse events are erythema, stinging, blistering, peeling, edema, pruritus, urticaria, burning, and general irritation of the skin. Several products are flammable: ketoconazole foam, ciclopirox solution, Jublia (efinaconazole), and tavaborole. They should not be used near heat or flame. Econazole may potentiate the effects of warfarin and increase bleeding risk. Luliconazole may inhibit cytochrome P450 (CYP) 2C19.

Clinical Rationale

The topical antifungals are recommended for the treatment of superficial, noninvasive fungal infections. For onychomycosis, topical antifungals are preferred over oral agents due to of lower risk of adverse events, fewer drug-drug interactions, and no need for laboratory monitoring.

Recommendation

It is recommended that at least three topical antifungal agents be available for use.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for ciclopirox solution 8%

Current Criteria:

- Diagnosis of mild to moderate onychomycosis of fingernails and toenails due to Trichophyton rubrum; **AND**
- Prescriber attests that patient is immunocompetent; **AND**
- Trial and failure, contraindication, or intolerance to terbinafine; **AND**
- If request is for ciclopirox nail kit, clinically valid reason for why the preferred topical ciclopirox 8% solution cannot be used

Proposed Criteria:

Remove PA Criteria

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for ciclopirox nail kit

Current Criteria:

- Diagnosis of mild to moderate onychomycosis of fingernails and toenails due to Trichophyton rubrum; **AND**
- Prescriber attests that patient is immunocompetent; **AND**
- Trial and failure, contraindication, or intolerance to terbinafine; **AND**
- If request is for ciclopirox nail kit, clinically valid reason for why the preferred topical ciclopirox 8% solution cannot be used

Proposed Criteria:

- ~~Diagnosis of mild to moderate onychomycosis of fingernails and toenails due to Trichophyton rubrum; **AND**~~
- ~~Prescriber attests that patient is immunocompetent; **AND**~~
- ~~Trial and failure, contraindication, or intolerance to terbinafine; **AND**~~
- ~~If request is for ciclopirox nail kit,~~ Clinically valid reason for why the preferred topical ciclopirox 8% solution cannot be used

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for JUBLIA, tavaborole soln

Current Criteria:

- Diagnosis of mild to moderate onychomycosis of fingernails and toenails; **AND**
- Trial and failure, contraindication, or intolerance to terbinafine; **AND**
- Trial and failure, contraindication, or intolerance to the preferred topical ciclopirox 8% solution

Proposed Criteria:

- Diagnosis of mild to moderate onychomycosis of ~~fingernails and~~ *the* toenails; **AND**
- ~~Trial and failure, contraindication, or intolerance to terbinafine; **AND**~~
- Trial and failure, contraindication, or intolerance to the preferred topical ciclopirox 8% solution

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for miconazole/zinc/petrolatum

Current Criteria:

- Diagnosis of complicated diaper dermatitis; **AND**
- Recipient must be four weeks of age or older; **AND**
- Trial and failure of 1 preferred agent

Proposed Criteria:

- *Clinically valid reason why the preferred Vusion cannot be used*
- ~~Diagnosis of complicated diaper dermatitis; **AND**~~
- ~~Recipient must be four weeks of age or older; **AND**~~
- ~~Trial and failure of 1 preferred agent~~

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• ciclopirox cream, gel, susp, and soln	1 package/Rx
• clotrimazole cream, soln, and shampoo	1 package/Rx
• clotrimazole/betamethasone	1 package/Rx
• econazole	1 package/Rx
• ERTACZO	1 package/Rx
• JUBLIA	1 package/Rx
• ketoconazole shampoo and cream	1 package/Rx
• KLAYESTA; NYSTOP (nystatin powder)	120 g/Rx
• LUZU (luliconazole)	1 package/Rx
• naftifine gel	1 package/Rx
• nystatin cream and ointment	1 package/Rx
• nystatin/triamcinolone	1 package/Rx
• OXISTAT (oxiconazole)	1 package/Rx
• tavaborole soln	1 package/Rx
• VUSION (miconazole/zinc/petrolatum)	1 package/Rx

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

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ATOPIC DERMATITIS AGENTS, TOPICAL

Re-Review: Pharmacy Initiatives

PDL Placement:

Atopic Dermatitis Agents, Topical			
Preferred		**Non-Preferred**	
ELIDEL [QL] (pimecrolimus)	tacrolimus [QL]	OPZELURA [PA, QL] (ruxolitinib)	ZORYVE cream [PA, QL] (roflumilast)
EUCRISA [PA, QL] (crisaborole)		pimecrolimus [PA, QL]	

Last Review Date: November 2022

Recent Significant Changes

- The American Academy of Allergy, Asthma and Immunology (AAAAI)/American College of Allergy, Asthma and Immunology (ACAAI) Atopic dermatitis (eczema) guidelines: 2023
- Drug Discontinuation:
  - PROTOPIC, 2023

Background

Atopic dermatitis, also referred to as atopic eczema, is a chronic, highly pruritic, and relapsing inflammatory skin condition. Atopic dermatitis is exacerbated by various environmental stimuli. It is associated with increased immunoglobulin E (IgE) levels and a history of atopy (asthma, allergic rhinitis, or eczema). In the United States, the prevalence of atopic dermatitis approximately 13% among children and 7% among adults. Atopic dermatitis is one of the most common skin disorders in children, with the majority of cases starting before 5 years of age.

The pathogenesis of atopic dermatitis can be explained by impaired epidermal barrier function due to structural and functional abnormalities in the skin as well as a cutaneous inflammatory response to environmental factors. Pruritus is one of the most common symptoms of atopic dermatitis, and it is an essential feature which provokes a vicious "itch-scratch" cycle that compromises the epidermal barrier, resulting in water loss, xerosis, microbial colonization, and secondary infection. The clinical manifestations of atopic dermatitis vary according to age and disease activity; however, almost all patients report dry skin. The infantile and childhood stages are characterized by pruritic, red, crusted lesions and generally involve the face, neck, and extensor skin surfaces. The adult stage of atopic dermatitis is more lichenified and localized to the flexural folds of the extremities.

The general treatment approach involves elimination of exacerbating factors, restoring the skin's abnormal barrier function, hydrating the skin, and controlling active disease with topical and/or systemic agents. Patients should avoid exacerbating factors including excessive bathing, low humidity environments, emotional stress, xerosis, and exposure to detergents. Thick creams with low water content or ointments which have zero water content protect against xerosis and should be utilized. Topical emollients and topical corticosteroids are typical first-line treatments. Additional topical treatment options include topical calcineurin inhibitors, topical phosphodiesterase-4 (PDE-4) inhibitors, and a topical Janus kinase (JAK) inhibitor. The use of systemic therapies is reserved for patients with moderate to severe disease. Phototherapy is an option for some patients.

Low- to high-potency topical corticosteroids are utilized one or more times daily for the treatment of acute flares, as well as intermittently to prevent relapses. There are tolerability and safety concerns regarding the use of topical corticosteroids including skin atrophy, striae, and telangiectasia, which may limit long-term use of these agents. These adverse reactions occur more frequently when topical corticosteroids are used on sensitive areas including skin folds and the face or neck.

Topical immunosuppressive agents for atopic dermatitis include Elidel (pimecrolimus) and tacrolimus. These agents inhibit calcineurin, a calcium-dependent phosphatase, by binding with high affinity to immunophilin-12 (FKBP-12), which is theorized to be the primary mode of inflammation reduction in atopic dermatitis. Tacrolimus and pimecrolimus provide immunosuppression via inhibition of T-cell activation.

Eucrisa (crisaborole) and Zoryve (roflumilast) are non-steroidal, topical treatments for mild to moderate atopic dermatitis that work by way of PDE-4 inhibition. Inflammation is associated with elevated PDE-4 enzyme activity and overactive PDE-4 has been shown to contribute to the signs and symptoms of atopic dermatitis. PDE-4 inhibitors enhance cellular control of inflammation by inhibiting PDE-4-mediated degradation of intracellular cyclic adenosine monophosphate (cAMP), thereby suppressing the release of cytokines.

Opzelura (ruxolitinib) is a non-steroidal, topical JAK inhibitor for mild to moderate atopic dermatitis. However, Opzelura use is limited to those patients who are not adequately controlled with other topical prescription therapies or when those therapies are not advisable. Ruxolitinib is available as an oral tablet and a topical cream; only the cream is indicated for atopic dermatitis.

The scope of this review includes agents FDA-approved for the treatment of atopic dermatitis. General anti-inflammatory agents such as the corticosteroids are not included. Although some products in this review have additional FDA-approved indications, only information pertaining to the indication of atopic dermatitis is included within this document.

Table 1. Medications Included Within Class Review

Drug	Generic Availability
ELIDEL (pimecrolimus)	✔
EUCRISA (crisaborole)	-
OPZELURA (ruxolitinib)	-
tacrolimus	✔
ZORYVE (roflumilast)	-

A multidisciplinary guideline panel by the American Academy of Allergy, Asthma and Immunology (AAAAI) and the American College of Allergy, Asthma and Immunology (ACAAI) issued recommendations for managing atopic dermatitis using both topical and systemic approaches. For topical agents, corticosteroids and calcineurin inhibitors are recommended. PDE-4 inhibitors (crisaborole) are suggested for use if patients who are refractory to moisturizers and prefer an alternative to topical corticosteroids. Topical JAK inhibitors (ruxolitinib) and adjunct topical antimicrobials are not recommended options.

Treatment guidelines generally agree that a stepwise approach to treatment is needed. Nonpharmacological therapies (e.g., lukewarm baths, skin moisturizers) are followed by topical corticosteroids and/or topical calcineurin inhibitors. Low- to high-potency topical corticosteroids are commonly first line in both adults and pediatric patients. The strength is selected based on severity, duration of treatment, location of exacerbation, and age of the patient. The topical calcineurin inhibitors pimecrolimus and tacrolimus are also recommended treatment options, with pimecrolimus being recommended primarily for mild-to-moderate atopic dermatitis. Crisaborole and ruxolitinib are additional topical options for adults with mild-to-moderate atopic dermatitis. The use of a topical calcineurin inhibitor is recommended for flares associated with specific clinical situations, including recalcitrance to steroids, sensitive areas (face, anogenital, skin folds), steroid-induced atrophy, and long-term uninterrupted topical steroid use.

Table 2. FDA-Approved Indications

Indication	ELIDEL	EUCRISA	OPZELURA	tacrolimus	ZORYVE
Second-line therapy for the short-term and non-continuous chronic treatment of mild to moderate AD in non-immunocompromised patients who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable	✔			✔	
Topical treatment of mild to moderate AD in patients aged ≥ 3 months		✔			
Topical treatment of mild to moderate AD in patients aged ≥ 6 years					✔

Indication	Elidel	Eucrisa	Opzelura	tacrolimus	Zoryve
Topical short-term and non-continuous chronic treatment of mild to moderate AD in non-immunocompromised patients aged ≥ 12 years whose disease is not adequately controlled with topical prescription therapies or when they are not advisable			✔ *		
Topical treatment of nonsegmental vitiligo in patients aged ≥ 12 years			✔ *		
Topical treatment of plaque psoriasis, including intertriginous areas in patients aged ≥ 6 years					✔ ^

Abbreviations: AD = Atopic Dermatitis; * 0.15% cream only; ^ 0.3% cream only.

Table 3. Safety Information

Drug	Contraindications	Warnings/Precautions	Adverse Events
crisaborole	Known hypersensitivity to crisaborole or any component of the formulation	Hypersensitivity reactions (including contact urticaria)	Application site pain (burning or stinging); contact urticaria
pimecrolimus	Known hypersensitivity to pimecrolimus or any other component	Not to be used on malignant or pre-malignant skin conditions; resolve bacterial or viral infections at the site; avoid exposure to sunlight while using; not to be used in immunocompromised patients **Boxed Warning:** Rare cases of malignancy (e.g., skin and lymphoma)	Burning; itching; redness; rash; hypersensitivity reactions
roflumilast	Moderate to severe liver impairment (Child-Pugh class B or C)		Headache; nausea; application site pain; diarrhea; vomiting
ruxolitinib	N/A	Serious infections; thrombocytopenia; anemia; neutropenia; lipid elevations; higher rate of all-cause mortality and sudden cardiovascular death; higher rate of malignancies; thrombosis **Boxed Warning:** serious infections; mortality; malignancy; major adverse cardiovascular events (MACE); thrombosis	Nasopharyngitis; diarrhea; bronchitis; ear infection; eosinophil count increased; urticaria; folliculitis; tonsilitis; rhinorrhea
tacrolimus	Known hypersensitivity to tacrolimus or any other component	Not to be used on malignant or pre-malignant skin conditions; resolve bacterial or viral infections at the site; avoid exposure to sunlight while using; not to be used in immunocompromised patients **Boxed Warning:** Rare cases of malignancy (e.g., skin and lymphoma)	Burning; itching; redness; rash; hypersensitivity reactions

Clinical Rationale

Guidelines for atopic dermatitis recommend topical corticosteroids and/or topical calcineurin inhibitors following treatment failure of nonpharmacological therapies. Eucrisa and Zoryve are non-steroidal, topical treatments options for mild to moderate atopic dermatitis.

Recommendation

It is recommended that at least two agents with different mechanisms be available for the treatment of topical atopic dermatitis.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for EUCRISA

Current Criteria:

- Diagnosis of atopic dermatitis; **AND**
- One of the following:
  - Patient is ≥ 2 years; **AND**
    - Trial and failure of 2 topical corticosteroids and 1 topical calcineurin Inhibitor (e.g., Elidel, tacrolimus ointment); **OR**
    - Trial and failure of a topical corticosteroid OR a topical calcineurin inhibitor AND conditions preclude use of both classes:
      - Conditions that preclude the use of steroids:
        - Treatment of sensitive areas (face, anogenital, skin folds)
        - Steroid Induced Atrophy
        - Long-term uninterrupted use
      - Conditions that preclude the use of topical calcineurin inhibitors:
        - Severely impaired skin barrier (Netherton Syndrome)
        - Risk/presence of new primary malignancy (e.g., skin cancer, lymphoma); **OR**
  - Patient is <2 years and greater than 3 months of age; **AND**
    - Trial and failure of 2 topical corticosteroids unless patient has one of the following conditions that would preclude the use of steroids:
      - Treatment of sensitive areas (face, anogenital, skin folds)
      - Steroid Induced Atrophy
      - Long-term uninterrupted use

Proposed Criteria:

- Diagnosis of atopic dermatitis; **AND**
- One of the following:
  - Patient is ≥ 2 years of age *and meets BOTH of the following:*
    - Trial and failure, *contraindication, or intolerance to a* ~~of 2~~ topical corticosteroid~~s and 1 topical calcineurin Inhibitor (e.g., Elidel or tacrolimus); **OR**~~*; **AND***
    - Trial and failure, *contraindication, or intolerance to* ~~of a topical corticosteroid OR~~ a topical calcineurin inhibitor; **OR** ~~AND conditions preclude use of both classes:~~
      - ~~Conditions that preclude the use of steroids:~~
        - ~~Treatment of sensitive areas (face, anogenital, skin folds)~~
        - ~~Steroid Induced Atrophy~~
        - ~~Long-term uninterrupted use~~
      - ~~Conditions that preclude the use of topical calcineurin inhibitors:~~
        - ~~Severely impaired skin barrier (Netherton Syndrome)~~
        - ~~Risk/presence of new primary malignancy (e.g., skin cancer, lymphoma); **OR**~~
  - Patient is <2 years and greater than 3 months of age; **AND**
    - Trial and failure, *contraindication, or intolerance to a* ~~of 2~~ topical corticosteroids ~~unless patient has one of the following conditions that would preclude the use of steroids:~~
      - ~~Treatment of sensitive areas (face, anogenital, skin folds)~~
      - ~~Steroid Induced Atrophy~~
      - ~~Long-term uninterrupted use~~

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for OPZELURA

Current Criteria:

Initial Criteria (2-month duration):

- One of the following:
  - Diagnosis of mild to moderate atopic dermatitis that is not adequately controlled with topical prescription therapies or when those therapies are not advisable; **AND**
    - Patient has an Investigator's Global Assessment (IGA) score of 2 (mild) to 3 (moderate); **OR**
  - Diagnosis of Nonsegmental Vitiligo; **AND**
- Patient is 12 years of age or older; **AND**
- Patient is not immunocompromised; **AND**
- Patient is not breastfeeding; **AND**
- Trial and failure of a preferred topical steroid UNLESS patient has one of the following conditions that precludes use:
  - Treatment of sensitive areas (face, anogenital, skin folds)
  - Steroid Induced Atrophy
  - Long-term uninterrupted use; **AND**
- Trial and failure of a preferred topical calcineurin inhibitor (e.g., Elidel or tacrolimus ointment) UNLESS patient has one of the following conditions that precludes use:
  - Severely impaired skin barrier (Netherton Syndrome)
  - Risk/Presence of new primary malignancy (e.g., skin cancer, lymphoma); **AND**
- Patient is not using concomitantly with any of the following:
  - Therapeutic biologics (e.g., Dupixent, Humira, etc.)
  - Other Janus kinase (JAK) inhibitors (e.g., Xeljanz, Rinvoq, etc.)
  - Potent immunosuppressants (e.g., azathioprine, cyclosporine, etc.); **AND**
- Provider shall:
  - Monitor CBC as clinically indicated to address thrombocytopenia, anemia, and neutropenia
  - Counsel and monitor for serious infections while patient is taking this drug

Renewal Criteria (6-month duration):

- Positive response to therapy [e.g., reduction in symptoms (itch, rash), re-pigmentation, etc.]

Proposed Criteria:

Initial Criteria ~~(2-month duration):~~

- One of the following:
  - Diagnosis of mild to moderate atopic dermatitis *and BOTH of the following (3-month approval duration):* ~~that is not adequately controlled with topical prescription therapies or when those therapies are not advisable; **AND**~~
    - *Patient is not immunocompromised; **AND***
    - *Opzelura will only be used for short-term and/or non-continuous chronic treatment; **OR***
    - ~~Patient has an Investigator's Global Assessment (IGA) score of 2 (mild) to 3 (moderate); **OR**~~
  - Diagnosis of Nonsegmental Vitiligo *(12-month approval duration)*; **AND**
- Patient is 12 years of age or older; **AND**
- ~~Patient is not immunocompromised; **AND**~~
- Patient is not breastfeeding; **AND**
- Trial and failure, *contraindication, or intolerance to a* ~~of a preferred~~ topical *corticosteroid* ~~steroid;~~ **AND** ~~UNLESS patient one of the following conditions that precludes use:~~
  - ~~Treatment of sensitive areas (face, anogenital, skin folds)~~
  - ~~Steroid Induced Atrophy~~
  - ~~Long-term uninterrupted use; **AND**~~
- Trial and failure, *contraindication, or intolerance to a* ~~of a preferred~~ topical calcineurin inhibitor; **AND** ~~(e.g., Elidel or tacrolimus ointment) UNLESS patient has one of the following conditions that precludes use:~~
  - ~~Severely impaired skin barrier (Netherton Syndrome)~~

- ~~Risk/Presence of new primary malignancy (e.g., skin cancer, lymphoma);~~ **~~AND~~**
- ~~Patient is not using concomitantly with any of the following:~~
  - ~~Therapeutic biologics (e.g., Dupixent, Humira, etc.)~~
  - ~~Other Janus kinase (JAK) inhibitors (e.g., Xeljanz, Rinvoq, etc.)~~
  - ~~Potent immunosuppressants (e.g., azathioprine, cyclosporine, etc.);~~ **~~AND~~**
- ~~Provider shall:~~ *Prescriber attests to each of the following:*
  - *Patient is not concurrently taking biologic agents (i.e., adalimumab, anakinra, etanercept, rituximab, tocilizumab, infliximab, abatacept) OR potent immunosuppressants (i.e., azathioprine, cyclosporine);*
  - *Benefits of using this agent outweigh the risks of heart-related events (heart attack, stroke, blood clots, etc.) or cardiovascular risk factors;*
  - *Risk of malignancy has been considered and it has been determined that Jak Kinase inhibitor therapy is appropriate;*
  - ~~Monitor CBC as clinically indicated to address thrombocytopenia, anemia, and neutropenia~~
  - ~~Counsel and monitor for serious infections while patient is taking this drug~~

Renewal Criteria (*12* ~~6~~-month duration):

- *Patient has* positive response to therapy [e.g., reduction in symptoms (itch, rash), re-pigmentation, etc.]

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for pimecrolimus

Current Criteria:

- Patient must have a diagnosis of atopic dermatitis; **AND**
- Therapeutic failure on a corticosteroid, but requirement is waived if treatment is for face or groin; **AND**
- Trial and failure of 1 preferred agent (e.g., Elidel® or tacrolimus ointment)

Proposed Criteria:

- ~~Patient must have a~~ Diagnosis of atopic dermatitis; **AND**
- ~~Therapeutic failure on a corticosteroid, but requirement is waived if treatment is for face or groin;~~ **~~AND~~**
- Trial and failure of 1 preferred *topical calcineurin inhibitor* ~~agent~~ (e.g., Elidel® or tacrolimus ointment)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for Zoryve cream

Current Criteria:

Initial Criteria:

- Patient is 6 years of age or older; **AND**
- Patient does not have moderate to severe liver impairment (Child-Pugh B or C); **AND**
- One of the following:
  - Diagnosis of plaque psoriasis and BOTH of the following:
    - Trial and failure, contraindication, or intolerance to 2 preferred topical antipsoriatic agents;
    - Request is for Zoryve 0.3% cream; **OR**
  - Diagnosis of mild to moderate atopic dermatitis and ALL of the following:
    - Trial and failure of a preferred topical steroid UNLESS patient one of the following conditions that precludes use:
      - Treatment of sensitive areas (face, anogenital, skin folds)
      - Steroid Induced Atrophy
      - Long-term uninterrupted use;

- Trial and failure of a preferred topical calcineurin inhibitor (e.g., Elidel®, tacrolimus) UNLESS patient has one of the following conditions that precludes use:
  - Severely impaired skin barrier (Netherton Syndrome)
  - Risk/Presence of new primary malignancy (e.g., skin cancer, lymphoma)
- Request is for Zoryve 0.15% cream

Renewal Criteria:

- Patient continues to be monitored for liver impairment; **AND**
- Documented clinical improvement in response to treatment; **AND**
- Patient does not have any treatment limiting adverse effects

Proposed Criteria:

Initial Criteria:

- Patient is 6 years of age or older; **AND**
- Patient does not have moderate to severe liver impairment (Child-Pugh B or C); **AND**
- One of the following:
  - Diagnosis of plaque psoriasis and BOTH of the following:
    - Trial and failure, contraindication, or intolerance to 2 preferred topical antipsoriatic agents;
    - Request is for Zoryve 0.3% cream; **OR**
  - Diagnosis of mild to moderate atopic dermatitis and ALL of the following:
    - Trial and failure, *contraindication, or intolerance to a* ~~of a preferred~~ topical *corticosteroid* ~~steroid UNLESS patient one of the following conditions that precludes use:~~
      - ~~Treatment of sensitive areas (face, anogenital, skin folds)~~
      - ~~Steroid Induced Atrophy~~
      - ~~Long-term uninterrupted use~~; **AND**
    - Trial and failure, *contraindication, or intolerance to a* ~~of a preferred~~ topical calcineurin inhibitor ~~(e.g., Elidel®, tacrolimus ointment) UNLESS patient has one of the following conditions that precludes use:~~
      - ~~Severely impaired skin barrier (Netherton Syndrome)~~
      - ~~Risk/Presence of new primary malignancy (e.g., skin cancer, lymphoma, lymphoproliferative disorders);~~
    - Request is for Zoryve 0.15% cream

Renewal Criteria:

- Patient continues to be monitored for liver impairment; **AND**
- Documented clinical improvement in response to treatment *(e.g. reduction in itch, rash, inflammation)*; ~~**AND**~~
- ~~Patient does not have any treatment limiting adverse effects~~

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• ELIDEL	1 package/Rx
• tacrolimus ointment	1 package/Rx
• EUCRISA	1 tube/month
• OPZELURA	240 g/month
• pimecrolimus	1 package/Rx
• ZORYVE cream	60 gram/28 days

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

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IMMUNOMODULATORS

Re-Review: Pharmacy Initiatives

PDL Placement:

Immunomodulators		
Preferred	**Non-Preferred**	
TNF Inhibitors		
ENBREL PA, QL (etanercept) HADLIMA PA, QL (adalimumab-bwwd) HUMIRA PA, QL (adalimumab) SIMLANDI PA, QL (adalimumab)	ABRILADA PA, QL (adalimumab-afzb) adalimumab PA, QL AMJEVITA PA, QL (adalimumab-atto) CIMZIA PA, QL (certolizumab) CYLTEZO PA, QL (adalimumab-adbm) HULIO PA, QL (adalimumab-fkjp)	HYRIMOZ PA, QL (adalimumab-adaz) IDACIO PA, QL (adalimumab-aacf) SIMPONI PA, QL (golimumab) YUFLYMA PA, QL (adalimumab-aaty) YUSIMRY PA, QL (adalimumab-aqvh) ZYMFENTRA PA, QL (infliximab-dyyb)
IL Inhibitors		
KINERET PA, QL (anakinra) TALTZ PA, QL (ixekizumab) TYENNE PA, QL (tocilizumab)	ACTEMRA PA, QL (tocilizumab) ARCALYST PA, QL (rilonacept) BIMZELX PA, QL (bimekizumab) COSENTYX PA, QL (secukinumab) KEVZARA PA, QL (sarilumab) OMVOH PA, QL (mirikizumab) SILIQ PA, QL (brodalumab)	SKYRIZI PA, QL (risankizumab) SPEVIGO PA, QL (spesolimab-sbzo) STELARA prefilled syringe PA, QL (ustekinumab) STELARA 45mg/0.5mL vial PA, QL (ustekinumab) TREMFYA PA, QL (guselkumab)
Miscellaneous		
ORENCIA PA, QL (abatacept) OTEZLA PA, QL (apremilast)	ENTYVIO PA, QL (vedolizumab) SOTYKTU PA, QL (deucravacitinib)	VELSIPITY PA, QL (etrasimod)

Last Review Date: February 2023

Recent Significant Changes

- Emerging immunomodulatory strategies for cell therapeutics. Trends in Biotechnology 2023

Background – General Overview

Immunomodulators treat a wide variety of conditions, including rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA), plaque psoriasis (PsO), psoriatic arthritis (PsA), ankylosing spondylitis (AS), hidradenitis suppurativa (HS), uveitis (UV), Crohn's Disease (CD), ulcerative colitis (UC), as well as other rare conditions .

T cells, B cells, and cytokines such as tumor necrosis factor (TNF), interleukin-1 (IL-1), and interleukin-6 (IL-6) play a key role in the inflammatory and immune process. This has led to the development of biologic agents to target these areas. Other immunomodulators targeting different cells and cytokines in the inflammatory and immune process are also FDA-approved.

Ankylosing Spondylitis (AS)

The ACR/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network joint recommendations for treatment of AS. Patients with active AS who do not respond to initial NSAID therapy are conditionally recommended to be treated with sulfasalazine, MTX, or tofacitinib; sulfasalazine or methotrexate should be considered only in patients with prominent peripheral arthritis or when TNF inhibitors are not available. Patients who do not respond to NSAID therapy are strongly recommended to receive treatment with a TNF inhibitor, although no particular TNF inhibitor is preferred. Treatment with a TNF inhibitor is conditionally recommended over tofacitinib, secukinumab, and ixekizumab in these patients. In patients with active disease who have primary nonresponse with a TNF inhibitor, treatment with secukinumab or ixekizumab is strongly recommended, and treatment with tofacitinib is conditionally recommended. Patients with secondary nonresponse to treatment with a TNF inhibitor are conditionally recommended to receive treatment with an alternative TNF inhibitor. In patients with AS and inflammatory bowel disease or recurrent iritis, TNF inhibitors are conditionally recommended over treatment with other biologics. In patients with stable disease who are

treated with an originator TNF inhibitor, the guideline strongly recommends continuing the originator TNF inhibitor over mandated switching to its biosimilar.

Joint recommendations for the management of axial spondyloarthritis are available from the Assessment of Spondyloarthritis international Society (ASAS) and EULAR and were updated in 2022. The guideline notes that radiographic axial spondyloarthritis and non-radiographic axial spondyloarthritis are part of the same disease spectrum, and therefore uses the term axial spondyloarthritis in recommendations. The guidelines state that NSAIDs should be used first-line in patients with pain and stiffness; other analgesics might be considered if NSAIDs have failed or are contraindicated or poorly tolerated. Glucocorticoid injections may be considered, but patients with axial disease should not receive long-term systemic glucocorticoids. Sulfasalazine may be considered in patients with peripheral arthritis, but patients with purely axial disease should normally not be treated with conventional DMARDs. TNF inhibitors, IL-17A inhibitors, or JAK inhibitors should be considered in patients with persistently high disease activity despite conventional treatments; current practice is to start with a TNF inhibitor or IL-17A inhibitor. In patients with a history of recurrent uveitis or active IBD, preference should be given to a monoclonal antibody against TNF. In patients with significant psoriasis, an IL-17 inhibitor may be preferred. Following failure of the first biologic or targeted synthetic DMARD, switching to another biologic DMARD (TNF inhibitor or IL-17A inhibitor) or a JAK inhibitor should be considered. For patients in sustained remission, tapering of a biologic DMARD can be considered.

Behçet Disease (BD)

BD is a chronic, relapsing and debilitating inflammatory multisystem disease of unknown etiology. This complex disease is characterized by recurrent oral ulcers (OU), genital ulcers (GU), uveitis, and different phenotypes may the joints, central nervous system, major blood vessels, heart, and gastrointestinal tract. BD follows a chronic course with unpredictable inflammatory attacks and remission periods. Treatment varies depending on involved organ/s, the severity and duration of involvement, the frequency of attacks, gender and patient's age. The primary goal of treatment is to suppress and prevent new inflammatory attacks to avoid irreversible organ damage, especially in the early, active stages of BD. Apremilast has been shown to be an important treatment option for mucocutaneous manifestations of the disease

Crohn's Disease (CD) and Ulcerative Colitis (UC)

Inflammatory bowel disease (IBD) is a spectrum of chronic idiopathic inflammatory intestinal conditions that cause gastrointestinal symptoms including diarrhea, abdominal pain, bleeding, fatigue, and weight loss. The exact cause of IBD is unknown; however, proposed etiologies involve a combination of infectious, genetic, and lifestyle factors. UC and CD are 2 forms of IBD that differ in pathophysiology and presentation; as a result of these differences, the approach to the treatment of each condition often differs.

CD can involve any part of the gastrointestinal tract and is characterized by transmural inflammation and "skip areas." Transmural inflammation may lead to fibrosis, strictures, sinus tracts, and fistulae. The incidence of CD varies from 3.1 to 20.2 per 100,000 person-years in the United States (U.S.). UC is characterized by recurrent episodes of inflammation of the mucosal layer of the colon. The inflammation, limited to the mucosa, commonly involves the rectum and may extend in a proximal and continuous fashion to affect other parts of the colon. The hallmark clinical symptom is an inflamed rectum accompanied by urgency, bleeding, and tenesmus. The existing data suggest that the U.S. incidence rate of UC varies between 2.2 to 19.2 per 100,000 person-years.

The goals of treatment in IBD include resolution of intestinal inflammation and healing of the mucosa, elimination of symptoms while minimizing adverse effects, maintenance of corticosteroid-free remission, prevention of complications/ hospitalization/surgery, and maintenance of a good nutritional state. T cells, B cells, and cytokines such as tumor necrosis factor (TNF), interleukin-1 (IL-1), and interleukin-6 (IL-6) play a key role in the inflammatory and immune process. This has led to the development of biologic agents to target these areas. The FDA has currently approved 4 originator TNF inhibitors for IBD indications: Cimzia (certolizumab), Humira (adalimumab), Remicade (infliximab), and Simponi (golimumab). Nine adalimumab biosimilars are also on the market: Abrilada (adalimumab-afzb), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hadlima (adalimumab-bwwd), Hulio (adalimumab-fkjp), Hyrimoz (adalimumab-adaz), Idacio (adalimumab-aacf), Yuflyma

(adalimumab-aaty), and Yusimry (adalimumab-aqvh). Abrilada and Cyltezo have an FDA rating of interchangeable with Humira.

A 2019 guideline from the American College of Gastroenterology (ACG) recommends 5-ASA therapy for induction of remission in mildly active UC, and budesonide, systemic corticosteroids, TNF inhibitor therapy (adalimumab, golimumab, or infliximab), vedolizumab, and tofacitinib for induction of remission in moderately to severely active disease. Vedolizumab and tofacitinib are recommended for induction of remission in patients who have failed previous TNF inhibitor therapy. For maintenance of remission in patients with previously mildly active disease, 5-ASA therapy is recommended, and in patients with previously moderately to severely active disease, continuation of TNF inhibitor therapy, vedolizumab, or tofacitinib is recommended after induction of remission with these agents.

For outpatients with moderate to severe UC, a 2020 American Gastroenterological Association (AGA) guideline strongly recommends using infliximab, adalimumab, golimumab, vedolizumab, tofacitinib, or ustekinumab over no treatment. However, for patients with less severe disease who place a higher value on the safety of 5-ASA therapy and a lower value on the efficacy of biologic agents, it is reasonable to choose step therapy with 5-ASA.

A 2021 AGA guideline on the medical management of moderate to severe CD strongly recommends the use of biologic monotherapy over thiopurine monotherapy for the induction of remission in adult outpatients and recommends TNF inhibitors or ustekinumab over no treatment for induction and maintenance of remission. In patients who are naïve to biologic drugs, infliximab, adalimumab, or ustekinumab are recommended over certolizumab pegol for the induction of remission and vedolizumab is suggested over certolizumab pegol. In patients who never responded to TNF inhibitors, the use of ustekinumab is recommended and the use of vedolizumab is suggested over no treatment for the induction of remission. In patients who previously responded to infliximab, the use of adalimumab or ustekinumab is recommended and the use of vedolizumab is suggested over no treatment for the induction of remission. The AGA recommends against the use of 5-ASA or sulfasalazine over no treatment for the induction or maintenance of remission. In patients with CD and active perianal fistula, infliximab is recommended over no treatment for the induction and maintenance of fistula remission. In patients with CD and active perianal fistula without perianal abscess, the use of biologic agents in combination with an antibiotic over a biologic drug alone is recommended for the induction of fistula remission.

Giant Cell Arteritis (GCA)

GCA is a systemic vasculitide involving inflammation of the large- and medium-sized arteries producing a wide variety of clinical manifestations. For the management of GCA, EULAR recommendations state that tocilizumab (or methotrexate as an alternative) should be used as an adjunctive therapy in patients who have refractory or relapsing disease or who are at an increased risk of glucocorticoid-related AEs or complications. A joint guideline from the ACR and Vasculitis Foundation recommends the use of oral or IV glucocorticoids, tocilizumab, and other non-glucocorticoid immunosuppressive drugs (eg, methotrexate, abatacept); specific recommendations depend on various factors such as the patient's clinical presentation, comorbidities, and prior therapies. For patients with newly diagnosed GCA, guidelines conditionally recommend the use of oral glucocorticoids with tocilizumab over oral GCs alone.

Hidradenitis Suppurativa (HS)

Based upon guidelines from the European Dermatology Forum, adalimumab is recommended among first-line therapies for HS, and infliximab may be considered a second-line option. The North American clinical management guidelines for HS indicate that immunomodulators are rapidly becoming the cornerstone of therapy for moderate to severe disease. Recommendations for the use of biologics includes adalimumab at the approved HS dose to improve disease severity and quality of life in patients with moderate to severe HS; infliximab is also recommended for moderate to severe disease, however optimal dosage was not noted. Anakinra and ustekinumab are noted to be possibly effective, while limited available evidence does not support the use of etanercept for HS.

Juvenile Idiopathic Arthritis (JIA)

The 2019 ACR and Arthritis Foundation guideline for the treatment of JIA focuses on therapy for non-systemic polyarthritis, sacroiliitis, and enthesitis. Recommendations for initial therapy include the use of DMARDs (MTX, leflunomide, or sulfasalazine); the preference for MTX over other agents is conditionally recommended. In children and adolescents with JIA and polyarthritis with moderate to high disease activity, addition of a biologic to DMARD (TNF inhibitor, abatacept, or tocilizumab) is conditionally recommended. Patients with continued disease activity and primary TNF inhibitor failure are conditionally recommended to receive abatacept or tocilizumab over a second TNF inhibitor. For children and adolescents with JIA and active sacroiliitis despite treatment with NSAIDs, it is strongly recommended to add TNF inhibitor therapy over continuing NSAID monotherapy.

A 2021 guideline from the ACR addresses the treatment of oligoarthritis, temporomandibular joint arthritis, and SJIA. For SJIA, an IL-1 inhibitor or IL-6 inhibitor is conditionally recommended for initial treatment; no specific agent is preferred. Monotherapy with an NSAID may also be considered for initial treatment of SJIA without macrophage activation syndrome. Systemic glucocorticoids are conditionally recommended as part of initial therapy for patients with macrophage activation syndrome. If residual arthritis is present despite these therapies, a conventional synthetic DMARD may be added, or a different biologic therapy may be tried. Patients without macrophage activation syndrome who experience incomplete response or intolerance to an initial IL-1 or IL-6 inhibitor may be switched to an alternative IL-1 or IL-6 inhibitor.

Plaque Psoriasis (PsO)

Joint guidelines from the American Academy of Dermatology (AAD)/National Psoriasis Foundation (NPF) state that topical medications (e.g., corticosteroids, vitamin D analogues) are the most common agents used to treat mild to moderate PsO and are commonly used as adjunctive therapy to phototherapy, systemic agents, and biologics. Although biologic therapies have changed the treatment landscape, non-biologic systemic agents (eg, MTX) either as monotherapy or in combination with biologics, are still widely used due to benefit for widespread disease, comparatively low cost, increased availability, and ease of administration. Methotrexate and apremilast are recommended for moderate to severe psoriasis in adults, however, MTX is considered less effective than adalimumab and infliximab for cutaneous psoriasis.

Joint guidelines from the AAD/NPF on the treatment of psoriasis with biologics address the effectiveness of these drugs as monotherapy or in combination to treat moderate-to-severe disease in adults. The guideline does not provide relevant ranking for preferences of individual biologics, but does recommend that etanercept, infliximab, adalimumab, ustekinumab, secukinumab, ixekizumab, brodalumab, guselkumab, risankizumab, and tildrakizumab can all be recommended as a monotherapy option. Further recommendations on specific presentations of the disease, combination therapy, and dosing recommendations are included in the guidance.

The AAD/NPF guideline on PsO in pediatric patients states that etanercept, adalimumab, and ustekinumab are effective biologic therapies for moderate to severe pediatric psoriasis. Infliximab can be recommended as monotherapy or in combination with MTX for use in pediatric patients with severe plaque or pustular psoriasis that is unresponsive to other systemic medications, rapidly progressive, unstable, and/or life threatening.

Psoriatic Arthritis (PsA)

EULAR 2023 PsA guidelines recommend biologic DMARDs in patients with peripheral arthritis and an inadequate response to at least 1 synthetic DMARD, such as MTX. In patients with peripheral arthritis and an inadequate response to at least one synthetic DMARD and at least one biologic DMARD, JAK inhibitors may be considered; JAK inhibitors may also be considered in patients for whom biologic DMARD therapy is not appropriate. Apremilast is considered a treatment option in patients with peripheral arthritis and an inadequate response to at least 1 synthetic DMARD, in whom biologics and JAK inhibitors are not appropriate. The choice of the mechanism of action should be based on musculoskeletal manifestations related to PsA; for patients with clinically relevant skin involvement, an IL-17A inhibitor (ixekizumab, secukinumab), IL-17A/F inhibitor (bimekizumab), IL-23 inhibitor (guselkumab, risankizumab), or IL-12/23 inhibitor (ustekinumab) are preferred; for patients with uveitis, TNF inhibitors (adalimumab, certolizumab, etanercept, infliximab, and golimumab) are

preferred. In patients with inadequate response or intolerance to a biologic DMARD or JAK inhibitor, switching to another biologic DMARD or JAK inhibitor should be considered, including one switch within a class.

The ACR/NPF guideline on PsA recommends that a TNF inhibitor is preferred in treatment-naïve patients with active PsA, although an oral therapy (MTX, sulfasalazine, leflunomide, cyclosporine, or apremilast) can be a first-line option in patients without severe PsA and without severe psoriasis, or if a patient has another compelling reason to avoid a TNF inhibitor. In patients who fail oral therapy, a switch to a TNF inhibitor is preferred and placed ahead of IL-17 biologics (secukinumab, ixekizumab, brodalumab), IL-12/23 biologics (ustekinumab), abatacept, and tofacitinib.

In 2020, the International Psoriasis Council Biosimilar Working Group published a consensus statement for the use of biosimilars in the treatment of patients with psoriasis. There was consensus from the Group that prescribing biosimilars to biologic-naïve patients or switching a stable patient from a reference product to a biosimilar product is appropriate if the patient and physician agree to do so. Furthermore, switching between different biosimilars should be performed with caution, until more evidence is generated supporting this practice, and multiple switches between various biosimilars and reference biologics is not the preferred option but is acceptable. Lastly, treatment switches should not occur in less than an adequate period of time (usually 6 months) from initiation of the reference product, allowing full assessment of its therapeutic effect

Rheumatoid Arthritis (RA)

The 2021 America College of Rheumatology (ACR) recommends the use of conventional DMARDs (eg, hydroxychloroquine, sulfasalazine, MTX, leflunomide), a TNF inhibitor, a non-TNF inhibitor biologic (tocilizumab, sarilumab, abatacept, rituximab [only in patients that have had an inadequate response to TNF inhibitors or have a history of lymphoproliferative disorder]), or a JAK inhibitor (Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)). For patients who are not at target, switching to a medication in a different class is conditionally recommended over switching to a medication in the same class for patients receiving a biologic or JAK inhibitor. Biosimilars are considered equivalent to FDA-approved originator biologics. Anakinra was excluded from the ACR guideline because of its low use and lack of new data.

The 2023 European Alliance of Association Rheumatology (EULAR) guidelines for RA management recommends that therapy with DMARDs should be initiated as soon as the RA diagnosis is made with treatment aimed at reaching a target of sustained remission or low disease activity in every patient. If the treatment target is not achieved with the first conventional synthetic DMARD (csDMARD) strategy, in the absence of poor prognostic factors, other csDMARDs should be considered. If poor prognostic factors are present with csDMARD failure, a biological DMARD should be added; JAK inhibitors may be considered, but pertinent risk factors should be well-thought-out. In patients who cannot use csDMARDs as a comedication, IL-6 inhibitors and targeted synthetic DMARDs may have some advantages compared with other biologic DMARDs. If a biologic or targeted synthetic DMARD has failed, treatment with another should be considered. If one TNF or IL-6 inhibitor therapy has failed, patients may receive an agent with another mode of action or a second TNF or IL-6 inhibitor.

An America College of Rheumatology (ACR) position statement on biosimilars states that the decision to substitute a biosimilar product for a reference drug should only be made by the prescriber and the patient. The ACR “specifically opposes insurer-mandated force switching to biosimilars”. Similarly, the Task Force on the Use of Biosimilars to Treat Rheumatological Disorders recommends that both healthcare providers and patients should take part in the decision-making process for switching amongst biosimilars.

Uveitis (UV)

Expert panel recommendations for the use of TNF inhibitors in patients with ocular inflammatory disorders are available from the American Uveitis Society. Infliximab and adalimumab can be considered as first-line immunomodulatory agents for the treatment of ocular manifestations of Behçet’s disease and as second-line immunomodulatory agents for the treatment of UV associated with juvenile arthritis. They also can be considered as potential second-line immunomodulatory agents for the treatment of severe ocular inflammatory conditions including posterior UV, panuveitis, severe UV associated with seronegative spondyloarthropathy, and

selected patients with scleritis. Etanercept seems to be associated with lower rates of treatment success in these conditions.

A 2019 guideline by the ACR and Arthritis foundation focusing on children with JIA-associated UV conditionally recommended starting a monoclonal antibody TNF inhibitor over etanercept in children and adolescents with chronic anterior UV. Children and adolescents with inadequate response to one monoclonal TNF inhibitor are conditionally recommended to be treated with an escalated dose and/or frequency of the TNF inhibitor over switching to another TNF inhibitor; patients failing dose escalation are conditionally recommended to switch to another monoclonal TNF inhibitor. Children and adolescents failing MTX and 2 monoclonal TNF inhibitors are conditionally recommended to receive abatacept or tocilizumab as biologic DMARD options.

A 2018 guideline by the Fundamentals of Care for Uveitis (FOCUS) International Consensus Group published guidance for non-corticosteroid systemic immunomodulatory therapy in noninfectious uveitis. For the treatment of noninfectious uveitis, the consensus group recommends use of adalimumab (evidence level 1B) and infliximab (evidence level 2B); Grade A recommendation.

Safety Information

All agents in the class carry precautions for reactivation of HBV or other viral infections, serious infections (including tuberculosis), new onset or exacerbation of central nervous system demyelinating disease and peripheral demyelinating disease, cytopenias and pancytopenia, worsening and new onset congestive heart failure, hypersensitivity reactions, lupus-like syndrome, malignancy and lymphoproliferative disorders, and avoiding live vaccinations and therapeutic infectious agents. Infliximab agents carry an additional warning for cardiovascular and cerebrovascular reactions during and after infusion. Typical adverse events (AEs) for the immunomodulator class include infusion site reactions, diarrhea, nausea/vomiting, abdominal pain, infections, hypertension, and headache. Consult the prescribing information for other drug-specific AEs. The immunomodulator agents should not be given with live (including attenuated) vaccines; additionally, non-live vaccines may not elicit a sufficient immune response. Do not give immunomodulators together.

TNF Inhibitors

Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hadlima (adalimumab-bwwd), Hulio (adalimumab-fkjp), Hyrimoz (adalimumab-adaz), Idacio (adalimumab-aacf), Cimzia (certolizumab), Enbrel (etanercept), Humira (adalimumab), Simlandi (adalimumab-ryvk), Simponi (golimumab), Yuflyma (adalimumab-aaty) and Yusimry (adalimumab-aqvh) all have boxed warnings for serious infections such as active tuberculosis, which may present with pulmonary or extrapulmonary disease; invasive fungal infections; and bacterial, viral, and other infections due to opportunistic pathogens. In addition, Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hadlima (adalimumab-bwwd), Hulio (adalimumab-fkjp), Hyrimoz, Idacio, Cimzia, Enbrel, Humira (adalimumab, Simlandi, Simponi, Yuflyma, and Yusimry all have warnings for increased risk of malignancies.

Interleukin Inhibitors

Actemra (tocilizumab), Cosentyx (secukinumab), Kevzara (sarilumab), Kineret (anakinra), Skyrizi (risankizumab), Stelara (ustekinumab), Taltz (ixekizumab), and Tyenne (tocilizumab-aazg) are contraindicated in patients with hypersensitivity to any component of the product. Kineret (anakinra) is also contraindicated in patients with hypersensitivity to *E coli*-derived proteins. Actemra (tocilizumab), Kevzara (sarilumab), and Tyenne (tocilizumab-aazg), all have boxed warnings for serious infections such as active tuberculosis, which may present with pulmonary or extrapulmonary disease; invasive fungal infections; and bacterial, viral, and other infections due to opportunistic pathogens. Siliq (brodalumab) has a boxed warning that suicidal ideation and behavior, including completed suicides, have occurred in patients treated with Siliq. The prescriber should weigh potential risks and benefits in patients with a history of depression and/or suicidal ideation or behavior, and patients should seek medical attention if these conditions arise or worsen during treatment.

Stelara (ustekinumab) carries a warning for noninfectious pneumonia. Actemra, Kevzara, Bimzelx, and Tyenne may increase lipid parameters and liver function tests. An increased incidence of CD and UC has been shown with Cosentyx (secukinumab), Taltz, Bimzelx; risk of new-onset CD or exacerbation of CD with Siliq. Bimzelx

carries a warning for suicidal ideation. Actemra, Kevzara, and Tyenne may cause gastrointestinal perforations. Hepatotoxicity has been shown with Actemra and Tyenne. Stelara may cause posterior reversible encephalopathy syndrome (PRES).

Siliq is available only through the Siliq Risk Evaluation and Mitigation Strategy (REMS) program. The goal of the program is to mitigate the risk of suicidal ideation and behavior, including completed suicides, which occurred in clinical trials. Key requirements of the REMS program include: 1) Prescribers must be certified with the program. 2)Patients must enroll in the program. 3) Pharmacies must be certified with the program and must only dispense to patients who are enrolled in the program.

Miscellaneous Agents

Otezla (apremilast) is contraindicated in patients with hypersensitivity to any component of the product. Otezla may also cause diarrhea, nausea, vomiting, depression, and weight loss. Orencia (abatacept) carries a risk of Cytomegalovirus and Epstein-Barr Virus reactivation.

Clinical Rationale

Immunomodulators are available for a variety of conditions associated with inflammation. Mechanisms of action and indications vary among the products. Guidelines recommend various biologics for the treatment of RA, PJIA, PsO and PsA based on patient-specific factors, including TNF inhibitors, IL-17 and IL-12/23 inhibitors, JAK inhibitors, and PDE-4 inhibitors.

Warnings, precautions, and adverse event profiles vary in this class. Caution is warranted with these biologic agents due to severe infections and malignancies that can occur with their use. Selection of an agent for a patient is determined by approved indications, response, administration method, tolerability, adverse event profile, and cost of the agent.

Recommendation

It is recommended that at least two immunomodulators be available for use and at least one agent for each FDA-approved indication should be available. Additionally, due to the risk of significant adverse events associated with these agents, including an increased risk of potentially life-threatening infections, it is recommended that all agents in this class be subject to clinical criteria. In addition, to prevent misuse, all agents in the category should be subject to quantity limits.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

IMMUNOMODULATORS – TNF INHIBITORS

Re-Review: Pharmacy Initiatives

PDL Placement:

Immunomodulators		
Preferred	**Non-Preferred**	
TNF Inhibitors		
ENBREL [PA, QL] (etanercept)	ABRILADA [PA, QL] (adalimumab-afzb)	HYRIMOZ [PA, QL] (adalimumab-adaz)
HADLIMA [PA, QL] (adalimumab-bwwd)	adalimumab [PA, QL]	IDACIO [PA, QL] (adalimumab-aacf)
HUMIRA [PA, QL] (adalimumab)	AMJEVITA [PA, QL] (adalimumab-atto)	SIMPONI [PA, QL] (golimumab)
SIMLANDI [PA, QL] (adalimumab)	CIMZIA [PA, QL] (certolizumab)	YUFLYMA [PA, QL] (adalimumab-aaty)
	CYLTEZO [PA, QL] (adalimumab-adbm)	YUSIMRY [PA, QL] (adalimumab-aqvh)
	HULIO [PA, QL] (adalimumab-fkjp)	ZYMFENTRA [PA, QL] (infliximab-dyyb)

Recent Significant Changes

- Humira biosimilars launched January 2023.

Background – TNF Inhibitors (see Immunomodulators - General Overview for further details)

T cells, B cells, and cytokines such as tumor necrosis factor (TNF), interleukin-1 (IL-1), and interleukin-6 (IL-6) play a key role in the inflammatory and immune process. This has led to the development of biologic agents to target these areas. The FDA has currently approved 5 originator TNF inhibitors: Cimzia (certolizumab), Enbrel (etanercept), Humira (adalimumab), Remicade (infliximab), and Simponi (golimumab). In addition, numerous Humira biosimilars are available: Abrilada (adalimumab-afzb), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hadlima (adalimumab-bwwd), Hulio (adalimumab-fkjp), Hyrimoz (adalimumab-adaz), Idacio (adalimumab-aacf), Simlandi (adalimumab-ryvk), Yusimry (adalimumab-aqvh), Yuflyma (adalimumab-aaty). Zymfentra (infliximab-dyyb) is the first subcutaneously formulation of Remicade.

Table 1. Medications Included Within Class Review

Drug	Alternative Available *	Type of Agent/Target
Injectables – Innovator agents		
CIMZIA (certolizumab)	-	TNFα inhibitor
ENBREL (etanercept)	-	sTNFR fusion protein, TNFα inhibitor
HUMIRA (adalimumab),	✔ §	TNFα inhibitor
SIMPONI (golimumab)	-	TNFα inhibitor
ZYMFENTRA (infliximab-dyyb)	-	TNFα inhibitor
Injectable – Biosimilar agents		
ABRILADA (adalimumab-afzb)	✔ **	TNFα inhibitor
AMJEVITA (adalimumab-atto)	N/A §	TNFα inhibitor
HADLIMA (adalimumab-bwwd)	N/A §	TNFα inhibitor
HULIO (adalimumab-fkjp)	N/A §	TNFα inhibitor
CYLTEZO (adalimumab-adbm)	✔ **	TNFα inhibitor
HYRIMOZ (adalimumab-adaz)	✔ **	TNFα inhibitor
IDACIO (adalimumab-aacf)	N/A §	TNFα inhibitor
SIMLANDI (adalimumab-ryvk)	✔ **	TNFα inhibitor
YUFLYMA (adalimumab-aaty)	N/A §	TNFα inhibitor
YUSIMRY (adalimumab-aqvh)	N/A §	TNFα inhibitor

Abbreviations: N/A = approved biosimilar, not interchangeable.

* Alternative agents are agents with the same molecular entity. For example, authorized generic, branded generic (unless not considered therapeutically equivalent by the Orange Book), generic, unbranded biologic, or interchangeable biologic.

§ Amjevita, Cyltezo, Hadlima, Hulio, Idacio, Yuflyma, and Yusimry have been FDA-approved as biosimilars to Humira (adalimumab).

**Abrilada, Cyltezo, Hyrimoz, and Simlandi are the only biosimilar products in this review that are designated interchangeable with their reference product, Humira (adalimumab).

Table 2. FDA-Approved Indications

Drug	Rheumatoid Arthritis (RA)	Polyarticular Juvenile Idiopathic Arthritis (PJIA)	Plaque Psoriasis (PsO)	Psoriatic Arthritis (PsA)	Ankylosing Spondylitis (AS)	Hidradenitis Suppurativa (HS)	Uveitis (UV)	Crohn's Disease (CD)	Ulcerative Colitis (UC)
AMJEVITA	✔ ‡‡	✔ ∫	✔ ‡	✔ ∫∫	✔	✔	✔ ▼	✔ *	✔ *
CIMZIA~~	✔		✔ ‡	✔	✔			✔ ^	
ENBREL	✔	✔	✔ ‡	✔ ┼	✔				
HADLIMA	✔ ‡‡	✔ ∫	✔ ‡	✔ ∫∫	✔	✔	✔ ▼	✔ *	✔ *
HULIO	✔ ‡‡	✔ ∫	✔ ‡	✔ ∫∫	✔	✔	✔ ▼	✔ *	✔ *
HUMIRA, ABRILADA, CYLTEZO, HYRIMOZ, SIMLANDI	✔ ‡‡	✔ ∫	✔ ‡	✔ ∫∫	✔	✔ ↑	✔ ▼	✔ *	✔ *
IDACIO	✔ ‡‡	✔ ∫	✔ ‡	✔ ∫∫	✔			✔ *	✔ *
SIMPONI	✔ ┼			✔ ┼	✔				✔ ^
YUFLYMA	✔ ‡‡	✔ ∫	✔ ‡	✔ ∫∫	✔	✔	✔ ▼	✔ *	✔ *
YUSIMRY	✔ ‡‡	✔ ∫	✔ ‡	✔ ∫∫	✔	✔	✔ ▼	✔ *	✔ *
ZYMFENTRA								✔ *	✔ *

*Moderately to severely active disease (following the treatment of an infliximab product administered IV for Zymfentra). Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Simlandi, Yuflyma, and Yuflyma are indicated in CD in adults and pediatric patients 6 years and older and for UC in adults. Humira is indicated in adults and pediatric patients 5 years and older in UC and in adult and pediatric patients 6 years and older in CD.

‡Indicated for the treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy, with the exception of Enbrel, which is indicated for the treatment of patients 4 years and older with chronic moderate to severe PsO who are candidates for systemic therapy or phototherapy; Taltz and Cosentyx, which are indicated for the treatment of patients 6 years and older with moderate-to-severe PsO who are candidates for systemic therapy or phototherapy; Stelara, which is indicated for the treatment of patients 6 years and older with moderate to severe PsO.

‡‡Indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active RA. Can be used alone or in combination with MTX or other DMARDs.

∫ Indicated for reducing signs and symptoms of juvenile idiopathic arthritis (JIA) for patients 2 years of age and older. Can be used alone or in combination with MTX.

∫∫ Indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA. Can be used alone or in combination with non-biologic DMARDs.

▼ Treatment of non-infectious intermediate, posterior, and panuveitis in adults.

^Indicated in reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy

↑ Only reference product Humira (adalimumab) is approved for ≥ 12 years for HS.

┼ In combination with MTX, is indicated for the treatment of adult patients with moderately to severely active RA.

┼┼ Alone or in combination with MTX, is indicated for the treatment of adult patients with active PsA.
┼┼┼ In adults with PsA (Enbrel may be used alone or in combination with MTX) and in pediatric patients aged ≥ 2 years with active juvenile PsA.
^indicated in moderate to severe UC with an inadequate response or intolerance to prior treatment or requiring continuous steroid therapy. (inducing and maintaining clinical response, improving endoscopic appearance of the mucosa during induction, inducing clinical remission, achieving and sustaining clinical remission in indication responders)
~~Cimzia is also indicated for the treatment of adults with active non-radiographic axial spondyloarthritis (NRAS) with objective signs of inflammation.
Humira only (no biosimilars or interchangeables) approved in pediatric patients for the following indications: 1) HS in patients aged 12 years and older. 2) Uveitis in patients aged 2 years and older.

Prior Authorization criteria for ENBREL

Current Criteria:

Initial Criteria (6-month duration):

- Diagnosis of Ankylosing Spondylitis
- Diagnosis of Juvenile Rheumatoid Arthritis (JRA), Juvenile Idiopathic Arthritis, or Active Juvenile Psoriatic Arthritis (JPsA):
  - Trial and failure, contraindication, or intolerance to methotrexate
- Diagnosis of chronic, moderate to severe Plaque Psoriasis and both of the following:
  - Trial and failure to ONE topical treatment of a corticosteroid, calcipotriene, or tazarotene; **AND**
  - Trial and failure, or contraindication, to ONE oral treatment of acitretin, methotrexate, or cyclosporine
- Diagnosis of MILD Psoriatic Arthritis
  - Trial and failure, contraindication, or intolerance to methotrexate
- Diagnosis of moderate to severe Psoriatic Arthritis
- Diagnosis of Rheumatoid Arthritis:
  - Trial and failure, contraindication, or intolerance to methotrexate; **AND**
  - If methotrexate is contraindicated, trial and failure of another oral DMARD is required

Renewal Criteria:

- Patient continues to meet initial approval criteria; **AND**
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, a 50% reduction of total PASI score, etc.)

Proposed Criteria:

Initial Criteria (6-month duration):

- Diagnosis of Ankylosing Spondylitis (AS); ***OR***
- ~~Diagnosis of Juvenile Rheumatoid Arthritis (JRA), Juvenile Idiopathic Arthritis (JIA), or Active Juvenile Psoriatic Arthritis (JPsA):~~
  - ~~Trial and failure, contraindication, or intolerance to methotrexate~~
- Diagnosis of chronic, moderate to severe Plaque Psoriasis and both of the following:
  - Trial and failure to ONE topical treatment of a corticosteroid, calcipotriene, or tazarotene; **AND**
  - Trial and failure, or contraindication, to ONE oral treatment of acitretin, methotrexate, or cyclosporine
- ~~Diagnosis of MILD Psoriatic Arthritis~~
  - ~~Trial and failure, contraindication, or intolerance to methotrexate~~
- Diagnosis of ~~moderate to severe~~ *active* Psoriatic Arthritis (*PsA) or active Juvenile Psoriatic arthritis (JPsA)*; ***OR***
- Diagnosis of Rheumatoid Arthritis *(RA)* or *Polyarticular Juvenile Idiopathic Arthritis (pJIA);* ***AND***
  - *Trial and failure, contraindication, or intolerance to ONE of the following:*
    - *Leflunomide*
    - *Methotrexate*
    - *Sulfasalazine*
  - ~~Trial and failure, contraindication, or intolerance to methotrexate; **AND**~~
  - ~~If methotrexate is contraindicated, trial and failure of another oral DMARD is required~~

Renewal Criteria:

- ~~Patient continues to meet initial approval criteria; **AND**~~
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, a 50% reduction of total PASI score, etc.)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for PREFERRED adalimumab products: HUMIRA, HADLIMA, SIMLANDI

Current Criteria:

Initial Criteria (6-month duration):

- Diagnosis of Ankylosing Spondylitis
- Diagnosis of Juvenile Rheumatoid Arthritis (JRA) or Juvenile Idiopathic Arthritis; **AND**
  - Trial and failure, contraindication, or intolerance to methotrexate
- Diagnosis of chronic, moderate to severe Plaque Psoriasis and both of the following:
  - Trial and failure to ONE topical treatment of a corticosteroid, calcipotriene, or tazarotene; **AND**
  - Trial and failure, or contraindication, to ONE oral treatment of acitretin, methotrexate, or cyclosporine
  - Trial and failure, or contraindication, to oral treatment with acitretin, methotrexate, cyclosporine
- Diagnosis of Generalized pustular psoriasis (GPP) confirmed by ONE of the following:
  - Presence of sterile, macroscopically visible pustules on non-acral skin and pustulation is NOT restricted to psoriatic plaques (i.e. occurs outside of psoriatic plaques)
  - Skin biopsy confirming presence of Kogoj's spongiform pustules
  - Genetic confirmation of IL36RN, CARD14, or AP1S3 mutation
- Diagnosis of MILD Psoriatic Arthritis:
  - Trial and failure, contraindication, or intolerance to methotrexate
- Diagnosis of moderate to severe Psoriatic Arthritis
- Diagnosis of Rheumatoid Arthritis:
  - Trial and failure, contraindication, or intolerance to methotrexate; **AND**
  - If methotrexate is contraindicated, trial and failure of another oral DMARD is required
- Diagnosis of MILD Ulcerative Colitis:
  - Trial and failure of a corticosteroid OR an immunosuppressive agent
- Diagnosis of moderate to severe Ulcerative Colitis
- Diagnosis of Crohn's disease and ONE off the following:
  - Previous trial and failure of infliximab in the past 365 days
  - Diagnosis of Crohn's disease classified as moderate, severe, or fistulizing
  - >90 days of drug therapy with one of the following: azathioprine, mercaptopurine, mesalamine, methotrexate, or systemic glucocorticoid
- Diagnosis of moderate to severe Hidradenitis Suppurativa (HS)
  - >90 days of drug therapy with one of the following: oral or topical antibiotic therapy, oral retinoid therapy, dapsone, or acitretin
- Diagnosis of non-infectious intermediate, posterior or panuveitis:
  - Diagnosis of Uveitis must be by, or in consultation with, an ophthalmologist
  - >90 days of drug therapy with one of the following: oral/injectable steroid therapy, methotrexate, mycophenolate, azathioprine, cyclosporine, tacrolimus, cyclophosphamide

Renewal Criteria:

- Patient continues to meet initial approval criteria; **AND**
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, a 50% reduction of total PASI score, <UC disease activity index, reduction in inflammatory bumps/abscesses, decreases in flares, etc.)

Proposed Criteria:

Initial Criteria (6-month duration):

- Diagnosis of Ankylosing Spondylitis *(AS)*; ***OR***
- ~~Diagnosis of Juvenile Rheumatoid Arthritis (JRA) or Juvenile Idiopathic Arthritis; **AND**~~
  - ~~Trial and failure, contraindication, or intolerance to methotrexate~~
- Diagnosis of chronic, moderate to severe Plaque Psoriasis and both of the following:

- Trial and failure to ONE topical treatment of a corticosteroid, calcipotriene, or tazarotene; **AND**
- Trial and failure, or contraindication, to ONE oral treatment of acitretin, methotrexate, or cyclosporine; **OR**

- Diagnosis of Generalized pustular psoriasis (GPP) confirmed by ONE of the following:
  - Presence of sterile, macroscopically visible pustules on non-acral skin and pustulation is NOT restricted to psoriatic plaques (i.e. occurs outside of psoriatic plaques)
  - Skin biopsy confirming presence of Kogoj's spongiform pustules
  - Genetic confirmation of IL36RN, CARD14, or AP1S3 mutation; **OR**
- ~~Diagnosis of MILD Psoriatic Arthritis:~~
  - ~~Trial and failure, contraindication, or intolerance to methotrexate~~
- Diagnosis of ~~moderate to severe~~ *active* Psoriatic Arthritis *(PsA)*; ***OR***
- Diagnosis of Rheumatoid Arthritis *(RA) or Polyarticular Juvenile Idiopathic Arthritis (pJIA);* ***AND***
  - *Trial and failure, contraindication, or intolerance to ONE of the following:*
    - *Leflunomide*
    - *Methotrexate*
    - *Sulfasalazine;* ***OR***
  - ~~Trial and failure, contraindication, or intolerance to methotrexate;~~ ~~**AND**~~
  - ~~If methotrexate is contraindicated, trial and failure of another oral DMARD is required~~
- ~~Diagnosis of MILD Ulcerative Colitis;~~ ~~***AND***~~
  - ~~Trial and failure of a corticosteroid OR an immunosuppressive agent~~
- Diagnosis of moderate*ly* to severely *active* Ulcerative Colitis *(UC)*; ***OR***
- Diagnosis of *moderately to severely active* Crohn's Disease *(CD)* and ONE off the following:
  - Previous trial and failure of infliximab in the past 365 days
  - Diagnosis of Crohn's disease classified as moderate, severe, or fistulizing
  - >90 days of drug therapy with one of the following: azathioprine, mercaptopurine, mesalamine, methotrexate, or systemic glucocorticoid; ***OR***
- Diagnosis of moderate to severe Hidradenitis Suppurativa (HS); ***OR*** ~~***AND***~~
  - ~~>90 days of drug therapy with one of the following: oral or topical antibiotic therapy, oral retinoid therapy, dapsone, or acitretin;~~ ~~***OR***~~
- Diagnosis of non-infectious intermediate, posterior or panuveitis *(UV)*~~;~~ ~~***AND***~~ *and BOTH of the following:*
  - Diagnosis of Uveitis must be by, or in consultation with, an ophthalmologist; **AND**
  - >90 days of drug therapy with one of the following: oral/injectable steroid therapy, methotrexate, mycophenolate, azathioprine, cyclosporine, tacrolimus, cyclophosphamide

Renewal Criteria:

- ~~Patient continues to meet initial approval criteria;~~ ~~**AND**~~
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, a 50% reduction of total PASI score, <UC disease activity index, reduction in inflammatory bumps/abscesses, decreases in flares, etc.)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for NONPREFERRED adalimumab products: ABRILADA, adalimumab, AMJEVITA, CYLTEZO, HULIO, HYRIMOZ, IDACIO, YUFLYMA, YUSIMRY

Current Criteria:

Initial Criteria (6-month duration):

- Diagnosis of one of the following:
  - Ankylosing Spondylitis
  - Psoriatic Arthritis
  - Rheumatoid Arthritis
  - Juvenile Idiopathic Arthritis (JIA)

- Plaque Psoriasis; **AND**
  - Trial and failure, contraindication, or intolerance to TWO preferred immunomodulators with same indication; **OR**
- Diagnosis of Crohn's Disease; **AND**
  - Trial and failure, contraindication, or intolerance to Humira/Hadlima 40 mg/0.4 mL, Entyvio, or infliximab; **OR**
- Diagnosis of moderate to severe Hidradenitis Suppurativa (HS); **AND**
  - Trial and failure, contraindication, or intolerance of Humira/Hadlima 40 mg/0.4 mL; **OR**
- Diagnosis of Ulcerative Colitis:
  - Trial and failure to two of the following (or have an intolerance or contraindication to all agents):
    - Humira or Hadlima 40 mg/0.4 mL
    - Entyvio
    - Infliximab
    - Xeljanz
    - Rinvoq

Renewal Criteria:

- Patient continues to meet initial approval criteria; **AND**
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, a 50% reduction of total PASI score, endoscopic remission etc.)

Proposed Criteria:

Initial Criteria (6-month duration):

- Diagnosis of one of the following:
  - Ankylosing Spondylitis *(AS)*
  - *Active* Psoriatic Arthritis *(PsA)*
  - Rheumatoid Arthritis *(RA)*
  - *Polyarticular* Juvenile Idiopathic Arthritis (*p*JIA)
  - Plaque Psoriasis *(PsO)*
  - *Moderately to severely active Crohn's Disease (CD)*
  - *Hidradenitis Suppurativa (HS)*
  - *Moderately to severely active Ulcerative Colitis* (UC)
  - *Non-infectious intermediate, posterior or panuveitis (UV);* **AND**
- *Clinically valid reason why ALL the preferred adalimumab products cannot be used*
  - ~~Trial and failure, contraindication, or intolerance to TWO preferred immunomodulators with same indication; **OR**~~
- ~~Diagnosis of Crohn's Disease; **AND**~~
  - ~~Trial and failure, contraindication, or intolerance to Humira/Hadlima 40 mg/0.4 mL, Entyvio, or infliximab; **OR**~~
- ~~Diagnosis of moderate to severe Hidradenitis Suppurativa (HS); **AND**~~
  - ~~Trial and failure, contraindication, or intolerance of Humira/Hadlima 40 mg/0.4 mL; **OR**~~
- ~~Diagnosis of Ulcerative Colitis:~~
  - ~~Trial and failure to two of the following (or have an intolerance or contraindication to all agents):~~
    - ~~Humira or Hadlima 40 mg/0.4 mL~~
    - ~~Entyvio~~
    - ~~Infliximab~~
    - ~~Xeljanz~~
    - ~~Rinvoq~~

Renewal Criteria:

- ~~Patient continues to meet initial approval criteria; **AND**~~
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, a 50% reduction of total PASI score, endoscopic remission etc.)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for Cimzia

Current Criteria:

Initial Criteria (6-month duration):

- One of the following:
  - Diagnosis of one of the following:
    - Ankylosing spondylitis
    - Axial spondyloarthritis, nonradiographic
    - Psoriatic arthritis:
    - Rheumatoid arthritis
    - Plaque psoriasis; **AND**
  - Trial and failure, contraindication, or intolerance to TWO preferred immunomodulators with same indication, **OR**
- Diagnosis of Crohn's Disease; **AND**
  - Trial and failure, contraindication, or intolerance to Humira/Hadlima 40 mg/0.4 mL, Entyvio, or infliximab

Renewal Criteria:

- Patient continues to meet initial approval criteria; **AND**
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, a 50% reduction of total PASI score, endoscopic remission etc.)

Proposed Criteria:

Initial Criteria (6-month duration):

- ~~One of the following:~~
- Diagnosis of one of the following:
  - Ankylosing spondylitis *(AS)*
  - Axial spondyloarthritis, nonradiographic *(nr-axSpA)*
  - *Active* Psoriatic arthritis *(PsA)*
  - Rheumatoid arthritis *(RA)*
  - Plaque psoriasis *(PsO)*
  - *Polyarticular Juvenile Idiopathic Arthritis (pJIA);* ***AND***
    - Trial and failure, contraindication, or intolerance to TWO preferred immunomodulators with same indication, **OR**
- Diagnosis of *moderately to severely active* Crohn's disease (*CD)*; **AND**
  - Trial and failure, contraindication, or intolerance to *a preferred adalimumab product* ~~Humira/Hadlima 40 mg/0.4 mL~~, Entyvio, or infliximab

Renewal Criteria:

- ~~Patient continues to meet initial approval criteria;~~ ~~**AND**~~
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, a 50% reduction of total PASI score, endoscopic remission etc.)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for Simponi

Current Criteria:

Initial Criteria (6-month duration):

- Diagnosis of Ankylosing Spondylitis, Psoriatic Arthritis, or Rheumatoid Arthritis:
  - Trial and failure, contraindication, or intolerance to 2 preferred immunomodulators with same indication

- Diagnosis of Ulcerative Colitis:
  - Trial and failure to two of the following (or have an intolerance or contraindication to all agents):
    - Humira or Hadlima 40 mg/0.4 mL
    - Entyvio
    - Infliximab
    - Xeljanz
    - Rinvoq

Renewal Criteria:

- Patient continues to meet initial approval criteria; **AND**
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, a 50% reduction of total PASI score, endoscopic remission etc.)

Proposed Criteria:

Initial Criteria (6-month duration):

- Diagnosis of Ankylosing Spondylitis (AS), *active* Psoriatic Arthritis (PsA), or Rheumatoid Arthritis (RA)*; **AND***
  - Trial and failure, contraindication, or intolerance to 2 preferred immunomodulators with same indication*; **OR***
- Diagnosis of *moderately to severely active* Ulcerative Colitis *(UC); **AND***
  - Trial and failure to two of the following (or have an intolerance or contraindication to all agents):
    - ~~Humira or Hadlima 40 mg/0.4 mL~~ *A preferred adalimumab product*
    - Entyvio
    - Infliximab
    - ~~Xeljanz~~ *a preferred JAK inhibitor (e.g. Xeljanz and Rinvoq)*
    - ~~Rinvoq~~

Renewal Criteria:

- ~~Patient continues to meet initial approval criteria; **AND**~~
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, a 50% reduction of total PASI score, endoscopic remission etc.)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for ZYMFENTRA

Current Criteria:

Initial Criteria

- Patient is 18 years of age or older; **AND**
- Diagnosis of ONE of the following:
  - Moderately to severely active Crohn's disease
  - Moderately to severely active Ulcerative Colitis; **AND**
- Prescriber attests that patient has received three IV doses of infliximab prior to transitioning to subcutaneous therapy; **AND**
- Submission of medical records demonstrating a positive clinical response following a treatment minimum of 10 weeks of infliximab IV

Renewal Criteria

- Diagnosis of ONE of the following:
  - Moderately to severely active Crohn's disease
  - Moderately to severely active Ulcerative Colitis; **AND**
- Disease response to therapy and tolerability compared to baseline (e.g., decreased UC disease activity index, endoscopic remission, decreased number of soft stools, decreased abdominal pain)

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• ENBREL, 25 mg dose	8 syringes/28 days
• ENBREL/MINI CARTRIDGE/SURECLICK, 50 mg dose	4 syringes/28 days
• HUMIRA	2 syringes/28 days*
• HUMIRA, Starter Packs	1 kit/28 days*
• HADLIMA 40 MG/0.4 ML	2 syringes/28 days*
• ABRILADA	2 injectors/28 days*
• adalimumab	2 injectors/28 days*
• AMJEVITA	2 injectors/28 days*
• CIMZIA	2 kits/28 days (4 syringes)
• CYLTEZO	2 injectors/28 days*
• HADLIMA	2 injectors/28 days*
• HULIO	2 injectors/28 days*
• HYRIMOZ	2 injectors/28 days*
• IDACIO	2 injectors/28 days*
• SIMLANDI	2 injectors/28 days*
• SIMPONI	1 syringe/28 days
• YUFLYMA	2 injectors/28 days*
• YUSIMRY	2 injectors/28 days*
• ZYMFENTRA	2/28 days

*For Hidradenitis Suppurative diagnosis only, dosage is 4 syringes/28 days

COMMITTEE VOTE

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IMMUNOMODULATORS – INTERLEUKIN (IL) INHIBITORS

Re-Review: Pharmacy Initiatives

PDL Placement:

Immunomodulators		
Preferred	**Non-Preferred**	
IL Inhibitors		
KINERET PA, QL (anakinra) TALTZ PA, QL (ixekizumab) TYENNE PA, QL (tocilizumab)	ACTEMRA PA, QL (tocilizumab) ARCALYST PA, QL (rilonacept) BIMZELX PA, QL (bimekizumab) COSENTYX PA, QL (secukinumab) KEVZARA PA, QL (sarilumab) OMVOH PA, QL (mirikizumab) SILIQ PA, QL (brodalumab)	SKYRIZI PA, QL (risankizumab) SPEVIGO PA, QL (spesolimab-sbzo) STELARA prefilled syringe PA, QL (ustekinumab) STELARA 45mg/0.5mL vial PA, QL (ustekinumab) TREMFYA PA, QL (guselkumab)

Recent Significant Changes

- Tyenne subcutaneous formulation, a biosimilar to Actemra (tocilizumab), launched In July 2024

Background – IL inhibitors (see Immunomodulators - General Overview for further details)

Immunomodulators treat a wide variety of conditions, including rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA), plaque psoriasis (PsO), psoriatic arthritis (PsA), ankylosing spondylitis (AS), hidradenitis suppurativa (HS), uveitis (UV), Crohn's Disease (CD), and ulcerative colitis (UC). These agents can be categorized based on their mechanism of action and which cells and cytokines are targeted in the inflammatory process. Actemra (tocilizumab) and Kevzara (sarilumab) have activity directed against the interleukin (IL)-6 receptor; Tyenne (tocilizumab-aazg) is a recently approved biosimilar of Actemra. Kineret (anakinra) targets the IL-1 receptor. Stelara (ustekinumab) targets the IL-12 and IL-23 cytokines. Cosentyx (secukinumab) and Taltz (ixekizumab) bind and neutralize IL-17A. Bimzelx (bimekizumab-bkzx) is a monoclonal antibody against IL-17A, IL-17F, and IL-17AF. Siliq (brodalumab) is an IL-17 receptor antagonist. Tremfya (guselkumab) and Skyrizi (risankizumab) are IL-23 antagonists.

Certain rare conditions for which immunomodulators are indicated are mentioned in this review but not discussed in detail. These include:

- Kineret for the treatment of deficiency of interleukin-1 receptor antagonist (DIRA) and CAPS, specifically neonatal-onset multisystem inflammatory disease (NOMID).
- Actemra for the treatment of systemic sclerosis-associated interstitial lung disease (SSc-ILD).
- Cosentyx (secukinumab) for enthesitis-related arthritis in patients 4 years and older.

Table 1. Medications Included Within Class Review

Drug	Alternative Available*	Type of Agent/Target
ACTEMRA (tocilizumab)	✔ **	Human monoclonal antibody targeting the IL-6 receptor
ARCALYST (rilonacept)	-	IL-1 inhibitor
BIMZELX (bimekizumab-bkzx)	-	Anti-IL17A/F/AF monoclonal antibody
COSENTYX (secukinumab)	-	Human monoclonal antibody to IL-17A
KEVZARA (sarilumab)	-	Human monoclonal antibody targeting IL-6 receptor
KINERET (anakinra)	-	IL-1 receptor antagonist
OMVOH (mirikizumab-mrkz)	-	IL-23 inhibitor
SILIQ (brodalumab)	-	Human monoclonal antibody against IL-17 receptor A (IL-17RA)
SKYRIZI (risankizumab-rzaa)	-	Human monoclonal antibody to IL-23
SPEVIGO (spesolimab-sbzo)	-	IL-36 inhibitor

Drug	Alternative Available*	Type of Agent/Target
STELARA (ustekinumab)	-	Human monoclonal antibody targeting the IL-12 and IL-23 cytokines
TALTZ (ixekizumab)	-	Human monoclonal antibody to IL-17A
TREMFYA (guselkumab)	-	Human monoclonal antibody to IL-23 cytokine
TYENNE (tocilizumab-aazg)	**	Human monoclonal antibody to IL-6 receptor

* Alternatives are agents with the same molecular entity For example, authorized generic, branded generic (unless not considered therapeutically equivalent by the Orange Book), generic, unbranded biologic, or interchangeable biologic.
** Tyenne (tocilizumab-aazg) is FDA-approved biosimilars to Actemra (tocilizumab). It is not interchangeable

Table 2. FDA-Approved Indications (see footnotes for less common indications)

Drug	RA	SJIA	PJIA	PsO	PsA	AS	CD	UC	DIRA
ACTEMRA	✔	✔	✔						
ARCALYST									✔
BIMZELX‡				✔	✔	✔			
COSENTYX				✔	✔	✔			
KEVZARA	✔		✔						
KINERET	✔								✔
OMVOH								✔	
SILIQ				✔					
SKYRIZI				✔	✔		✔	✔	
SPEVIGO				✔					
STELARA				✔	✔		✔	✔	
TALTZ				✔	✔	✔			
TREMFYA				✔	✔			✔	
TYENNE	✔	✔	✔						

RA=rheumatoid arthritis, SJIA=systemic juvenile idiopathic arthritis, PJIA=polyarticular JIA; PsO=plaque psoriasis, PsA=psoriatic arthritis, AS=ankylosing spondylitis, CD=Crohn's Disease, UC=ulcerative colitis; DIRA=deficiency of interleukin-1 receptor antagonist
Actemra is also indicated for Giant Cell Arteritis, Systemic Sclerosis-Associated Interstitial Lung Disease, Cytokine Release Syndrome, and COVID-19; Cosentyx is also for hidradenitis suppurativa (HS), active non-radiographic axial spondyloarthritis (NRAS), and active Enthesitis-related arthritis (ERA); Taltz and Bimzelx are also indicated active non-radiographic axial spondyloarthritis (NRAS); Kevzara is also indicated for treatment of polymyalgia rheumatica (PMR); Tyenne is also indicated for GCA; Kineret is also indicated for the treatment of Neonatal-Onset Multisystem Inflammatory Disease (NOMID)

Prior Authorization criteria for KINERET

Current Criteria:

Initial Criteria (6-month duration):

- Diagnosis of Rheumatoid Arthritis:
  - Trial and failure, contraindication, or intolerance to methotrexate; **AND**
  - If methotrexate is contraindicated, trial and failure of another oral DMARD is required
- Diagnosis of Neonatal-Onset Multisystem Inflammatory Disease (NOMID)
- Diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

Renewal Criteria:

- Patient continues to meet initial approval criteria; **AND**
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, etc.)

Proposed Criteria:

Initial Criteria (6-month duration):

- Diagnosis of Rheumatoid Arthritis *(RA);* ***AND***
  - *Trial and failure, contraindication, or intolerance to ONE of the following:*
    - *Leflunomide*
    - *Methotrexate*
    - *Sulfasalazine;* ***OR***
  - ~~Trial and failure, contraindication, or intolerance to methotrexate;~~ ~~**AND**~~
  - ~~If methotrexate is contraindicated, trial and failure of another oral DMARD is required~~
- Diagnosis of Neonatal-Onset Multisystem Inflammatory Disease (NOMID); ***OR***
- Diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

Renewal Criteria:

- ~~Patient continues to meet initial approval criteria;~~ ~~**AND**~~
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, etc.)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for TALTZ

Current Criteria:

Initial Criteria (6-month duration):

- Diagnosis of chronic, moderate to severe Plaque Psoriasis; **AND**
  - Patient is 6 years of age or older; **AND**
  - Trial and failure to a topical treatment of a corticosteroid, calcipotriene, OR tazarotene; **AND**
  - Trial and failure, or contraindication, to oral treatment with acitretin, methotrexate, cyclosporine
- Diagnosis of MILD Psoriatic Arthritis:
  - Trial and failure, contraindication, or intolerance to methotrexate
- Diagnosis of moderate to severe Psoriatic Arthritis
- Diagnosis of Axial spondyloarthritis (axSpA), Active Ankylosing Spondylitis (AS), or Active non-radiographic axial spondyloarthritis (nr-axSpA)

Renewal Criteria:

- Patient continues to meet initial approval criteria; **AND**
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, a 50% reduction of total Psoriasis Area Severity Index (PASI) score, etc.)

Proposed Criteria:

Initial Criteria (6-month duration):

- Diagnosis of chronic, moderate to severe Plaque Psoriasis *(PsO) and BOTH of the following*; ~~**AND**~~
  - ~~Patient is 6 years of age or older;~~ ~~**AND**~~
  - Trial and failure to a topical treatment of a corticosteroid, calcipotriene, OR tazarotene; **AND**
  - Trial and failure, or contraindication, to oral treatment with acitretin, methotrexate, cyclosporine; **OR**
- ~~Diagnosis of MILD Psoriatic Arthritis:~~
  - ~~Trial and failure, contraindication, or intolerance to methotrexate~~
- Diagnosis of ~~moderate to severe~~ *active* Psoriatic Arthritis *(PsA)*; ***OR***
- Diagnosis of Axial spondyloarthritis (axSpA), Active Ankylosing Spondylitis (AS), or Active non-radiographic axial spondyloarthritis (nr-axSpA)

Renewal Criteria:

- ~~Patient continues to meet initial approval criteria;~~ ~~**AND**~~
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, a 50% reduction of total Psoriasis Area Severity Index (PASI) score, etc.)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for Tyenne

Current Criteria:

Initial Criteria: (6-month duration)

- Diagnosis of Rheumatoid Arthritis; **AND**
  - Trial and failure, contraindication, or intolerance to methotrexate;
  - If methotrexate is contraindicated, trial and failure of another oral DMARD is required
- Diagnosis of active Polyarticular Juvenile Idiopathic Arthritis; **AND**
  - Trial and failure, contraindication, or intolerance to methotrexate
- Diagnosis of active Systemic Juvenile Idiopathic Arthritis
- Diagnosis of Giant Cell Arteritis and ONE of the following:
  - Trial/ failure of > 90 days of therapy with systemic glucocorticoids, azathioprine, or methotrexate; **OR**
  - Occurrence of GCA relapse while patient on prednisone doses greater than 20 mg/day, **OR**
  - Contraindication or intolerance to all the above agents

Renewal Criteria:

- Patient continues to meet initial approval criteria; **AND**
- Disease response to therapy and tolerability compared to baseline (e.g., decrease number of tender/swollen joint course)

Proposed Criteria:

Initial Criteria: (6-month duration)

- Diagnosis of Rheumatoid Arthritis *(RA)* or *active Polyarticular Juvenile Idiopathic Arthritis (pJIA)*; **AND**
  - *Trial and failure, contraindication, or intolerance to ONE of the following:*
    - *Leflunomide*
    - *Methotrexate*
    - *Sulfasalazine; **OR***
  - ~~Trial and failure, contraindication, or intolerance to methotrexate;~~
  - ~~If methotrexate is contraindicated, trial and failure of another oral DMARD is required~~
- ~~Diagnosis of active Polyarticular Juvenile Idiopathic Arthritis; **AND**~~
  - ~~Trial and failure, contraindication, or intolerance to methotrexate~~
- Diagnosis of active Systemic Juvenile Idiopathic Arthritis *(SJIA)*; **OR**
- Diagnosis of Giant Cell Arteritis *(GCA)* and ONE of the following:
  - Trial and failure of > 90 days of therapy with systemic glucocorticoids, azathioprine, or methotrexate *unless contraindicated or intolerance*; **OR**
  - Occurrence of GCA relapse while patient on prednisone doses greater than 20 mg/day, **OR**
  - *Patient will be utilizing systemic glucocorticoids with tocilizumab*
  - ~~Contraindication or intolerance to all the above agents~~

Renewal Criteria:

- ~~Patient continues to meet initial approval criteria; **AND**~~
- Disease response to therapy and tolerability compared to baseline (e.g., decrease number of tender/swollen joint course)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for Actemra, Actemra ACTPen

Current Criteria:

Initial Criteria (6-month duration):

- Diagnosis of Rheumatoid Arthritis and BOTH of the following:
  - Trial and failure, contraindication, or intolerance to methotrexate

- Clinically valid reason why the preferred product Tyenne cannot be used*;* **OR**
- Diagnosis of active Polyarticular Juvenile Idiopathic Arthritis and BOTH of the following:
  - Trial and failure, contraindication, or intolerance to methotrexate
  - Clinically valid reason why the preferred product Tyenne cannot be used; **OR**
- Diagnosis of active Systemic Juvenile Idiopathic Arthritis; **AND**
  - Clinically valid reason why the preferred product Tyenne cannot be used; **OR**
- Diagnosis of Giant Cell Arteritis and BOTH of the following:
  - One of the following:
    - Trial and failure of > 90 days of therapy with systemic glucocorticoids, azathioprine, or methotrexate
    - Occurrence of GCA relapse while patient on prednisone doses greater than 20 mg/day
    - Contraindication or intolerance to all the above agents
  - Clinically valid reason why the preferred product Tyenne cannot be used
- Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) and ALL the following:
  - Patient is 18 years of age or older; **AND**
  - Patient's onset of disease was 5 years ago or less; **AND**
  - Patient has active disease with elevated inflammatory markers or platelets

Renewal Criteria:

- Patient continues to meet initial approval criteria; **AND**
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts)

Proposed Criteria:

Initial Criteria (6-month duration):

- Diagnosis of Rheumatoid Arthritis *(RA) or active Polyarticular Juvenile Idiopathic Arthritis (pJIA)* and BOTH of the following:
  - *Trial and failure, contraindication, or intolerance to ONE of the following:*
    - *Leflunomide*
    - *Methotrexate*
    - *Sulfasalazine; **AND***
  - ~~Trial and failure, contraindication, or intolerance to methotrexate~~
  - Clinically valid reason why the preferred product Tyenne cannot be used*;* **OR**
- ~~Diagnosis of active Polyarticular Juvenile Idiopathic Arthritis and BOTH of the following:~~
  - ~~Trial and failure, contraindication, or intolerance to methotrexate~~
  - ~~Clinically valid reason why the preferred product Tyenne cannot be used; **OR**~~
- Diagnosis of active Systemic Juvenile Idiopathic Arthritis *(SJIA)*; **AND**
  - Clinically valid reason why the preferred product Tyenne cannot be used; **OR**
- Diagnosis of Giant Cell Arteritis *(GCA) and* BOTH of the following:
  - One of the following:
    - Trial and failure of > 90 days of drug therapy with systemic glucocorticoids, azathioprine, or methotrexate, *unless contraindicated or intolerance; **OR***
    - Occurrence of GCA relapse while patient on prednisone doses greater than 20 mg/day; ***OR***
    - *Patient will be utilizing systemic glucocorticoid with tocilizumab; **AND***
    - ~~Contraindication or intolerance to all the above agents~~
  - Clinically valid reason why the preferred product Tyenne cannot be used; ***OR***
- Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) and ALL the following:
  - Patient is 18 years of age or older; **AND**
  - Patient's onset of disease was 5 years ago or less; **AND**
  - Patient has active disease with elevated inflammatory markers or platelets

Renewal Criteria:

- ~~Patient continues to meet initial approval criteria; **AND**~~
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for Bimzelx

Current Criteria:

Initial Criteria

- Diagnosis of chronic, moderate to severe Plaque Psoriasis; **AND**
- Patient has a contraindication, drug-drug interaction, or adverse reaction to ALL preferred immunomodulator agents with same indication; **AND**
- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment; **AND**
- Patient will not receive live vaccines during therapy;

Renewal Criteria

- Patient continues to meet initial approval criteria; **AND**
- Disease response to therapy and tolerability compared to baseline (e.g., a 50% reduction of total PASI scor)

Proposed Criteria:

Initial Criteria

- Diagnosis of m*oderate to severe Plaque Psoriasis (PsO), Active Psoriatic Arthritis (PsA), or Ankylosing Spondylitis (AS)* ~~chronic, moderate to severe Plaque Psoriasis;~~ **AND**
  - *Trial and failure, contraindication, or intolerance to TWO preferred immunomodulators with the same indication;* ***OR***
- ~~Patient has a contraindication, drug-drug interaction, or adverse reaction to ALL preferred immunomodulator agents with same indication;~~ ~~**AND**~~
- *Diagnosis of Non-Radiographic Axial Spondyloarthritis (nr-axSpA);* ***AND***
  - *Trial and failure, contraindication, or intolerance to Taltz*
- ~~Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment;~~ ~~**AND**~~
- ~~Patient will not receive live vaccines during therapy;~~

Renewal Criteria

- ~~Patient continues to meet initial approval criteria;~~ ~~**AND**~~
- Disease response to therapy and tolerability compared to baseline (e.g., a 50% reduction of total Psoriasis Area Severity Index (PASI) score, etc.)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for Cosentyx

Current Criteria:

Initial Criteria (6-month duration):

- Diagnosis of chronic, moderate to severe Plaque Psoriasis in patients 6 years of age and older; **AND**
  - Trial and failure, contraindication, or intolerance to TWO preferred immunomodulators with same indication
- Diagnosis of Ankylosing Spondylitis in adults; **AND**
  - Trial and failure, contraindication, or intolerance to TWO preferred immunomodulators with same indication
- Diagnosis of Psoriatic Arthritis in patients 2 years of age and older; **AND**
  - Trial and failure, contraindication, or intolerance to TWO preferred immunomodulators with same indication
- Diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation; **AND**

- Trial and failure, contraindication, or intolerance of Taltz
- Diagnosis of Active Enthesitis-related arthritis in patients 4 years of age and older; **AND**
  - Failed an adequate trial of TWO NSAIDs (unless contraindicated); **AND**
- Diagnosis of moderate to severe Hidradenitis Suppurativa (HS); **AND**
  - Trial and failure, contraindication, or intolerance of Humira/Hadlima 40 mg/0.4 mL

Renewal Criteria:

- Patient continues to meet initial criteria; **AND**
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, a 50% reduction of total Psoriasis Area Severity Index (PASI) score, reduction in inflammatory bumps/abscesses, decreases in flares, etc.)

Proposed Criteria:

Initial Criteria (6-month duration):

- Diagnosis of chronic, moderate to severe Plaque Psoriasis *(PsO)*, *Ankylosing Spondylitis (AS), active Psoriatic Arthritis (PsA)* ~~in patients 6 years of age and older;~~ **AND**
  - Trial and failure, contraindication, or intolerance to TWO preferred immunomodulators with same indication; ***OR***
- ~~Diagnosis of Ankylosing Spondylitis in adults; **AND**~~
  - ~~Trial and failure, contraindication, or intolerance to TWO preferred immunomodulators with same indication~~
- ~~Diagnosis of Psoriatic Arthritis in patients 2 years of age and older; **AND**~~
  - ~~Trial and failure, contraindication, or intolerance to TWO preferred immunomodulators with same indication~~
- Diagnosis of active Non-Radiographic Axial Spondyloarthritis (nr-axSpA) with objective signs of inflammation; **AND**
  - Trial and failure, contraindication, or intolerance of Taltz; **OR**
- Diagnosis of active Enthesitis-Related Arthritis *(ERA)* ~~in patients 4 years of age and older~~; **AND**
  - Failed an adequate trial of ~~TWO~~ *a* NSAID~~s~~ (unless contraindicated); **OR** ~~**AND**~~
- Diagnosis of moderate to severe Hidradenitis Suppurativa (HS); **AND**
  - Trial and failure, contraindication, or intolerance of *a preferred adalimumab product* ~~Humira/Hadlima 40 mg/0.4 mL~~

Renewal Criteria:

- ~~Patient continues to meet initial criteria; **AND**~~
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, a 50% reduction of total Psoriasis Area Severity Index (PASI) score, reduction in inflammatory bumps/abscesses, decreases in flares, etc.)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for KEVZARA

Current Criteria:

Initial Criteria (6-month duration):

- Diagnosis of Rheumatoid Arthritis; **AND**
  - Trial and failure, contraindication, or intolerance to 2 preferred immunomodulators with same indication: **OR**
- Diagnosis of active Polyarticular Juvenile Idiopathic Arthritis and All of the following:
  - Patient weighs at least 63 kg
  - Trial and failure, contraindication, or intolerance to methotrexate
  - Trial and failure or intolerance to a TNF-inhibitor (e.g. Humira, Enbrel); **OR**
- Diagnosis of Polymyalgia Rheumatic; **AND**

- Trial and failure, contraindication, or intolerance to systemic corticosteroids; **AND**
- Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment and continues to be screened during therapy; **AND**
- Patient will not receive live vaccines during therapy or for 30 days prior to initiation of therapy; **AND**
- Will NOT be approved if patient meets ANY of the following:
  - Active infection, including clinically important localized infections
  - Absolute neutrophil count (ANC) < 2,000/mm3
  - Platelet count < 150,000/mm3
  - AST or ALT > 1.5 times the upper limit of normal (ULN)

Renewal Criteria (6-month duration):

- Patient continues to meet initial approval criteria; **AND**
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts)

Proposed Criteria:

Initial Criteria (6-month duration):

- Diagnosis of Rheumatoid Arthritis *(RA) or active Polyarticular Juvenile Idiopathic Arthritis (pJIA)*; **AND**
  - Trial and failure, contraindication, or intolerance to 2 preferred immunomodulators with same indication: **OR**
- ~~Diagnosis of active Polyarticular Juvenile Idiopathic Arthritis and All of the following:~~
  - ~~Patient weighs at least 63 kg~~
  - ~~Trial and failure, contraindication, or intolerance to methotrexate~~
  - ~~Trial and failure or intolerance to a TNF-inhibitor (e.g. Humira, Enbrel);~~ ~~**OR**~~
- Diagnosis of Polymyalgia Rheumatic *(PR)*; **AND**
  - Trial and failure, contraindication, or intolerance to systemic corticosteroids~~;~~ ~~**AND**~~
- ~~Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment and continues to be screened during therapy;~~ ~~**AND**~~
- ~~Patient will not receive live vaccines during therapy or for 30 days prior to initiation of therapy;~~ ~~**AND**~~
- ~~Will NOT be approved if patient meets ANY of the following:~~
  - ~~Active infection, including clinically important localized infections~~
  - ~~Absolute neutrophil count (ANC) < 2,000/mm3~~
  - ~~Platelet count < 150,000/mm3~~
  - ~~AST or ALT > 1.5 times the upper limit of normal (ULN)~~

Renewal Criteria (~~6~~ *12* - month duration):

- ~~Patient continues to meet initial approval criteria;~~ ~~**AND**~~
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for OMVOH AUTO-INJECTOR

Current Criteria:

Initial Criteria: (6-month duration)

- Diagnosis of Ulcerative Colitis; **AND**
- Trial and failure to two of the following (or have an intolerance or contraindication to all agents):
  - Humira or Hadlima 40 mg/0.4 mL
  - Entyvio
  - Infliximab
  - Xeljanz
  - Rinvoq

Renewal Criteria:

- Patient continues to meet the initial criteria; **AND**
- Disease response to therapy and tolerability compared to baseline (e.g. endoscopic remission etc.)

Proposed Criteria:

Initial Criteria: (6-month duration)

- Diagnosis of *moderate to severe* Ulcerative Colitis *(UC)*; **AND**
- Trial and failure to two of the following (or have an intolerance or contraindication to all agents):
  - *A preferred adalimumab product* ~~Humira or Hadlima 40 mg/0.4 mL~~
  - Entyvio
  - Infliximab
  - ~~Xeljanz~~ *a preferred JAK inhibitor (e.g. Xeljanz or Rinvoq)*
  - ~~Rinvoq~~

Renewal Criteria:

- ~~Patient continues to meet the initial criteria; **AND**~~
- Disease response to therapy and tolerability compared to baseline (e.g. endoscopic remission etc.)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for Siliq

Current Criteria:

Initial Criteria (6-month duration):

- Patient has a diagnosis of moderate to severe plaque psoriasis; **AND**
- Patient has a contraindication, drug-drug interaction, or adverse reaction to ALL preferred immunomodulator agents with same indication; **AND**
- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment; **AND**
- Patient will not receive live vaccines during therapy; **AND**
- Patient does not have a history of Crohn's disease; **AND**
- Prescriber and patient have met the requirements of the Siliq REMS program

Renewal Criteria:

- Patient continues to meet initial approval criteria; **AND**
- Disease response to therapy and tolerability compared to baseline (e.g., a 50% reduction of total Psoriasis Area Severity Index (PASI) score, etc.)

Proposed Criteria:

Initial Criteria (6-month duration):

- ~~Patient has a~~ Diagnosis of moderate to severe Plaque Psoriasis *(PsO)*; **AND**
- Patient has a contraindication, drug-drug interaction, or adverse reaction to ~~ALL~~ TWO preferred immunomodulator agents with same indication; **AND**
- ~~Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment; **AND**~~
- ~~Patient will not receive live vaccines during therapy; **AND**~~
- Patient does not have a history of Crohn's disease *(CD)*; **AND**
- Prescriber and patient have met the requirements of the Siliq REMS program

Renewal Criteria:

- ~~Patient continues to meet initial approval criteria; **AND**~~
- Disease response to therapy and tolerability compared to baseline (e.g., a 50% reduction of total Psoriasis Area Severity Index (PASI) score, etc.)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for Skyrizi

Current Criteria:

Initial Criteria (6-month duration):

- Age 18 years or older; **AND**
- Patient has been evaluated for the presence of latent TB infection prior to initiating treatment and continues to monitor during treatment; **AND**
- Patient does not have a clinically important active infection; **AND**
- Patient will not receive live vaccines during therapy or for 30 days prior to initiation of therapy; **AND**
- ONE of the following:
  - Diagnosis of moderate-to-severe plaque psoriasis (PsO); **AND**
    - One of the following:
      - Involvement of at least 10% of body surface area (BSA)
      - Psoriasis area and severity index (PASI) score of 12 or greater
      - Incapacitation due to plaque location (e.g., head and neck, palms, soles, or genitalia); **AND**
    - Patient did not respond adequately (or is not a candidate) to a 3-month minimum trial of phototherapy (e.g., Psoralens with UVA light [PUVA] or UVB with coal tar or dithranol); **AND**
    - Trial and failure, contraindication, intolerance to 2 preferred immunomodulators with same indication
  - Diagnosis of active psoriatic arthritis (PsA) for at least 6-months; **AND**
    - ≥ 5 tender joints and ≥ 5 swollen joints, active plaque psoriasis or psoriatic nail disease at baseline; **AND**
    - Trial and failure, contraindication, or intolerance to 2 preferred immunomodulators with the same indication
  - Diagnosis of moderately to severely active Crohn's disease (CD); **AND**
    - Patient has a Crohn's disease activity index (CDAI) of 220 to 450; **AND**
    - Simple endoscopic score for Crohn's disease (SES-CD) ≥6 (or ≥4 for isolated ileal disease); **AND**
    - Trial and failure, contraindication, or intolerance to Humira/Hadlima 40 mg/0.4 mL, Entyvio, or infliximab
  - Diagnosis of moderately to severely active Ulcerative colitis (UC); **AND**
    - Trial and failure to two of the following (or have an intolerance or contraindication to all agents):
      - Humira or Hadlima 40 mg/0.4 mL
      - Entyvio
      - Infliximab
      - Xeljanz
      - Rinvoq

Renewal Criteria:

- Patient continues to meet the initial criteria; **AND**
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, a 50% reduction of total PASI score, endoscopic remission etc.)

Proposed Criteria:

Initial Criteria (6-month duration):

- ~~Age 18 years or older; **AND**~~
- ~~Patient has been evaluated for the presence of latent TB infection prior to initiating treatment and continues to monitor during treatment; **AND**~~
- ~~Patient does not have a clinically important active infection; **AND**~~
- ~~Patient will not receive live vaccines during therapy or for 30 days prior to initiation of therapy; **AND**~~
- ONE of the following:
  - Diagnosis of moderate-to-severe plaque psoriasis (PsO) or *active psoriatic arthritis (PsA)*; **AND**
    - ~~One of the following:~~

- ~~Involvement of at least 10% of body surface area (BSA)~~
- ~~Psoriasis area and severity index (PASI) score of 12 or greater~~
- ~~Incapacitation due to plaque location (e.g., head and neck, palms, soles, or genitalia);~~ **~~AND~~**

– ~~Patient did not respond adequately (or is not a candidate) to a 3-month minimum trial of phototherapy (e.g., Psoralens with UVA light [PUVA] or UVB with coal tar or dithranol);~~ **~~AND~~**

– Trial and failure, contraindication, or intolerance to 2 preferred immunomodulators with same indication; ***OR***

- ~~Diagnosis of active psoriatic arthritis (PsA) for at least 6 months;~~ **~~AND~~**
  - ~~≥ 5 tender joints and ≥ 5 swollen joints, active plaque psoriasis or psoriatic nail disease at baseline;~~ **~~AND~~**
  - ~~Trial and failure, contraindication, or intolerance to 2 preferred immunomodulators with same indication~~
- Diagnosis of moderately to severely active Crohn's disease (CD); **AND**
  - ~~Patient has a Crohn's disease activity index (CDAI) of 220 to 450;~~ **~~AND~~**
  - ~~Simple endoscopic score for Crohn's disease (SES-CD) ≥6 (or ≥4 for isolated ileal disease);~~ **~~AND~~**
  - Trial and failure, contraindication, or intolerance to *a preferred adalimumab product* ~~Humira/Hadlima 40 mg/0.4 mL~~, Entyvio, or infliximab; ***OR***
- Diagnosis of moderately to severely active Ulcerative colitis (UC); **AND**
  - Trial and failure to two of the following (or have an intolerance or contraindication to all agents):
    - *A preferred adalimumab product* ~~Humira or Hadlima 40 mg/0.4 mL~~
    - Entyvio
    - Infliximab
    - ~~Xeljanz~~ *a preferred JAK inhibitor (e.g. Xeljanz or Rinvoq)*
    - ~~Rinvoq~~

Renewal Criteria:

- ~~Patient continues to meet the initial criteria;~~ **~~AND~~**
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, a 50% reduction of total PASI score, endoscopic remission etc.)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for STELARA PREFILLED SYRINGE AND 45 MG/0.5 ML VIAL

Current Criteria:

Initial Criteria (6-month duration):

- Diagnosis of Plaque Psoriasis:
  - Trial/failure, contraindication, or intolerance to 2 preferred immunomodulators with same indication
- Diagnosis of Psoriatic Arthritis:
  - Trial and failure, contraindication, or intolerance to 2 preferred immunomodulators with same indication
- Diagnosis of Crohn's disease or Ulcerative Colitis:
  - Trial and failure to two of the following (or have an intolerance or contraindication to all agents):
    - Humira or Hadlima 40 mg/0.4 mL
    - Entyvio
    - Infliximab
    - Xeljanz
    - Rinvoq

Renewal Criteria:

- Patient continues to meet the initial criteria; **AND**
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, a 50% reduction of total PASI score, endoscopic remission etc.)

Proposed Criteria:

Initial Criteria (6-month duration):

- Diagnosis of Plaque Psoriasis *(PsO)* or *active Psoriatic Arthritis (PsA)*; ***AND***
  - Trial and failure, contraindication, or intolerance to 2 preferred immunomodulators with same indication; ***OR***
- ~~Diagnosis of Psoriatic Arthritis;~~
  - ~~Trial and failure, contraindication, or intolerance to 2 preferred immunomodulators with same indication~~
- *Diagnosis of moderately to severely active Crohn's disease (CD);* ***AND***
  - *Trial and failure, contraindication, or intolerance to a preferred adalimumab product, Entyvio, or infliximab;* ***OR***
- Diagnosis of ~~Crohn's disease or~~ *moderately to severely active* Ulcerative Colitis *(UC)*; ***AND***
  - Trial and failure to two of the following (or have an intolerance or contraindication to all agents):
    - ~~–~~ *A preferred adalimumab product* ~~Humira or Hadlima 40 mg/0.4 mL~~
    - Entyvio
    - Infliximab
    - ~~– Xeljanz~~ *a preferred JAK inhibitor (e.g. Xeljanz or Rinvoq)*
    - ~~– Rinvoq~~

Renewal Criteria:

- ~~Patient continues to meet the initial criteria;~~ ~~**AND**~~
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, a 50% reduction of total PASI score, endoscopic remission etc.)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for TREMFYA PREFILLED SYRINGE

Current Criteria:

Initial Criteria (6-month duration):

- Diagnosis of Plaque Psoriasis:
  - Age 18 years or older; **AND**
  - Patient has been evaluated for the presence of latent TB infection prior to initiating treatment and will be monitored throughout treatment; **AND**
  - Patient does not have a clinically important active infection; **AND**
  - Patient will not receive live vaccines during therapy or for 30 days prior to initiation of therapy; **AND**
  - Patient has moderate-to-severe plaque psoriasis for at least 6-months with at least 1 of the following:
    - Involvement of at least 10% of body surface area (BSA); **OR**
    - Psoriasis Area and Severity Index (PASI) score of 12 or greater; **OR**
    - Incapacitation due to plaque location (e.g., head and neck, palms, soles, or genitalia); **AND**
  - Patient did not respond adequately (or is unable to access) to a 3-month minimum trial of phototherapy (e.g., Psoralens with UVA light [PUVA] or UVB with coal tar or dithranol); **AND**
  - Trial and failure to ALL preferred immunomodulator agents with the same indication
- Diagnosis of Psoriatic Arthritis:
  - Trial and failure, contraindication, or intolerance to 2 preferred immunomodulators with same indication

Renewal Criteria:

- Patient continues to meet initial criteria; **AND**
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, a 50% reduction of total Psoriasis Area Severity Index (PASI) score, etc.)

Proposed Criteria:

Initial Criteria (6-month duration):

- ~~Diagnosis of Plaque Psoriasis:~~
  - ~~Age 18 years or older; **AND**~~
  - ~~Patient has been evaluated for the presence of latent TB infection prior to initiating treatment and will be monitored throughout treatment; **AND**~~
  - ~~Patient does not have a clinically important active infection; **AND**~~
  - ~~Patient will not receive live vaccines during therapy or for 30 days prior to initiation of therapy; **AND**~~
  - ~~Patient has moderate-to-severe plaque psoriasis for at least 6 months with at least 1 of the following:~~
    - ~~Involvement of at least 10% of body surface area (BSA); **OR**~~
    - ~~Psoriasis Area and Severity Index (PASI) score of 12 or greater; **OR**~~
    - ~~Incapacitation due to plaque location (e.g., head and neck, palms, soles, or genitalia); **AND**~~
  - ~~Patient did not respond adequately (or is unable to access) to a 3-month minimum trial of phototherapy (e.g., Psoralens with UVA light [PUVA] or UVB with coal tar or dithranol); **AND**~~
  - ~~Trial and failure to ALL preferred immunomodulator agents with the same indication~~
- Diagnosis of *Plaque Psoriasis (PsO) or* Psoriatic Arthritis *(PsA)*; **AND**
  - Trial and failure, contraindication, or intolerance to 2 preferred immunomodulators with same indication; **OR**
- Diagnosis of *moderately to severely active* Ulcerative Colitis (UC); **AND**
  - Trial and failure to two of the following (or have an intolerance or contraindication to all agents):
    - ~~–~~ *A preferred adalimumab product*
    - Entyvio
    - Infliximab
    - *a preferred JAK inhibitor (e.g. Xeljanz or Rinvoq)*

Renewal Criteria:

- ~~Patient continues to meet initial criteria; **AND**~~
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, a 50% reduction of total Psoriasis Area Severity Index (PASI) score, etc.)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for TREMFYA AUTOINJECTOR

Current Criteria:

- Patient must meet ALL Tremfya prefilled-syringe criteria; **AND**
- Provider must provide clinical rationale as to why the autoinjector is required over the prefilled syringe

Proposed Criteria:

- Patient must meet ALL Tremfya prefilled-syringe criteria ~~**AND**~~
- ~~Provider must provide clinical rationale as to why the autoinjector is required over the prefilled syringe~~

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for ARCALYST

Current Criteria:

- Patient has diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS), and Muckle-Wells Syndrome (MWS); **OR**
- Patient has diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA); **AND**
  - Patient has tried and failed or have contraindication or intolerance to preferred agent Kineret; **OR**

- Patient has diagnosis of recurrent pericarditis (RP); **AND**
  - Trial and failure, contraindication, or intolerance to ONE of the following:
    - Colchicine
    - Corticosteroids
    - NSAIDS

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for SPEVIGO

Current Criteria:

Initial Criteria:

- Patient is 12 years of age and older; **AND**
- Patient weights at least 40 kg; **AND**
- Diagnosis of Generalized pustular psoriasis (GPP) confirmed by ONE of the following:
  - Presence of sterile, macroscopically visible pustules on non-acral skin and pustulation is NOT restricted to psoriatic plaques (i.e. occurs outside of psoriatic plaques)
  - Skin biopsy confirming presence of Kogoj's spongiform pustules;
  - Genetic confirmation of IL36RN, CARD14, or AP1S3 mutation; **AND**
- Prescriber attest to ALL of the following:
  - Treatment is NOT for an active GPP flare
  - Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment
  - Patient will not receive live vaccines during therapy and 16 weeks after treatment; **AND**
- Trial and failure to BOTH of the following (or have an intolerance or contraindication to all agents):
  - A TNF inhibitor (e.g. adalimumab, infliximab, and etanercept)
  - Taltz; **AND**
- Prescribed by, or in consultation with, a dermatologist

Renewal Criteria:

- Submission of medical records (e.g. chart notes) documenting disease response to therapy and tolerability compared to baseline (e.g., decreased number of GPP flares)

Note: The Spevigo subcutaneous formulation is not FDA approved for the treatment of GPP flare and will not be approved for that diagnosis. A SQ loading dose is not required following treatment of a GPP flare with IV Spevigo

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• KINERET	1 syringe/day
• TALTZ	1 syringe/28 days
• TYENNE	4 injections (3.6mL)/28 days
• ACTEMRA, ACTEMRA ACTPEN	3.6 mL/28 days
• ARCALYST	8 vials/month
• BIMZELX	2 injections/56 days

• COSENTYX 300 mg dose	2 pens/28 days
• COSENTYX 150 mg dose	1 pen/28 days
• KEVZARA	2 pens or syringes/30 days
• OMVOH AUTOINJECTOR	2 autoinjectors/28 days
• SILIQ	2 syringes/28 days
• SKYRIZI cartridge	1 per 8 weeks
• SKYRIZI autoinjector, prefilled syringe, prefilled syringe kit	2 per 84 days
• SPEVIGO	2/28 days
• STELARA prefilled syringe 45 mg/0.5 mL vial	Plaque psoriasis, Psoriatic arthritis: 1 injection/84 days Crohn's disease, Ulcerative Colitis: 1 injection/56 days
• TREMFYA autoinjector	1 autoinjector (1 mL)/56 days
• TREMFYA prefilled syringe	1 syringe (1 mL)/56 days

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

IMMUNOMODULATORS – MISCELLANEOUS

Re-Review: Pharmacy Initiatives

PDL Placement:

Immunomodulators		
Preferred	**Non-Preferred**	
Miscellaneous		
ORENCIA [PA, QL] (abatacept) OTEZLA [PA, QL] (apremilast)	ENTYVIO [PA, QL] (vedolizumab) SOTYKTU [PA, QL] (deucravacitinib)	VELSIPITY [PA, QL] (etrasimod)

Recent Significant Changes

- In April 2024, the FDA approved Otezla for the treatment of pediatric patients ≥ 6 years of age and weighing ≥ 20 kg with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
  - Otezla was previously approved for treatment of adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy.

Background – Miscellaneous (see Immunomodulators - General Overview for further details)

Immunomodulators treat a wide variety of conditions, including rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA), plaque psoriasis (PsO), psoriatic arthritis (PsA), Crohn's disease (CD), and ulcerative colitis (UC). T cells, B cells, and cytokines such as tumor necrosis factor (TNF), interleukin-1 (IL-1), and interleukin-6 (IL-6) play a key role in the inflammatory and immune process. This has led to the development of biologic agents to target these areas. Other immunomodulators targeting different cells and cytokines in the inflammatory and immune process are also FDA approved.

Certain rare conditions for which immunomodulators are indicated are mentioned in this review but not discussed in detail. These include Orencia for prophylaxis of acute graft-versus-host disease (GVHD) and Otezla for treatment of oral ulcers associated with Behçet disease.

Table 1. Medications Included Within Class Review

Drug	Alternative Available *	Type of Agent/Target
Injectables – Innovator agents		
ENTYVIO (vedolizumab)	-	α4-β7 integrin receptor antagonist
ORENCIA (abatacept)	-	sCTLA-4-Ig recombinant fusion protein
Oral agents		
OTEZLA (apremilast)	-	Small-molecule phosphodiesterase 4 inhibitor
SOTYKTU (deucravacitinib)	-	Tyrosine kinase 2 (TYK2) inhibitor
VELSIPITY (etrasimod)	-	Sphingosine 1-Phosphate (S1P) Receptor Modulator

Table 2. FDA-Approved Indications (see footnotes for less common indications)

Drug	Rheumatoid Arthritis (RA)	Polyarticular Juvenile Idiopathic Arthritis (PJIA)	Plaque Psoriasis (PsO)	Psoriatic Arthritis (PsA)	Ulcerative Colitis (UC)	Crohn's Disease (CD)
ENTYVIO (vedolizumab)					✔ ^	✔ ^
ORENCIA∞∞,∞, * (abatacept)	✔ ∞∞	✔ ⌂		✔		
OTEZLA~ (apremilast)			✔ ⌂⌂	✔		
SOTYKTU (deucravacitinib)			✔ ‡			
VELSIPITY (etrasimod)					✔ ^	

* Also indicated for the prophylaxis of acute GVHD.
^ moderately to severely active disease
‡ Indicated for the treatment of chronic moderate to severe PsO who are candidates for systemic therapy or phototherapy

∞ Indicated for the reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active RA in patients who have failed one or more DMARDs. Can be used alone or in combination with DMARDs other than TNF blocking agents.
∞∞ Indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active RA. May be used as monotherapy or concomitantly with DMARDs other than TNF antagonists.
~ Otezla also indicated for treatment of adults with oral ulcers associated with Behçet disease.
☖ Indicated for reducing signs and symptoms in patients ≥ 2 years with moderate to severely active PJIA. May be used as monotherapy or with MTX.
☖☖ Indicated for the treatment of patients 6 years and older weighing at least 20 kg who are candidates for phototherapy or systemic therapy.

Prior Authorization criteria for ORENCIA

Current Criteria:

Initial Criteria: (6-month duration)

- Diagnosis of Rheumatoid Arthritis:
  - Trial and failure, contraindication, or intolerance to methotrexate; **AND**
  - If methotrexate is contraindicated, trial and failure of another oral DMARD is required
- Diagnosis of Polyarticular Juvenile Idiopathic Arthritis
  - Trial and failure, contraindication, or intolerance to methotrexate
- Diagnosis of MILD Psoriatic Arthritis:
  - Trial and failure, contraindication, or intolerance to methotrexate
- Diagnosis of moderate to severe Psoriatic Arthritis
- Prophylaxis of acute graft versus host disease:
  - In combination with a calcineurin inhibitor and methotrexate; **AND**
  - In patients undergoing hematopoietic stem cell transplantation from a matched or 1 allele-mismatched unrelated-donor

Renewal Criteria:

- Patient continues to meet initial approval criteria; **AND**
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, a 50% reduction of total Psoriasis Area Severity Index (PASI) score, etc.)

Proposed Criteria:

Initial Criteria (6-month duration):

- Diagnosis of Rheumatoid Arthritis *(RA) or Polyarticular Juvenile Idiopathic Arthritis (pJIA)*; **AND**
  - *Trial and failure, contraindication, or intolerance to ONE of the following:*
    - *Leflunomide*
    - *Methotrexate*
    - *Sulfasalazine; **OR***
  - ~~Trial and failure, contraindication, or intolerance to methotrexate; **AND**~~
  - ~~If methotrexate is contraindicated, trial and failure of another oral DMARD is required~~
- ~~Diagnosis of Polyarticular Juvenile Idiopathic Arthritis~~
  - ~~Trial and failure, contraindication, or intolerance to methotrexate~~
- ~~Diagnosis of MILD Psoriatic Arthritis:~~
  - ~~Trial and failure, contraindication, or intolerance to methotrexate~~
- Diagnosis of ~~moderate to severe~~ *active* Psoriatic Arthritis *(PsA);*
- ~~Prophylaxis of acute graft versus host disease:~~
  - ~~In combination with a calcineurin inhibitor and methotrexate; **AND**~~
  - ~~In patients undergoing hematopoietic stem cell transplantation from a matched or 1 allele-mismatched unrelated-donor~~

Renewal Criteria:

- ~~Patient continues to meet initial approval criteria; **AND**~~
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, a 50% reduction of total Psoriasis Area Severity Index (PASI) score, etc.)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for Otezla

Current Criteria:

Initial Criteria: (6-month duration)

- Diagnosis of Plaque Psoriasis:
  - Trial and failure to a topical treatment of a corticosteroid, calcipotriene, OR tazarotene; **AND**
  - Trial and failure, or contraindication, to oral treatment with Soriatane®, methotrexate, cyclosporine
- Diagnosis of MILD Psoriatic Arthritis:
  - Trial and failure, contraindication, or intolerance to methotrexate
- Diagnosis of moderate to severe Psoriatic Arthritis
- Diagnosis of oral lesions associated with Behçet's Disease
  - Patient has active oral ulcers; **AND**
  - Trial and failure, contraindication, or intolerance to colchicine; **AND**
  - Trial and failure, contraindication, or intolerance to a corticosteroid, methotrexate, or azathioprine

Renewal Criteria:

- Patient continues to meet initial approval criteria; **AND**
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, a 50% reduction of total Psoriasis Area Severity Index (PASI) score, etc.)

Proposed Criteria:

Initial Criteria: (6-month duration)

- Diagnosis of Plaque Psoriasis *(PsO) and BOTH of the following*:
  - Trial and failure to a topical treatment of a corticosteroid, calcipotriene, OR tazarotene; ~~**AND**~~
  - Trial and failure, or contraindication, to oral treatment with Soriatane, methotrexate, cyclosporine; **OR**
- ~~Diagnosis of MILD Psoriatic Arthritis; ***AND***~~
  - ~~Trial and failure, contraindication, or intolerance to methotrexate~~
- Diagnosis of ~~moderate to severe~~ *active* Psoriatic Arthritis; ***OR***
- Diagnosis of oral lesions associated with Behçet's Disease and BOTH of the following:
  - Patient has active oral ulcers; **AND**
  - Trial and failure, contraindication, or intolerance to colchicine; ~~**AND**~~
  - ~~Trial and failure, contraindication, or intolerance to a corticosteroid, methotrexate, or azathioprine~~

Renewal Criteria:

- ~~Patient continues to meet initial approval criteria; **AND**~~
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, a 50% reduction of total Psoriasis Area Severity Index (PASI) score, etc.)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for Sotyktu

Current Criteria:

Initial Criteria (6-month duration):

- Diagnosis of moderate to severe Plaque Psoriasis; **AND**
- Trial and failure, contraindication, or intolerance to 2 preferred immunomodulators with same indication

Renewal Criteria:

- Patient continues to meet initial approval criteria; **AND**
- Disease response to therapy and tolerability compared to baseline (e.g., 50% reduction of total PASI score,)

Proposed Criteria:

Initial Criteria (6-month duration):

- Diagnosis of moderate to severe Plaque Psoriasis *(PsO)*; **AND**
- Trial and failure, contraindication, or intolerance to 2 preferred immunomodulators with same indication

Renewal Criteria:

- ~~Patient continues to meet initial approval criteria;~~ ~~**AND**~~
- Disease response to therapy and tolerability compared to baseline (e.g., a50% reduction of total PASI score)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for VELSIPITY

Current Criteria:

Initial Criteria (3-month duration)

- Patient is ≥ 18 years old; **AND**
- Diagnosis of moderately to severely active ulcerative colitis (UC); **AND**
- Trial and failure to TWO of the following (or have an intolerance or contraindication to all agents):
  - Humira
  - Entyvio
  - Infliximab
  - Xeljanz
  - Rinvoq
- Patient does NOT have any of the following:
  - Recent (within the previous 6 months) myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure with hospitalization, or Class III/IV heart failure
  - History or presence of Mobitz Type II second-degree, or third-degree atrioventricular block, sick sinus syndrome, or sino-atrial block (unless treated with a functioning pacemaker);

Renewal Criteria

- Patient continues to meet initial criteria; **AND**
- Disease response to therapy and tolerability compared to baseline (e.g., endoscopic remission, decreased stool frequency, decreased rectal bleeding)

Proposed Criteria:

Initial Criteria (~~3~~ *6* -month duration)

- Patient is ≥ 18 years old; **AND**
- Diagnosis of moderately to severely active Ulcerative colitis (UC); **AND**
- Trial and failure to two of the following (or have an intolerance or contraindication to all agents):
  - ~~Humira~~ *A preferred adalimumab product*
  - Entyvio
  - Infliximab; ***AND***
  - ~~Xeljanz~~ *a preferred JAK inhibitor (e.g. Xeljanz and Rinvoq);* ***AND***
  - ~~Rinvoq~~
- Patient does NOT have any of the following:
  - Recent (within the previous 6 months) myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure with hospitalization, or Class III/IV heart failure
  - History or presence of Mobitz Type II second-degree, or third-degree atrioventricular block, sick sinus syndrome, or sino-atrial block (unless treated with a functioning pacemaker)

Renewal Criteria

- ~~Patient continues to meet initial criteria;~~ ~~**AND**~~
- Disease response to therapy and tolerability compared to baseline (e.g., endoscopic remission, decreased stool frequency, decreased rectal bleeding)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for ENTYVIO

Current Criteria:

Initial Criteria: (4-month duration)

- Diagnosis of moderate to severe Crohn's disease or severe ulcerative colitis (UC); **AND**
- Trial and failure, contraindication, or intolerance of a TNF- inhibitor (e.g., Humira, Infliximab) supported by paid claims or chart notes; **AND**
- Prescriber attests that patient has or will receive ≥ 2 IV doses prior to transitioning to subcutaneous therapy

Renewal Criteria:

- Patient is established on Entyvio therapy for > 14 weeks (supported by paid claims or chart notes); **AND**
- Documentation of positive disease response to therapy and tolerability compared to baseline (e.g., decreased UC disease activity index, endoscopic remission, decreased stool frequency)

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• ORENCIA	4 mL/28 days
• OTEZLA 30 mg	2/day
• OTEZLA STARTER PACK	1/Rx
• ENTYVIO	2 injections/28 days
• SOTYKTU	1/day
• VELSIPITY	1/day

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

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ANTI-RHEUMATIC: KINASE INHIBITORS

Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred
Anti-Rheumatic: Kinase Inhibitors	RINVOQ PA, QL (upadacitinib) RINVOQ LQ PA, QL(upadacitinib) XELJANZ PA, QL (tofacitinib)	OLUMIANT PA, QL (baricitinib) XELJANZ XR PA, QL (tofacitinib) XELJANZ soln PA, QL (tofacitinib)

Last Review Date: August 2023

Recent Significant Changes

- No significant changes since last review

Background

Immunomodulators treat a wide variety of conditions, including rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), atopic dermatitis (AD), Crohn's Disease (CD), and ulcerative colitis (UC).

Xeljanz/Xeljanz XR/Xeljanz oral solution (tofacitinib), Rinvoq (upadacitinib), and Olumiant (baricitinib), which target Janus-associated kinase (JAK) pathways are oral immunomodulator agents on the market. By inhibiting the JAK pathway, the ability of cytokines to produce inflammation is reduced. Olumiant (baricitinib) is also approved for the treatment of COVID-19 in hospitalized patients requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). Information on COVID-19-related indications will not be addressed in this review.

Table 1. Medications Included Within Class Review

Drug	Alternative Available*	Type of Agent/Target
OLUMIANT (baricitinib)	-	Small molecule Janus kinase (JAK) inhibitor
RINVOQ/RINVOQ LQ (upadacitinib)	-	Small molecule Janus kinase (JAK) inhibitor
XELJANZ/XELJANZ XR (tofacitinib)	-	Small molecule Janus kinase (JAK) inhibitor

* Alternatives are agents with the same molecular entity. For example, authorized generic, branded generic (unless not considered therapeutically equivalent by the Orange Book), generic, unbranded biologic, or interchangeable biologic.

Rheumatoid Arthritis (RA)

The 2021 America College of Rheumatology (ACR) recommends the use of conventional DMARDs (eg, hydroxychloroquine, sulfasalazine, MTX, leflunomide), a TNF inhibitor, a non-TNF inhibitor biologic (tocilizumab, sarilumab, abatacept, rituximab), or a JAK inhibitor (Xeljanz [(tofacitinib]), Olumiant [(baricitinib]), Rinvoq [upadacitinib]). For patients who are not at target, switching to a medication in a different class is conditionally recommended over switching to a medication in the same class for patients receiving a biologic or JAK inhibitor. Biosimilars are considered equivalent to FDA-approved originator biologics.

The 2023 European Alliance of Association Rheumatology (EULAR) guidelines for RA management recommends therapy with DMARDs should be initiated as soon as the RA diagnosis is made with treatment aimed at reaching a target of sustained remission or low disease activity in every patient. If the treatment target is not achieved with the first conventional synthetic DMARD (csDMARD) strategy, in the absence of poor prognostic factors, other csDMARDs should be considered. If poor prognostic factors are present with csDMARD failure, a biological DMARD should be added; JAK inhibitors may be considered, but pertinent risk factors should be well-thought-out. In patients who cannot use csDMARDs as a comedication, IL-6 inhibitors and targeted synthetic DMARDs may have some advantages compared with other biologic DMARDs. If a biologic or targeted synthetic DMARD has failed, treatment with another should be considered. If one TNF or IL-6 inhibitor therapy has failed, patients may receive an agent with another mode of action or a second TNF or IL-6 inhibitor.

Table 2. Food and Drug Administration (FDA) Approved Indications See package insert for full indication details.

Drug	Rheumatoid Arthritis (RA)	Polyarticular Juvenile Idiopathic Arthritis (PJIA)	Psoriatic Arthritis (PsA)	Ankylosing Spondylitis (AS)	Crohn's Disease (CD)	Ulcerative Colitis (UC)
OLUMIANT (baricitinib) ⌂⌂	✔ *,⌂					
RINVOQ~~ (upadacitinib)	✔ *,⌂	✔ *,**,⌂	✔ *,**,⌂	✔ *,⌂	✔ **	✔ **
RINVOQ LQ (upadacitinib)		✔ *,**,⌂	✔ *,**,⌂			
XELJANZ/XELJANZ XR (tofacitinib)	✔ *,⌂	✔ *,**,⌂	✔ *,⌂	✔ *,⌂		

*Patients with moderately to severely active disease who have had an inadequate response or intolerance to ≥ 1 DMARD (Actemra, Kevzara, Tyenne) or ≥ 1 TNF antagonists (Olumiant, Rinvoq, Xeljanz).
**Patients 2 years and older.
~~Rinvoq is also indicated for the treatment of adults with active non-radiographic axial spondyloarthritis (NRAS) with objective signs of inflammation as well as treatment of adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable.
⌂ Not recommended for use in combination with other JAK inhibitors (Rinvoq only), biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine.
⌂⌂ Indicated for severe alopecia areata in adults.

Juvenile Idiopathic Arthritis (JIA)

The 2019 ACR and Arthritis Foundation guideline for the treatment of JIA focuses on therapy for non-systemic polyarthritis, sacroiliitis, and enthesitis. Recommendations for initial therapy include the use of DMARDs (MTX, leflunomide, or sulfasalazine); the preference for MTX over other agents is conditionally recommended. In children and adolescents with JIA and polyarthritis with moderate to high disease activity, addition of a biologic to DMARD (TNF inhibitor, abatacept, or tocilizumab) is conditionally recommended. Patients with continued disease activity and primary TNF inhibitor failure are conditionally recommended to receive abatacept or tocilizumab over a second TNF inhibitor. Children and adolescents with JIA and active sacroiliitis despite treatment with NSAIDs are strongly recommended to add TNF inhibitor therapy over continuing NSAID monotherapy.

A 2021 guideline from the ACR addresses the treatment of oligoarthritis, temporomandibular joint arthritis, and Systemic Juvenile Idiopathic Arthritis (SJIA). For SJIA, an IL-1 inhibitor or IL-6 inhibitor is conditionally recommended for initial treatment; no specific agent is preferred. Monotherapy with an NSAID may also be considered for initial treatment of SJIA without macrophage activation syndrome. Systemic glucocorticoids are conditionally recommended as part of initial therapy for patients with macrophage activation syndrome. If residual arthritis is present despite these therapies, a conventional synthetic DMARD may be added, or a different biologic therapy may be tried. Patients without macrophage activation syndrome who experience incomplete response or intolerance to an initial IL-1 or IL-6 inhibitor may be switched to an alternative IL-1 or IL-6 inhibitor.

Psoriatic Arthritis (PsA)

EULAR 2023 PsA guidelines recommend biologic DMARDs in patients with peripheral arthritis and an inadequate response to at least 1 synthetic DMARD, such as MTX. In patients with peripheral arthritis and an inadequate response to at least one synthetic DMARD and at least one biologic DMARD, JAK inhibitors may be considered; JAK inhibitors may also be considered in patients for whom biologic DMARD therapy is not appropriate. Apremilast is considered a treatment option in patients with peripheral arthritis and an inadequate response to at least 1 synthetic DMARD, in whom biologics and JAK inhibitors are not appropriate. The choice of the mechanism of action should be based on musculoskeletal manifestations related to PsA; for patients with clinically relevant skin involvement, an IL-17A inhibitor (ixekizumab, secukinumab), IL-17A/F inhibitor

(bimekizumab), IL-23 inhibitor (guselkumab, risankizumab), or IL-12/23 inhibitor (ustekinumab) are preferred; for patients with uveitis, TNF inhibitors (adalimumab, certolizumab, etanercept, infliximab, and golimumab) are preferred. In patients with inadequate response or intolerance to a biologic DMARD or JAK inhibitor, switching to another biologic DMARD or JAK inhibitor should be considered, including one switch within a class.

The ACR/NPF guideline on PsA recommends that a TNF inhibitor is preferred in treatment-naïve patients with active PsA, although an oral therapy (MTX, sulfasalazine, leflunomide, cyclosporine, or apremilast) can be a first-line option in patients without severe PsA and without severe psoriasis, or if a patient has another compelling reason to avoid a TNF inhibitor. In patients who fail oral therapy, a switch to a TNF inhibitor is preferred and placed ahead of IL-17 biologics (secukinumab, ixekizumab, brodalumab), IL-12/23 biologics (ustekinumab), abatacept, and tofacitinib.

Ankylosing Spondylitis (AS)

The ACR/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network joint recommendations for treatment of AS. Patients with active AS who do not respond to initial NSAID therapy are conditionally recommended to be treated with sulfasalazine, MTX, or tofacitinib; sulfasalazine or methotrexate should be considered only in patients with prominent peripheral arthritis or when TNF inhibitors are not available. Patients who do not respond to NSAID therapy are strongly recommended to receive treatment with a TNF inhibitor, although no particular TNF inhibitor is preferred. Treatment with a TNF inhibitor is conditionally recommended over tofacitinib, secukinumab, and ixekizumab in these patients. In patients with active disease who have primary nonresponse with a TNF inhibitor, treatment with secukinumab or ixekizumab is strongly recommended, and treatment with tofacitinib is conditionally recommended. Patients with secondary nonresponse to treatment with a TNF inhibitor are conditionally recommended to receive treatment with an alternative TNF inhibitor. In patients with AS and inflammatory bowel disease or recurrent iritis, TNF inhibitors are conditionally recommended over treatment with other biologics. In patients with stable disease who are treated with an originator TNF inhibitor, the guideline strongly recommends continuing the originator TNF inhibitor over mandated switching to its biosimilar.

Joint recommendations for the management of axial spondyloarthritis are available from the Assessment of Spondyloarthritis international Society (ASAS) and EULAR and were updated in 2022. The guideline notes that radiographic axial spondyloarthritis and non-radiographic axial spondyloarthritis are part of the same disease spectrum, and therefore uses the term axial spondyloarthritis in recommendations. The guidelines state that NSAIDs should be used first-line in patients with pain and stiffness; other analgesics might be considered if NSAIDs have failed or are contraindicated or poorly tolerated. Glucocorticoid injections may be considered, but patients with axial disease should not receive long-term systemic glucocorticoids. Sulfasalazine may be considered in patients with peripheral arthritis, but patients with purely axial disease should normally not be treated with conventional DMARDs. TNF inhibitors, IL-17A inhibitors, or JAK inhibitors should be considered in patients with persistently high disease activity despite conventional treatments; current practice is to start with a TNF inhibitor or IL-17A inhibitor. In patients with a history of recurrent uveitis or active IBD, preference should be given to a monoclonal antibody against TNF. In patients with significant psoriasis, an IL-17 inhibitor may be preferred. Following failure of the first biologic or targeted synthetic DMARD, switching to another biologic DMARD (TNF inhibitor or IL-17A inhibitor) or a JAK inhibitor should be considered. For patients in sustained remission, tapering of a biologic DMARD can be considered.

Crohn's Disease (CD) and Ulcerative Colitis (UC)

A 2019 guideline from the American College of Gastroenterology (ACG) recommends 5-ASA therapy for induction of remission in mildly active UC, and budesonide, systemic corticosteroids, TNF inhibitor therapy (adalimumab, golimumab, or infliximab), vedolizumab, and tofacitinib for induction of remission in moderately to severely active disease. Vedolizumab and tofacitinib are recommended for induction of remission in patients who have failed previous TNF inhibitor therapy. For maintenance of remission in patients with previously mildly active disease, 5-ASA therapy is recommended, and in patients with previously moderately to severely active disease, continuation of TNF inhibitor therapy, vedolizumab, or tofacitinib is recommended after induction of remission with these agents.

For adult outpatients with moderate to severe UC, a 2020 American Gastroenterological Association (AGA) guideline strongly recommends using infliximab, adalimumab, golimumab, vedolizumab, tofacitinib, or ustekinumab over no treatment. However, for patients with less severe disease who place a higher value on the safety of 5-ASA therapy and a lower value on the efficacy of biologic agents, it is reasonable to choose gradual step therapy with 5-ASA.

A 2021 AGA guideline on the medical management of moderate to severe CD strongly recommends the use of biologic monotherapy over thiopurine monotherapy for the induction of remission in adult outpatients and recommends TNF inhibitors or ustekinumab over no treatment for induction and maintenance of remission. In patients who are naïve to biologic drugs, infliximab, adalimumab, or ustekinumab are recommended over certolizumab pegol for the induction of remission and vedolizumab is suggested over certolizumab pegol. In patients who never responded to TNF inhibitors, the use of ustekinumab is recommended and the use of vedolizumab is suggested over no treatment for the induction of remission. In patients who previously responded to infliximab, the use of adalimumab or ustekinumab is recommended and the use of vedolizumab is suggested over no treatment for the induction of remission. The AGA recommends against the use of 5-ASA or sulfasalazine over no treatment for the induction or maintenance of remission. In patients with CD and active perianal fistula, infliximab is recommended over no treatment for the induction and maintenance of fistula remission. In patients with CD and active perianal fistula without perianal abscess, the use of biologic agents in combination with an antibiotic over a biologic drug alone is recommended for the induction of fistula remission.

Safety Information

Olumiant (baricitinib), Rinvoq (upadacitinib), and Xeljanz / Xeljanz XR/Xeljanz oral solution (tofacitinib) all have warnings for serious infections such as active tuberculosis, which may present with pulmonary or extrapulmonary disease; invasive fungal infections; and bacterial, viral, and other infections due to opportunistic pathogens.

In addition, these agents all have warnings for increased risk of malignancies. Xeljanz/Xeljanz XR/Xeljanz oral solution (tofacitinib), Rinvoq (upadacitinib), and Olumiant (baricitinib) have warnings for increased risk of thrombosis and death, including sudden cardiovascular death. In September 2021, the FDA announced that its review of a large, randomized safety clinical trial comparing Xeljanz (tofacitinib) vs a TNF inhibitor in RA found an increased risk of serious heart-related events such as heart attack or stroke, cancer, blood clots, and death with tofacitinib. The final results showed an increased risk of adverse events (AEs) with the lower dose as well as the higher dose. The FDA believes that baricitinib and upadacitinib have similar risks because they share the same mechanism of action. The FDA has limited all approved uses of baricitinib, tofacitinib, and upadacitinib to certain patients who have not responded or cannot tolerate 1 or more TNF inhibitors.

The immunomodulator agents should not be given with live (including attenuated) vaccines; additionally, non-live vaccines may not elicit a sufficient immune response.

Clinical Rationale

JAK inhibitors are oral immunomodulator agents used to treat a variety of inflammatory conditions. Due to increased risk heart attack or stroke, cancer, blood clots, and death, JAK inhibitors are recommended after inadequate response to one or more tumor necrosis factor (TNF) blockers.

Recommendation

Since kinase inhibitors are considered 2nd line therapy, as well as the risk of significant adverse events, it is recommended that the kinase inhibitors be subject to prior authorization.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for RINVOQ

Current Criteria:

Initial Criteria (6-month duration):

- Prescriber attests to each of the following:
  - Patient is not concurrently taking biologic agents (i.e., adalimumab, anakinra, etanercept, rituximab, tocilizumab, infliximab) OR potent immunosuppressants (i.e., azathioprine, cyclosporine); **AND**
  - Benefits of using this agent outweigh the risks of heart-related events (heart attack, stroke, blood clots, etc.) or cardiovascular risk factors; **AND**
  - Risk of malignancy has been considered and it has been determined that Jak Kinase inhibitor therapy is appropriate; **AND**
- One of the following:
  - Diagnosis of moderately to severely active rheumatoid arthritis OR active psoriatic arthritis; **AND**
    - Trial and failure or intolerance to methotrexate (unless there is a documented absolute contraindication such as alcohol abuse, cirrhosis, chronic liver disease); **AND**
    - Trial and failure or intolerance to a TNF-inhibitor (e.g. Humira, Enbrel)
  - Diagnosis of moderately to severely active Ulcerative Colitis (UC); **AND**
    - Trial and failure, contraindication, or intolerance to TNF-inhibitor (e.g. Humira, Enbrel)
  - Diagnosis of moderately to severely active Crohn's Disease; **AND**
    - Trial and failure or intolerance to a TNF-inhibitor (e.g., Humira);
  - Diagnosis of moderate to severe Atopic Dermatitis; **AND**
    - Trial and failure (documented by claims) or contraindication to 1 topical corticosteroid of medium-to-high potency (e.g., mometasone, fluocinolone); **AND**
    - Trial and failure, contraindication, or intolerance to a topical calcineurin inhibitor
  - Diagnosis of active ankylosing spondylitis; **AND**
    - Trial and failure or intolerance to a TNF-inhibitor (e.g. Humira, Enbrel);
  - Diagnosis of active non-radiographic axial spondylarthritis (nr-axSpA) with objective signs of inflammation; **AND**
    - Trial and failure or intolerance to a TNF-inhibitor (e.g. Humira, Enbrel)

Renewal Criteria:

- Patient continues to meet initial approval criteria; **AND**
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, lower UC disease activity index, etc.)

Proposed Criteria:

Initial Criteria (6-month duration):

- Prescriber attests to each of the following:
  - Patient is not concurrently taking biologic agents (i.e., adalimumab, anakinra, etanercept, rituximab, tocilizumab, infliximab) OR potent immunosuppressants (i.e., azathioprine, cyclosporine); **AND**
  - Benefits of using this agent outweigh the risks of heart-related events (heart attack, stroke, blood clots, etc.) or cardiovascular risk factors; **AND**
  - Risk of malignancy has been considered and it has been determined that Jak Kinase inhibitor therapy is appropriate; **AND**
- One of the following:
  - Diagnosis of moderately to severely active rheumatoid arthritis *(RA)* OR *active polyarticular juvenile idiopathic arthritis (pJIA)* ~~active psoriatic arthritis; **AND**~~ *and BOTH of the following:*
    - *Trial and failure, contraindication, or intolerance to ONE of the following:*
      - *Leflunomide*
      - *Methotrexate*
      - *Sulfasalazine; **AND***
    - ~~Trial and failure or intolerance to methotrexate (unless there is a documented absolute contraindication such as alcohol abuse, cirrhosis, chronic liver disease); **AND**~~

- Trial and failure or intolerance to a TNF-inhibitor (e.g. Humira, Enbrel); **OR**
- *Diagnosis of active psoriatic arthritis (PSA);* ***AND***
  - Trial and failure or intolerance to a TNF-inhibitor (e.g. Humira, Enbrel); ***OR***
- Diagnosis of moderately to severely active Ulcerative Colitis (UC); **AND**
  - Trial and failure, contraindication, or intolerance to TNF-inhibitor (e.g. Humira, Enbrel); ***OR***
- Diagnosis of moderately to severely active Crohn's Disease; **AND**
  - Trial and failure or intolerance to a TNF-inhibitor (e.g., Humira); ***OR***
- Diagnosis of moderate to severe Atopic Dermatitis *and BOTH of the following*:
  - Trial and failure (~~documented by claims) or~~ contraindication, *or intolerance* to ONE topical corticosteroid of medium-to-high potency (e.g., mometasone, fluocinolone); **AND**
  - Trial and failure, contraindication, or intolerance to a topical calcineurin inhibitor; ***OR***
- Diagnosis of active ankylosing spondylitis; **AND**
  - Trial and failure or intolerance to a TNF-inhibitor (e.g. Humira, Enbrel); ***OR***
- Diagnosis of active non-radiographic axial spondylarthritis (nr-axSpA) with objective signs of inflammation; **AND**
  - Trial and failure or intolerance to a TNF-inhibitor (e.g. Humira, Enbrel)

Renewal Criteria:

- ~~Patient continues to meet initial approval criteria; **AND**~~
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, lower UC disease activity index, etc.)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for RINVOQ LQ

Current Criteria:

Initial Criteria (6-month duration):

- Prescriber attests to each of the following:
  - Patient is not concurrently taking biologic agents (i.e., adalimumab, anakinra, etanercept, rituximab, tocilizumab, infliximab) OR potent immunosuppressants (i.e., azathioprine, cyclosporine); **AND**
  - Benefits of using this agent outweigh the risks of heart-related events (heart attack, stroke, blood clots, etc.) or cardiovascular risk factors
  - Risk of malignancy has been considered and it has been determined that Jak Kinase inhibitor therapy is appropriate; **AND**
- One of the following:
  - Diagnosis of active Polyarticular Juvenile Idiopathic Arthritis (pJIA); **AND**
    - Trial and failure, contraindication, or intolerance to ONE of the following:
      - Leflunomide
      - Methotrexate
      - Sulfasalazine; ***OR***
  - Diagnosis of active psoriatic arthritis (PSA); **AND**
- Trial and failure or intolerance to a TNF-inhibitor (e.g. Humira, Enbrel); **AND**
- One of the following:
  - Patient weighs <30 kg
  - Patient is unable to swallow solid dosage forms

Renewal criteria:

- One of the following:
  - Patient weighs <30 kg
  - Patient is unable to swallow oral dosage forms; **AND**
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, etc.)

Proposed Criteria:
Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for XELJANZ tablet

Current Criteria:
Initial Criteria (6-month duration):
- Prescriber attests to each of the following:
  - Patient is not concurrently taking biologic agents (i.e., adalimumab, anakinra, etanercept, rituximab, tocilizumab, infliximab) OR potent immunosuppressants (i.e., azathioprine, cyclosporine); **AND**
  - Benefits of using this agent outweigh the risks of heart-related events (heart attack, stroke, blood clots, etc.) or cardiovascular risk factors
  - Risk of malignancy has been considered and it has been determined that Jak Kinase inhibitor therapy is appropriate; **AND**
- One of the following:
  - Diagnosis of moderately to severely active Rheumatoid Arthritis (RA), active Polyarticular Course Juvenile Idiopathic Arthritis (pcJIA), or active Psoriatic Arthritis (PsA); **AND**
    - Trial and failure or intolerance to methotrexate (unless there is a documented absolute contraindication such as alcohol abuse, cirrhosis, chronic liver disease); **AND**
    - Trial and failure or intolerance to a TNF-inhibitor (e.g. Humira, Enbrel)
  - Diagnosis of moderately to severely active Ulcerative Colitis (UC); **AND**
    - Trial and failure, contraindication, or intolerance to Humira
  - Diagnosis of Ankylosing spondylitis; **AND**
    - Trial and failure or intolerance to a TNF-inhibitor (e.g. Humira, Enbrel)

Renewal Criteria:
- Patient continues to meet initial approval criteria; **AND**
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, lower UC disease activity index, etc.)

Proposed Criteria:
Initial Criteria (6-month duration):
- Prescriber attests to each of the following:
  - Patient is not concurrently taking biologic agents (i.e., adalimumab, anakinra, etanercept, rituximab, tocilizumab, infliximab) OR potent immunosuppressants (i.e., azathioprine, cyclosporine); **AND**
  - Benefits of using this agent outweigh the risks of heart-related events (heart attack, stroke, blood clots, etc.) or cardiovascular risk factors
  - Risk of malignancy has been considered and it has been determined that Jak Kinase inhibitor therapy is appropriate; **AND**
- One of the following:
  - Diagnosis of moderately to severely active Rheumatoid Arthritis (RA) *or* active Polyarticular Course Juvenile Idiopathic Arthritis (pcJIA) ~~or active Psoriatic Arthritis (PsA); **AND**~~ *and BOTH of the following:*
    - *Trial and failure, contraindication, or intolerance to ONE of the following:*
      - *Leflunomide*
      - *Methotrexate*
      - *Sulfasalazine;* **AND**
    - ~~Trial and failure or intolerance to methotrexate (unless there is a documented absolute contraindication such as alcohol abuse, cirrhosis, chronic liver disease); **AND**~~
    - Trial and failure or intolerance to a TNF-inhibitor (e.g. Humira, Enbrel); ***OR***
  - *Diagnosis of active Psoriatic Arthritis (PsA); **AND***

- *Trial and failure or intolerance to a TNF-inhibitor (e.g. Humira, Enbrel);* ***OR***
  - Diagnosis of moderately to severely active Ulcerative Colitis (UC); **AND**
    - Trial and failure, contraindication, or intolerance to Humira; ***OR***
  - Diagnosis of Ankylosing spondylitis; **AND**
    - Trial and failure or intolerance to a TNF-inhibitor (e.g. Humira, Enbrel)

Renewal Criteria:

- ~~Patient continues to meet initial approval criteria;~~ ~~**AND**~~
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, lower UC disease activity index, etc.)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for OLUMIANT

Current Criteria:

Initial Criteria (6-month duration):

- Prescriber attests to each of the following:
  - Patient is not concurrently taking biologic agents (i.e., adalimumab, anakinra, etanercept, rituximab, tocilizumab, infliximab) OR potent immunosuppressants (i.e., azathioprine, cyclosporine); **AND**
  - Benefits of using this agent outweigh the risks of heart-related events (heart attack, stroke, blood clots, etc.) or cardiovascular risk factors
  - Risk of malignancy has been considered and it has been determined that Jak Kinase inhibitor therapy is appropriate; **AND**
- One of the following:
  - Diagnosis of moderately to severely active Rheumatoid Arthritis; **AND**
    - Trial and failure or intolerance to methotrexate (unless there is a documented absolute contraindication such as alcohol abuse, cirrhosis, chronic liver disease); **AND**
    - Trial and failure, contraindication, or intolerance a preferred TNF-inhibitors (e.g., Enbrel, Humira); **AND**
    - Trial and failure, contraindication, or intolerance to ONE preferred agent; **OR**
  - Diagnosis of severe alopecia areata; **AND**
    - Patient is at least 18 years old but less than 21 years old (indication is not a covered benefit in patients > 21 years old); **AND**
    - Recipient has ≥ 50% scalp hair loss; **AND**
    - Prescriber attests patient does not have other underlying causes of hair loss (e.g. male pattern hair loss (androgenic alopecia), female pattern hair loss, telogen effluvium, traction alopecia, and tinea capitis); **AND**
    - Recipient must be evaluated every 4 months by a physician and submit chart documentation indicating patient has had improved hair growth/decreased hair loss

Renewal Criteria:

- For a diagnosis of Rheumatoid Arthritis, patient continues to meet initial approval criteria; **AND**
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, lower UC disease activity index, etc.)

Note: Will not be covered for COVID-19 treatment in post hospitalized patients

Proposed Criteria:

Initial Criteria (6-month duration):

- Prescriber attests to each of the following:
  - Patient is not concurrently taking biologic agents (i.e., adalimumab, anakinra, etanercept, rituximab, tocilizumab, infliximab) OR potent immunosuppressants (i.e., azathioprine, cyclosporine); **AND**

- Benefits of using this agent outweigh the risks of heart-related events (heart attack, stroke, blood clots, etc.) or cardiovascular risk factors
- Risk of malignancy has been considered and it has been determined that Jak Kinase inhibitor therapy is appropriate; **AND**

- One of the following:
  - Diagnosis of moderately to severely active Rheumatoid Arthritis *(RA)*~~;~~ ~~**AND**~~ *and ALL of the following:*
    - *Trial and failure, contraindication, or intolerance to ONE of the following:*
      - *Leflunomide*
      - *Methotrexate*
      - *Sulfasalazine; **AND***
    - ~~Trial and failure or intolerance to methotrexate (unless there is a documented absolute contraindication such as alcohol abuse, cirrhosis, chronic liver disease); **AND**~~
    - Trial and failure, contraindication, or intolerance a preferred TNF-inhibitors (e.g., Enbrel, Humira); **AND**
    - Trial and failure, contraindication, or intolerance to ONE preferred agent; **OR**
  - Diagnosis of severe alopecia areata *and ALL of the following:* ~~**AND**~~
    - Patient is at least 18 years old but less than 21 years old (indication is not a covered benefit in patients > 21 years old); **AND**
    - Recipient has ≥ 50% scalp hair loss; **AND**
    - Prescriber attest patient does not have other underlying causes of hair loss (e.g. male pattern hair loss (androgenic alopecia), female pattern hair loss, telogen effluvium, traction alopecia, and tinea capitis); **AND**
    - Recipient must be evaluated every 4 months by a physician and submit chart documentation indicating patient has had improved hair growth/decreased hair loss

Renewal Criteria:

- ~~For a diagnosis of Rheumatoid Arthritis, patient continues to meet initial approval criteria; **AND**~~
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, lower UC disease activity index, *Alopecia areata: improvement from baseline in extent and density of scalp hair loss* ~~etc.~~)

Note: Will not be covered for COVID-19 treatment in post hospitalized patients

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for XELJANZ solution

Current Criteria:

Initial Criteria:

- Prescriber attests to each of the following:
  - Patient is not concurrently taking biologic agents (i.e., adalimumab, anakinra, etanercept, rituximab, tocilizumab, infliximab) OR potent immunosuppressants (i.e., azathioprine, cyclosporine); **AND**
  - Benefits of using this agent outweigh the risks of heart-related events (heart attack, stroke, blood clots, etc.) or cardiovascular risk factors
  - Risk of malignancy has been considered and it has been determined that Jak Kinase inhibitor therapy is appropriate; **AND**
- Diagnosis of active Polyarticular Course Juvenile Idiopathic Arthritis (pcJIA); **AND**
- Trial and failure or intolerance to methotrexate (unless there is a documented absolute contraindication such as alcohol abuse, cirrhosis, chronic liver disease); **AND**
- Trial and failure or intolerance to a TNF-inhibitor (e.g. Humira, Enbrel); **AND**
- Trial and failure, contraindication, or intolerance to ONE preferred agent

Renewal Criteria:

- Patient continues to meet initial approval criteria; **AND**

- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, lower UC disease activity index, etc.)

Proposed Criteria:

Initial Criteria *(6-month duration):*

- Prescriber attests to each of the following:
  - Patient is not concurrently taking biologic agents (i.e., adalimumab, anakinra, etanercept, rituximab, tocilizumab, infliximab) OR potent immunosuppressants (i.e., azathioprine, cyclosporine); **AND**
  - Benefits of using this agent outweigh the risks of heart-related events (heart attack, stroke, blood clots, etc.) or cardiovascular risk factors
  - Risk of malignancy has been considered and it has been determined that Jak Kinase inhibitor therapy is appropriate; **AND**
- Diagnosis of active Polyarticular ~~Course~~ Juvenile Idiopathic Arthritis (pJIA); **AND**
- *Trial and failure, contraindication, or intolerance to ONE of the following:*
  - *Leflunomide*
  - *Methotrexate*
  - *Sulfasalazine; **AND***
- ~~Trial and failure or intolerance to methotrexate (unless there is a documented absolute contraindication such as alcohol abuse, cirrhosis, chronic liver disease); **AND**~~
- Trial and failure or intolerance to a TNF-inhibitor (e.g. Humira, Enbrel); **AND**
- *One of the following:*
  - *Patient weighs <40 kg*
  - *Patient is unable to swallow oral dosage forms*
- ~~Trial and failure, contraindication, or intolerance to ONE preferred agent;~~

Renewal Criteria:

- ~~Patient continues to meet initial approval criteria; **AND**~~
- *One of the following:*
  - *Patient weighs <40 kg*
  - *Patient is unable to swallow oral dosage forms; **AND***
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts~~, lower UC disease activity index, etc~~.)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for XELJANZ XR 11 MG

Current Criteria:

- See Xeljanz® tablet prior authorization criteria; **AND**
  - Trial and failure, contraindication, or intolerance to ONE preferred agent; **AND**
  - Provider must provide peer-reviewed medical literature documenting why the requested drug for the requested indication is the only appropriate choice versus the immediate release product

Proposed Criteria:

- See Xeljanz® tablet prior authorization criteria; **AND**
  - Clinically valid reason why the preferred Xeljanz immediate release product cannot be used
  - ~~Trial and failure, contraindication, or intolerance to ONE preferred agent; **AND**~~
  - ~~Provider must provide peer-reviewed medical literature documenting why the requested drug for the requested indication is the only appropriate choice versus the immediate release product~~

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for XELJANZ XR 22 MG

Current Criteria:

Initial Criteria: (6-month duration)

- Prescriber attests to each of the following:
  - Patient is not concurrently taking biologic agents (i.e., adalimumab, anakinra, etanercept, rituximab, tocilizumab, infliximab) OR potent immunosuppressants (i.e., azathioprine, cyclosporine); **AND**
  - Benefits of using this agent outweigh the risks of heart-related events (heart attack, stroke, blood clots, etc.) or cardiovascular risk factors
  - Risk of malignancy has been considered and it has been determined that Jak Kinase inhibitor therapy is appropriate; **AND**
- Diagnosis of moderately to severely active Ulcerative Colitis (UC); **AND**
- Trial and failure, contraindication, or intolerance to Humira; **AND**
- Trial and failure, contraindication, or intolerance to ONE preferred agent; **AND**
- Provider must provide peer-reviewed medical literature documenting why the requested drug for the requested indication is the only appropriate choice versus the immediate release product

Renewal Criteria:

- Patient continues to meet initial approval criteria; **AND**
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, lower UC disease activity index, etc.)

Proposed Criteria:

Initial Criteria: (6-month duration)

- Prescriber attests to each of the following:
  - Patient is not concurrently taking biologic agents (i.e., adalimumab, anakinra, etanercept, rituximab, tocilizumab, infliximab) OR potent immunosuppressants (i.e., azathioprine, cyclosporine); **AND**
  - Benefits of using this agent outweigh the risks of heart-related events (heart attack, stroke, blood clots, etc.) or cardiovascular risk factors
  - Risk of malignancy has been considered and it has been determined that Jak Kinase inhibitor therapy is appropriate; **AND**
- Diagnosis of moderately to severely active Ulcerative Colitis (UC); **AND**
- Trial and failure, contraindication, or intolerance to *preferred adalimumab product* ~~Humira~~; **AND**
- *Clinically valid reason why the preferred Xeljanz immediate release product cannot be used*
- ~~Trial and failure, contraindication, or intolerance to ONE preferred agent; **AND**~~
- ~~Provider must provide peer-reviewed medical literature documenting why the requested drug for the requested indication is the only appropriate choice versus the immediate release product~~

Renewal Criteria:

- ~~Patient continues to meet initial approval criteria; **AND**~~
- Disease response to therapy and tolerability compared to baseline (e.g., decrease in number of tender and swollen joint counts, lower UC disease activity index, etc.)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• OLUMIANT	1/day
• *RINVOQ LQ*	*30 mL/day*
• RINVOQ	1/day
• XELJANZ solution	10 mL/day
• XELJANZ IR tablet	2/day
• XELJANZ XR tablet	1/day

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

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~~Anti-Inflammatory: Immunoglobulins~~ Respiratory and Allergy Biologics

Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred		Non-Preferred
Immunoglobulins	Adbry PA, QL (tralokinumab) Dupixent PA, QL (dupilumab) Fasenra pen PA, QL (benralizumab) *Ebglyss PA, QL (lebrikizumab)*	Nucala PA, QL (mepolizumab) Tezspire PA, QL (tezepelumab) Xolair PA (omalizumab)	Cibinqo PA, QL (abrocitinib)

Last Review Date: August 2023

Recent Significant Changes

- EPOS/ EUFOREA update on indication and evaluation of biologics in chronic rhinosinusitis with nasal polyps 2023

Background

The respiratory and allergy biologics include the interleukin-5 (IL-5) antagonists Cinqair (reslizumab), Fasenra (benralizumab), and Nucala (mepolizumab), the immunoglobulin E (IgE) inhibitor Xolair (omalizumab), the interleukin-4 (IL-4) inhibitor Dupixent (dupilumab), and the thymic stromal lymphopoietin (TSLP) blocker Tezspire (tezepelumab). Respiratory and allergy biologics are a mainstay of treatment for severe asthma; in addition, various agents in this class are also indicated for use in chronic idiopathic urticaria (CIU), eosinophilic granulomatosis with polyangiitis (EGPA), chronic rhinosinusitis with nasal polyposis (CRSwNP), hypereosinophilic syndromes (HES), eosinophilic esophagitis (EoE), and IgE-mediated food allergy.

Fasenra and Nucala are humanized monoclonal antibody IL-5 antagonists. Fasenra binds to the IL-5 receptor on immune effector cells, whereas Nucala bind to the IL-5 cytokine. Eosinophils play a key role in the pathobiology of airway disorders by contributing to inflammation through the release of leukotrienes and pro-inflammatory cytokines. Increases in eosinophils are often correlated with greater asthma severity. IL-5, a cytokine critical to eosinophil differentiation and survival, has been isolated as a potential target in eosinophilic asthma.

Xolair is a recombinant DNA-derived monoclonal antibody that selectively binds to human anti-IgE. It reduces the allergic response mediators and is useful in a subset of patients with allergic asthma. In addition, Xolair is approved for CIU in patients ≥ 12 years of age who remain symptomatic despite antihistamine treatment, as add-on maintenance treatment of CRSwNP in adult patients with inadequate response to nasal corticosteroids, and for IgE mediated food allergy in patients ≥ 1 year of age for the reduction of allergic reactions with accidental exposure.

Tezspire, a human monoclonal antibody, is a TSLP blocker. It binds to human TSLP, an epithelial cell-derived cytokine, and blocks its interaction with the TSLP receptor to reduce biomarkers and cytokines associated with inflammation. TSLP has also been shown to affect non-Type 2 inflammatory processes between airway structural and immune cells, and there are many cell types activated by, or that respond to, TSLP (including mast cells, basophils, natural killer T cells, and neutrophils) that may play a role in asthma beyond Type 2 inflammation.

Dupixent is a human monoclonal antibody that inhibits signaling of IL-4 and IL-13. This results in a reduction of the release of inflammatory mediators including cytokines, chemokines, nitric oxide, and IgE. These actions are useful for eosinophilic asthma, EoE, and add-on therapy for inadequately controlled CRSwNP. Dupixent is also approved to treat prurigo nodularis (PN) and moderate to severe atopic dermatitis (AD).

Adbry (tralokinumab), Ebglyss (lebrikizumab), and Cibinqo (abrocitinib) are indicated for AD. Adby and are IL-13 antagonists, which reduce the release of inflammatory mediators including cytokines, chemokines, nitric oxide, and IgE. Cibinqo, a JAK inhibitor, works by blocking inflammation-causing JAK1 and JAK2 enzymes, responsible for signaling several cytokines and growth factors.

Table 1. Medications Included Within Class Review

Drug	Generic Availability
ADBRY (tralokinumab-ldrm)	-
CIBINQO (abrocitinib)	-
EBGLYSS (lebrikizumab)	-
DUPIXENT (dupilumab)	-

Drug	Generic Availability
FASENRA (benralizumab)	-
NUCALA (mepolizumab)	-
TEZSPIRE (tezepelumab)	-
XOLAIR (omalizumab)	-

Table 2. FDA-Approved Indications – PART 1

Indication	DUPIXENT	FASENRA	NUCALA	TEZSPIRE	XOLAIR
Moderate to severe persistent asthma in patients ≥ 6 years of age with a positive skin test or in vitro reactivity to a perennial aeroallergen and inadequately controlled symptoms ICS					✔
Add-on maintenance treatment for patients ≥ 6 years of age with severe asthma with an eosinophilic phenotype		✔	✔		
Add-on maintenance treatment for patients ≥ 6 years of age with moderate-to-severe asthma with an eosinophilic phenotype or with oral corticosteroid dependent asthma	✔				
Add-on maintenance treatment for patients ≥ 18 years of age with severe asthma with an eosinophilic phenotype					
Add-on maintenance treatment for patients ≥ 12 years of age with severe asthma				✔	
Add-on maintenance treatment in adults with uncontrolled COPD and an eosinophilic phenotype	✔				
Add-on maintenance treatment in adult patients with inadequately controlled CRSwNP	✔		✔	✔	
Treatment of adult and pediatric patients ≥ 1 year of age and weighing ≥ 15 kg with EoE	✔				
Treatment of adult patients with EGPA		✔	✔		
Treatment of adults and adolescents ≥ 12 years of age with CIU who remain symptomatic despite H1-antihistamine treatment.					✔
Treatment of patients ≥ 12 years of age with HES for ≥ 6 months without an identifiable non-hematologic secondary cause			✔		
IgE-mediated food allergy in adults and children ≥ 1 year of age for the reduction of allergic reactions with accidental exposure					✔

Table 3. FDA-Approved Indications – PART 2

Indication	ADBRY	CIBINQO	DUPIXENT	EBGLYSS
Treatment of moderate-to-severe AD in patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable	✔ *		✔ ^	✔ ~
Treatment of refractory, moderate to severe atopic dermatitis in patients whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.		✔		
Treatment of adult patients with prurigo nodularis (PN)			✔	

* Indicated for patients 12 years of age
^ indicated for patients aged 6 months and older
~ Indicated for patients 12 years of age and older who weigh at least 40 kg

Asthma

Asthma is a chronic lung disease that inflames and narrows the airways, making it difficult to breathe. Asthma causes recurring periods of wheezing, chest tightness, shortness of breath, and coughing. Asthma affects people of all ages but most often starts during childhood. A combination of factors such as genetics, certain respiratory infections during childhood, and contact with airborne allergens can contribute to its development. Most patients with asthma also have allergies. Pharmacologic options for asthma management are categorized as: (1) controller medications (ex. corticosteroids, long-acting beta2-agonists (LABAs), leukotriene receptor antagonists, various add-on therapies) to achieve and maintain control of persistent asthma or prevent exacerbations (also referred to as maintenance treatment, as appropriate), and (2) reliever medications (ex. short-acting beta2-agonists (SABA) , anti-inflammatory relievers, short-acting muscarinic antagonists) for symptom relief and before exercise to prevent exercise-induced asthma symptoms (also referred to as rescue inhalers).

The 2024 Global Initiative for Asthma (GINA) report also provides a stepwise approach to asthma management. Treatment recommendations are based on patient age, and stepping down should be considered when asthma symptoms have been well-controlled and lung function has been stable for ≥ 3 months. Inhaled corticosteroids (ICS)/beta2-agonist combination products are recommended for both controller (i.e., maintenance treatment) and reliever use in patients ≥ 6 years of age, while the preferred controller option in patients ≤ 5 years of age consists of low-dose ICS plus as-needed SABA as a reliever. In patients ≥ 6 years of age diagnosed with severe asthma and uncontrolled on Step 4 treatment (e.g., with maintenance ICS/LABA therapy), phenotyping for Type 2 inflammation into categories such as severe allergic, aspirin-exacerbated, allergic bronchopulmonary aspergillosis, chronic rhinosinusitis, nasal polyposis, atopic dermatitis, or eosinophilic asthma is recommended.

Add-on treatment with a biologic agent should be considered as follows:

- Severe allergic asthma: Anti-IgE treatment with omalizumab
- Severe eosinophilic asthma: Add-on anti-IL-5 therapy
- Severe eosinophilic/Type 2 asthma: Anti-IL4 therapy (dupilumab)
- Patients requiring oral corticosteroids for maintenance therapy: Anti-IL4 therapy (dupilumab)
- Severe asthma: Anti-TSLP therapy (tezepelumab)

Atopic Dermatitis (AD)

Atopic dermatitis (AD), also referred to as atopic eczema, is a chronic, highly pruritic, and relapsing inflammatory skin condition characterized by dry skin, erythema, oozing, crusting, and severe pruritus. Atopic dermatitis is exacerbated by various environmental stimuli. It is associated with increased immunoglobulin E (IgE) levels and a history of atopy (asthma, allergic rhinitis, or eczema). The prevalence of atopic dermatitis is estimated to be approximately 13% among children and 7% among adults. Atopic dermatitis is one of the most common skin disorders in children, with the most cases starting before the age of 5 years.

Topical emollients and topical corticosteroids are typical first-line treatments for atopic dermatitis. Additional topical treatment options include topical calcineurin inhibitors, topical phosphodiesterase-4 (PDE-4) inhibitors, and a topical Janus kinase (JAK) inhibitor. The use of systemic therapies is reserved for patients with moderate to severe disease. Phototherapy is an option for some patients. FDA-approved systemic medications include subcutaneous (SC) biologic interleukin inhibitors and oral JAK inhibitors.

Chronic Idiopathic Urticaria (CIU)

CIU, also called chronic spontaneous urticaria (CSU), is defined by the presence of hives on most days of the week for 6 weeks or longer, with or without angioedema. The hives are circumscribed, raised, erythematous plaques, often with central pallor and variable in size. No external allergic cause or contributing disease process can be identified in 80 to 90% of adults and children with CIU. CIU affects up to 1% of the general. The condition is more common in adults than children and typically begins in the third to fifth decades of life. CIU is a self-limited disorder in most patients although the condition generally has a prolonged duration of 2 to 5 years. Non-sedating H1-antihistamines are the cornerstone of therapy for CIU. Limited courses of oral glucocorticoids are often used in combination with antihistamines for refractory symptoms. Other pharmacologic options for patients who do not respond to H1-antihistamines include the use of H2-antihistamines, leukotriene modifiers, cyclosporine, tacrolimus, mycophenolate, hydroxychloroquine, sulfasalazine, dapsone, and Xolair.

Guidelines recommend treatment with omalizumab in patients with symptoms despite treatment with a 4-fold dose of modern second-generation antihistamines. This is a change from previous guidelines in which use of either omalizumab or cyclosporine after failure of high-dose antihistamines was recommended. However, due to adverse effects and the lack of an approved indication, the new recommendation was that cyclosporine should only be considered if omalizumab does not provide an adequate response.

Chronic Obstructive Pulmonary Disease (COPD)

Chronic obstructive pulmonary disease (COPD) is a chronic respiratory disease caused by abnormalities of the airways and/or alveoli. Symptoms typically include dyspnea, chest tightness, fatigue, activity limitation, and cough with or without sputum production. Patients with COPD may also experience exacerbations, which are periods of acute worsening of respiratory symptoms. The main treatment goals in COPD are to reduce symptoms and the risk of future exacerbations. Most of the drugs used to treat COPD are inhaled, including bronchodilators and corticosteroids, and are frequently prescribed as components of combination therapy. Choice of therapy depends on a patient's symptoms and their risk of exacerbations.

In September 2024, Dupixent (dupilumab) was approved for add-on maintenance treatment of adult patients with inadequately controlled COPD and an eosinophilic phenotype. Dupixent is the first biologic to be approved for the treatment of COPD. In clinical studies, treatment with dupilumab resulted in a lower annualized rate of exacerbations, better lung function and quality of life, and less severe symptoms than placebo in adults with COPD who had type 2 inflammation as indicated by elevated blood eosinophil counts.

Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)

CRSwNP has a prevalence of approximately 2.7% in adults, and peaks in the sixth decade of life. Symptoms include nasal obstruction, reduced sense of smell, and sleep disturbance, all of which can substantially impact the quality of life. The majority of cases are idiopathic but may be due to genetic, metabolic, or immunologic causes, resulting in inflammation characterized by eosinophilia and elevated levels of IL-4, IL-5, IL-13. Common treatment options for CRSwNP include saline irrigation and intranasal glucocorticoids in patients with mild symptoms, and short-term systemic glucocorticoids, surgery, and biologic agents in patients with severe symptoms. Biologic agents in this review indicated for CRSwNP are Dupixent, Nucala, and Xolair.

In 2023, the European Forum for Research and Education in Allergy and Airway Diseases (EUFOREA) published an updated expert consensus focused on the use of biologics for CRSwNP. Biologics are indicated in patients with bilateral nasal polyps and previous sinus surgery who also meet 3 of the following criteria:

1) Evidence of type 2 inflammation (biological biomarkers);
2) The need for systemic corticosteroids (≥ 2 courses per year or > 3 months of low dose steroids);
3) Contraindications to systemic corticosteroids, significant quality-of-life impairment, significant loss of smell, and diagnosis of comorbid asthma.

Once eligibility has been determined, a patient's preference for a surgical or non-surgical approach should be considered if funding within the healthcare system allows. In patients who have never had surgery, the aforementioned criteria need to be met before a biologic is indicated. Patients with previous sinus surgery plus severe asthma may also qualify for treatment in consultation with their pulmonologist. Lastly, biologics should not be initiated in the following situations:

- CRSwNP and lack of signs of type 2 inflammation
- Cystic fibrosis
- Unilateral nasal polyps
- Mucoceles
- General contraindications for biological treatments (e.g., immunodeficiencies)

Eosinophilic Esophagitis (EoE)

EoE is a chronic allergic inflammatory disease in which eosinophils build up in the lining of the esophagus. The presence of eosinophils cause inflammation in the esophagus, which may cause the following symptoms: vomiting, stomach or chest pain, failure to thrive, and difficulty swallowing. Front-line treatments for EoE include proton pump inhibitors and topical glucocorticoids. Additionally, Dupixent was approved for EoE in 2022.

In 2020, the American Gastroenterological Association and the Joint Task Force on Allergy Immunology Practice Parameters (AGA/JTF) published a guideline on the management of EoE. In patients with symptomatic esophageal eosinophilia, the AGA/JTF suggests using proton pump inhibition over no treatment. Furthermore, for patients with EoE, topical glucocorticoids are recommended over no treatment and topical glucocorticoids are suggested rather than oral glucocorticoids. Authors did not recommend the use of the following therapies outside of a clinical trial setting based on the available data in patients with EoE at the time of guideline publication: anti-IL13, anti-IL4, anti-IL5, and anti-tumor necrosis factor therapies, montelukast, cromolyn sodium, and immunomodulators. The guideline suggested against the use of anti-IgE therapy for EoE.

Eosinophilic Granulomatosis with Polyangiitis (EGPA)

EGPA, previously called Churg-Strauss syndrome, is a systemic necrotizing vasculitis that affects small-to-medium-sized vessels. It is typically associated with eosinophilia and severe asthma. EGPA is a rare condition with a prevalence of approximately 13 cases per 1 million persons. It has a higher incidence in patients with asthma. Systemic glucocorticoids are the mainstay of treatment for EGPA. For refractory EGPA, the addition of cyclophosphamide, azathioprine, mepolizumab, methotrexate, rituximab, or intravenous immunoglobulins (IVIG) can be considered. In more than 85% of patients with EGPA, remission can be achieved with glucocorticoids with or without an immunosuppressant; however, relapses occur in more than 33% of patients.

In 2021, a joint guideline from the American College of Rheumatology and Vasculitis Foundation published recommendations for the management of EGPA along with other related conditions. The following relevant conditional recommendations were provided:

- Patients with active, severe EGPA should be treated with cyclophosphamide or rituximab over Nucala for remission induction.
- Patients with active, non-severe EGPA should be treated with Nucala and glucocorticoids over methotrexate, azathioprine, or mycophenolate mofetil and glucocorticoids.
- Patients with severe EGPA whose disease has entered remission should be treated with methotrexate, azathioprine, or mycophenolate mofetil over Nucala for remission maintenance.
- Patients with EGPA who have experienced relapse with non-severe disease manifestations (i.e., asthma and/or sinonasal disease) while receiving methotrexate, azathioprine, or mycophenolate mofetil: Nucala should be added over switching to another agent.
- Patients with EGPA who have experienced relapse with non-severe disease manifestations (asthma and/or sinonasal disease) while receiving low-dose glucocorticoids and no other therapy: Nucala should be added over adding methotrexate, azathioprine, or mycophenolate mofetil.
- Patients with EGPA and high serum IgE levels who have experienced relapse with non-severe disease manifestations (asthma and/or sinonasal disease) while receiving methotrexate, azathioprine, or mycophenolate mofetil: Nucala should be added over adding omalizumab.

Hypereosinophilic Syndromes (HES)

HES are disorders characterized by the overproduction of eosinophils, which causes organ damage. Treatment for idiopathic HES may include systemic glucocorticoids, imatinib, hydroxyurea, interferon alfa, alemtuzumab, and Janus kinase inhibitors. Additionally, Nucala is approved for HES. The World Health Organization guidance on eosinophilic disorders has stated that identification of rearranged PDGFRA or PDGFRB is important in the management of eosinophilic disorders as those variants respond to imatinib. For patients with idiopathic HES (without imatinib-sensitive variants), corticosteroids are first-line therapy; second-line options include hydroxyurea, interferon-alfa, other cytotoxic chemotherapy agents, and hematopoietic stem cell transplant.

IgE-mediated Food Allergy

IgE-mediated food allergy is a leading cause of anaphylaxis. Common food allergens include cow's milk, egg, peanut, tree nuts, fish/shellfish, wheat, sesame seed, and soy. Food-related reactions are associated with a broad range of signs and symptoms that can involve the skin, gastrointestinal tract, respiratory tract, and the cardiovascular system. Xolair is approved for IgE-mediated food allergy in adults and children ≥ 1 year of age for the reduction of allergic reactions with accidental exposure. Guidelines for food allergies mostly focus on nutritional interventions and have not been updated to include recommendations for omalizumab.

Prurigo nodularis (PN)

Prurigo nodularis (PN) is a chronic, inflammatory skin condition characterized by nodules and severe pruritus. Nodules typically appear on the trunk and the extensor surfaces of the extremities and are distributed symmetrically. Severe pruritus can lead to scratching to the point of excoriation and bleeding and has a significant negative impact on patients' quality of life.

Specific causes of PN are unknown; however, neural and immunologic process and a chronic itch-scratch cycle are likely to be involved. Interleukin (IL)-31, a cytokine secreted by several types of immune cells, is increased in patients with PN, and IL-31 levels in the dermis are positively correlated with itch severity.

Treatment of PN may include topical therapy, phototherapy, and/or systemic therapy. No topical therapies are specifically approved for this indication; however, topical corticosteroids may be effective at reducing itch and improving lesion appearance. Other topical anti-inflammatory and anti-itch treatments may be used but have more limited evidence. Based on a systematic review, systemic thalidomide, cyclosporine, and methotrexate appear to have some efficacy in this condition, but their use may be limited by adverse effects (AEs).

Safety Information

Possible AEs or safety concerns associated with tralokinumab and dupilumab include injection-site reactions, serious allergic reactions, and ophthalmic issues such as conjunctivitis or keratitis. Abrocitinib and upadacitinib have boxed warnings for serious infections, mortality, malignancy, MACE, and thrombosis; abrocitinib is also contraindicated in patients taking antiplatelet therapies (with the exception of low-dose aspirin) during the first 3 months of therapy. Abrocitinib and upadacitinib are also associated with laboratory abnormalities, including various cytopenias and lipid abnormalities. Upadacitinib has additional warnings for hypersensitivity reactions, gastrointestinal perforations, and fetal harm when administered to pregnant women. Safety information for the respiratory agents in this review is summarized on Table 4.

Table 4. Safety Information – Respiratory Agents

Drug	Warning/Precautions	Adverse Reactions
DUPIXENT	Eosinophilic pneumonia and vasculitis; New or worsening eye symptoms (conjunctivitis, keratitis); new or worsening joint symptoms/arthralgias; Pre-existing helminth infections; Use of live vaccines should be avoided	Asthma: injection site reactions, oropharyngeal pain, eosinophilia CRSwNP: injection site reactions, eosinophilia, insomnia, toothache, gastritis, arthralgia, conjunctivitis EoE: injection site reactions, upper respiratory tract infections, arthralgia, herpes viral infections
EBGLYSS	Ocular effects: Conjunctivitis and keratitis; Use of live attenuated vaccines should be avoided	Injection site pain or reactions, herpes zoster, and eye and eyelid inflammation (including redness, swelling, and itching)
FASENRA	Pre-existing helminth infections	Headache, pharyngitis
NUCALA	Herpes zoster infections; Pre-existing helminth infections	Headache, injection site reaction, back pain, fatigue
TEZSPIRE	Should not be used to treat acute asthma symptoms or asthma exacerbations; Pre-existing helminth infections; Use of live attenuated vaccines should be avoided	Pharyngitis, arthralgia, back pain
XOLAIR	Malignant neoplasms; Systemic eosinophilia; Abrupt discontinuation of corticosteroids should be avoided; Signs and symptoms of serum sickness; Serum IgE levels increased; Should not be used for emergency treatment of allergic reactions **Boxed warning**: anaphylaxis	Asthma: arthralgia, pain, leg pain, fatigue, dizziness, fracture, arm pain, pruritis, dermatitis CIU: arthralgia, cough, headache, nasopharyngitis, nausea, sinusitis, upper respiratory tract infection, viral upper respiratory tract infection CRSwNP: headache, injection site reaction, arthralgia, upper abdominal pain, dizziness

Clinical Rationale

Respiratory and allergy biologics include the IgE inhibitor Xolair, the IL-4 inhibitor Dupixent, the IL-5 antagonists Fasenra and Nucala, and the TSLP blocker Tezspire. These agents are a mainstay of treatment for severe asthma; in addition, various agents in the class are indicated for use in EGPA, CIU, CRSwNP, HES, EoE, and IgE-mediated food allergy.

Systemic therapies approved for the treatment of moderate to severe atopic dermatitis include Adbry, Cibinqo, and Dupixent. Guidelines for the treatment of atopic dermatitis recommend the use of topical treatments upfront in therapy and systemic agents when not adequately controlled with topical prescription therapies or when those topical therapies are not advisable.

Recommendation

It is recommended that the ~~immunoglobulin~~ *Respiratory and Allergy Biologics* class be subject to clinical criteria.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for ADBRY, CIBINQO, DUPIXENT, *EBGLYSS*

Current Criteria:

Initial Criteria (6-month duration):

- Patient is ≥ 12 years of age; **AND**
- Diagnosis of moderate to severe atopic dermatitis with ONE of the following:
  - Involvement of at least 10% of body surface area (BSA); **OR**
  - Scoring Atopic Dermatitis (SCORAD) score of 20 or more); **OR**
  - Investigator's Global Assessment (IGA) with a score ≥ 3); **OR**
  - Eczema Area and Severity Index (EASI) score of ≥ 16); **OR**
  - Incapacitation due to AD lesion location (e.g., head, neck, palms, soles, genitalia); **AND**
- Trial and failure (documented by claims) or contraindication to both of the following:
  - A topical corticosteroid of medium to high potency (e.g., mometasone, fluocinolone)
  - A topical calcineurin inhibitor; **AND**
- Prescribed by, or in consultation with, a dermatologist, allergist, or immunologist; **AND**
- If request is for Cibinqo, trial and failure, contraindication, or intolerance of Dupixent or Adbry

Renewal Criteria:

- Documented positive response to therapy (e.g., pruritus, BSA involvement, EASI, IGA, SCORAD)

Proposed Criteria:

Initial Criteria: (6-month duration)

- Patient is ≥ 12 years of age; **AND**
- Diagnosis of moderate to severe atopic dermatitis with ONE of the following:
  - Involvement of at least 10% of body surface area (BSA); **OR**
  - Scoring Atopic Dermatitis (SCORAD) score of 20 or more); **OR**
  - Investigator's Global Assessment (IGA) with a score ≥ 3); **OR**
  - Eczema Area and Severity Index (EASI) score of ≥ 16); **OR**
  - Incapacitation due to AD lesion location (e.g., head, neck, palms, soles, genitalia); **AND**
- Trial and failure (documented by claims) or contraindication to both of the following:
  - A topical corticosteroid of medium to high potency (e.g., mometasone, fluocinolone)
  - A topical calcineurin inhibitor; **AND**
- Prescribed by, or in consultation with, a dermatologist, allergist, or immunologist; **AND**
- If request is for Cibinqo, trial and failure, contraindication, or intolerance of ~~Dupixent or Adbry~~ *a preferred agent indicated for atopic dermatitis (e.g., Adbry, Dupixent, Ebglyss)*

Renewal Criteria:

- Documented positive response to therapy (e.g., *improved* pruritus, BSA involvement, EASI, IGA, *or* SCORAD)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for DUPIXENT

Current Criteria:

Eosinophilic or Corticosteroid-Dependent Asthma Diagnosis

Initial Criteria: (6-month duration)

- Patient is ≥ 6 years old; **AND**
- One of the following:
  - Patient is currently dependent on oral corticosteroids for the treatment of asthma; **OR**
  - Dupixent will be used to treat eosinophilic asthma as defined by one of the following:
    - Baseline (pre-treatment) peripheral blood eosinophil level > 150 cells per microliter
    - Peripheral blood eosinophil levels > 300 cells/microliter within the past 12 months; **AND**
      - Asthma is inadequately controlled as shown by one of the following:
        - One or more asthma exacerbation requiring systemic corticosteroids within the past 12 months
        - Any prior intubation for an asthma exacerbation
        - Prior asthma-related hospitalization within the past 12 months; **AND**
- Patient is currently being treated with ONE of the following, unless there is a contraindication:
  - Combination therapy including both of the following:
    - One medium or high dose inhaled corticosteroid (ICS)
    - One additional asthma controller medication [e.g., LABA, leukotriene, antagonist, theophylline]; **OR**
  - One maximally dosed combination inhaled corticosteroid (ICS)/ LABA) product (e.g., Advair [fluticasone propionate/salmeterol], Dulera [mometasone/formoterol], Symbicort [budesonide/formoterol]); **AND**
- Dupixent will be used as adjunct therapy along with above asthma treatment; **AND**
- Prescribed by, or in consultation with, a pulmonologist, allergist, or immunologist

Renewal Criteria:

- Documentation of a positive clinical response (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications); **AND**
- Patient is being treated with ONE of the following, unless there is a contraindication:
  - Combination therapy including both a high-dose ICS and an additional asthma controller medication
  - One maximally dosed combination inhaled corticosteroid (ICS)/ LABA) product

Diagnosis of Prurigo Nodularis (PN)

Initial Criteria:

- Patient age ≥ 18 years of age; **AND**
- Both of the following:
  - WI-NRS ≥ 7 on a scale of 0 to 10*;* **OR**
  - Patient has 20 or more nodular lesions (IGA PN-S > 3); **AND**
- Inadequate response, intolerance, contraindication to a topical steroid OR topical calcineurin inhibitor; **AND**
- Prescribed by, or in consultation with, a pulmonologist, allergist, or immunologist

Renewal Criteria:

- Documentation of positive clinical response (e.g., improved WI-NRS or IGA PN-S score)

Chronic rhinosinusitis with nasal polyposis (CRSwNP) Diagnosis

Initial Criteria (6-month duration):

- Patient is ≥ 18 years of age; **AND**
- One of the following:
  - Presence of bilateral nasal polyps
  - Patient has previously required surgical removal of bilateral nasal polyps; **AND**
- Documentation of inadequate response, intolerance, or contraindication to BOTH of the following: Nasal corticosteroid spray AND Oral corticosteroid; **AND**
- Must be used in combination with intranasal corticosteroid, unless contraindication or intolerance; **AND**
- Prescribed by, or in consultation with, an allergist, immunologist, otolaryngologist, or pulmonologist

Renewal Criteria:

- Documentation of positive clinical response to therapy; **AND**
- Will continue to use in combination with intranasal corticosteroids

Eosinophilic Esophagitis (EoE) Diagnosis

Initial Criteria (6-month duration):

- Patient weighs at least 15 kg; **AND**
- Provider attests that patient meets both of the following:
  - ≥ 15 intraepithelial eosinophils per high-power field (eos/hpf) following treatment course of a PPI
  - Symptoms of esophageal dysfunction (e.g., feeding difficulties, vomiting, pain, dysphagia); **AND**
- Trial and failure or contraindication, to swallowed inhaled corticosteroids such as budesonide or fluticasone; **AND**
- Prescribed by, or in consultation with, a gastroenterologist, allergist, or immunologist

Renewal Criteria:

- Provider attests patient's clinical improvement is demonstrated by reduction in esophageal intraepithelial eosinophil count or symptoms of dysphagia

Proposed Criteria:

Asthma

Initial Criteria (6-month duration):

- Patient is ≥ 6 years old; **AND**
- Diagnosis of moderate to severe asthma; **AND**
- One of the following:
  - ~~Dupixent will be used to treat eosinophilic asthma as defined by one of the following:~~
    - ~~Baseline (pre-treatment) peripheral blood eosinophil level > 150 cells per microliter~~
    - ~~Peripheral blood eosinophil levels > 300 cells/microliter within the past 12 months;~~ ~~**OR**~~
  - *Asthma is an eosinophilic phenotype as defined by a baseline (pre- treatment) peripheral blood eosinophil level ≥ 150 cells/µL or peripheral blood eosinophil levels > 300 cells/mcL;* ***OR***
  - Patient is currently dependent on oral corticosteroids for the treatment of asthma; **AND**
- Asthma is inadequately controlled as shown by one of the following:
  - *Two* ~~one~~ more exacerbations requiring systemic corticosteroids within the past 12 months; **OR**
  - ~~Any prior intubation for an asthma exacerbation;~~ ~~**OR**~~
  - ~~Prior asthma-related hospitalization within the past 12 months;~~ ~~**OR**~~
  - *Asthma-related emergency treatment (e.g., hospitalization, intensive care unit stay, or mechanical ventilation in the past 12 months*; **OR**
  - *Patient is currently dependent on oral corticosteroids for the treatment of asthma;* ***AND***
- Patient is currently being treated with ONE of the following, unless there is a contraindication:
  - Combination therapy including BOTH of the following:
    - One medium or high dose inhaled corticosteroid (ICS); **AND**
    - One additional asthma controller medication [e.g., LABA, leukotriene antagonist, theophylline]; **OR**
  - One maximally dosed combination inhaled ICS/ LABA *or ICS/LAMA/LABA product*; **AND**
- Will be used as adjunct therapy along with above asthma treatment; **AND**
- Prescribed by, or in consultation with, a pulmonologist, allergist, or immunologist

Renewal Criteria:

- Documentation of a positive clinical response (e.g., reduction in exacerbations, improvement of FEV1, decreased use of rescue medications); **AND**
- Patient is being treated with ONE of the following, unless there is a contraindication:
  - Combination therapy including both a high-dose ICS and an additional asthma controller medication
  - One maximally dosed combination inhaled ICS/ LABA *or ICS/LAMA/LABA* product

Chronic Obstructive Pulmonary Disease (COPD)

Initial Criteria (6-month duration):

- *Patient is ≥ 18 years of age;* ***AND***
- Diagnosis of COPD; **AND**
- *Eosinophilic phenotype confirmed by peripheral blood eosinophil levels > 300 cells/mcL;* ***AND***
- *COPD is inadequately controlled as shown by one of the following:*
  - *Two or more exacerbations requiring systemic corticosteroids and/or antibiotics within the past 12 months;* ***OR***
  - *COPD-related emergency treatment (e.g., hospitalization in the past 12 months, mechanical ventilation);* ***AND***
- *Patient is currently receiving standard of care COPD treatment, unless contraindicated (i.e., ICS/LAMA/LABA);* ***AND***
- *Post-bronchodilator FEV1/FVC ratio <0 and FEV1 ≤ 79%;* ***AND***
- *Medication will be used as maintenance add-on therapy*
- ***Renewal Criteria***
- *Positive clinical response to treatment (e.g., improved FEV1 from baseline, reduction in COPD exacerbations);* ***AND***
- *Patient is currently receiving standard of care COPD treatment, unless contraindicated (i.e., ICS/LAMA/LABA);* ***AND***
- *Medication will be used as maintenance add-on therapy*

Chronic rhinosinusitis with nasal polyposis (CRSwNP)

Initial Criteria (6-month duration):

- Patient is ≥ *12* ~~18~~ years of age; **AND**
- Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) *confirmed by ONE of the following:*
  - *Presence of bilateral nasal polyps*
  - *Patient has previously required surgical removal of bilateral nasal polyps;* ***AND***
- ~~One of the following:~~
  - ~~Presence of bilateral nasal polyps~~
  - ~~Patient has previously required surgical removal of bilateral nasal polyps;~~ ~~**AND**~~
- ~~Documentation of inadequate response, intolerance, or contraindication to BOTH of the following:~~
  - ~~Nasal corticosteroid spray~~
  - ~~Oral corticosteroid;~~ ~~**AND**~~
- *One of the following:*
  - *Patient has required prior sinus surgery*
  - *Patient has required systemic corticosteroids for CRSwNP*
  - *Symptoms persist after trial of TWO of the following classes of agents:*
    - *Nasal saline irrigations*
    - *Intranasal corticosteroids*
    - *Antileukotriene agents*
- Must be used in combination with intranasal corticosteroid, unless contraindication or intolerance; **AND**
- Prescribed by, or in consultation with, an allergist, immunologist, otolaryngologist, or pulmonologist

Renewal Criteria:

- Documentation of positive clinical response to therapy; **AND**
- Will continue to use in combination with intranasal corticosteroids

Eosinophilic Esophagitis (EoE)

Initial Criteria (6-month duration):

- Patient *is >1 years of age and* weighs at least 15 kg; **AND**
- Diagnosis of eosinophilic esophagitis (EOE) *as confirmed by an esophageal biopsy demonstrating ≥ 15 intraepithelial eosinophils per high power field (documentation required);* ***AND***
- *Patient is experiencing symptoms related to esophageal dysfunction (e.g., dysphagia, food impaction, chest pain that may not respond to antacids, gastroesophageal reflux disease-like symptoms)*

- ~~Provider attests that patient meets BOTH of the following:~~
  - ~~≥ 15 intraepithelial eosinophils per high-power field (eos/hpf) following treatment course of a proton pump inhibitor~~
  - ~~Symptoms of esophageal dysfunction (e.g., feeding difficulties, vomiting, pain, dysphagia);~~ **~~AND~~**
- *Symptoms are inadequately controlled after a trial of ONE of the following:*
  - *Proton pump inhibitor (e.g., pantoprazole, omeprazole);* ***OR***
  - *Topical esophageal corticosteroids (e.g., budesonide, fluticasone)* ~~Trial and failure, or contraindication, to swallowed inhaled corticosteroids such as budesonide or fluticasone~~; **AND**
- Prescribed by, or in consultation with, a gastroenterologist, allergist, or immunologist

Renewal Criteria:

- Documentation of positive clinical response to therapy (e.g., reduction of esophageal intraepithelial eosinophil count, improvement of symptoms) ~~Provider attests patient's clinical improvement is demonstrated by reduction in esophageal intraepithelial eosinophil count or symptoms of dysphagia~~

Prurigo Nodularis (PN)

Initial Criteria:

- Patient age ≥ 18 years; **AND**
- Diagnosis of Prurigo Nodularis (PN); **AND**
- ~~WI-NRS ≥ 7 on a scale of 0 to 10;~~ **~~AND~~**
- Patient has 20 or more nodular lesions (IGA PN-S > 3); **AND**
- Inadequate response, intolerance, or contraindication to a topical steroid ~~OR topical calcineurin inhibitor~~; **AND**
- Prescribed by, or in consultation with, a ~~pulmonologist~~ *dermatologist*, allergist, or immunologist

Renewal Criteria:

- Documentation of positive clinical response (e.g., improved *symptoms or* ~~WI-NRS or~~ IGA PN-S)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for FASENRA

Current Criteria:

Initial Criteria (6-month duration):

- Diagnosis of severe asthma; **AND**
- Patient is ≥ 6 years old; **AND**
- One of the following:
  - Patient is currently dependent on oral corticosteroids for the treatment of asthma; **OR**
  - Fasenra will be used to treat eosinophilic asthma as defined by one of the following:
    - Baseline (pre-treatment) peripheral blood eosinophil level > 150 cells per microliter
    - Peripheral blood eosinophil levels > 300 cells/microliter within the past 12 months; **AND**
      - Asthma is inadequately controlled as shown by one of the following:
        - ≥ 1 asthma exacerbation requiring systemic corticosteroid within the past 12 months
        - Any prior intubation for an asthma exacerbation
        - Prior asthma-related hospitalization within the past 12 months; **AND**
- Patient is currently being treated with ONE of the following, unless there is a contraindication:
  - Combination therapy including both of the following:
    - One high dose inhaled corticosteroid (ICS)
    - One additional asthma controller medication [e.g., long-acting beta-2 agonist LABA, leukotriene receptor antagonist, theophylline]; **OR**
  - One maximally dosed combination inhaled corticosteroid (ICS)/ LABA) product (e.g., Advair [fluticasone propionate/salmeterol], Dulera [mometasone/formoterol], Symbicort [budesonide/formoterol]); **AND**
- Fasenra will be used as adjunct therapy along with above asthma treatment; **AND**
- Prescribed by, or in consultation with, a pulmonologist, allergist, or immunologist

Renewal Criteria:

- Documentation of a positive clinical response (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications); **AND**
- Patient is being treated with ONE of the following, unless there is a contraindication:
  - Combination therapy including both a high-dose ICS and an additional asthma controller medication
  - One maximally dosed combination inhaled corticosteroid (ICS)/ LABA) product

Proposed Criteria:

Asthma

Initial Criteria (6-month duration):

- Patient is ≥ 6 years old; **AND**
- Diagnosis of moderate to severe asthma; **AND**
- One of the following:
  - ~~Dupixent will be used to treat eosinophilic asthma as defined by one of the following:~~
    - ~~Baseline (pre-treatment) peripheral blood eosinophil level > 150 cells per microliter~~
    - ~~Peripheral blood eosinophil levels > 300 cells/microliter within the past 12 months;~~ ~~**OR**~~
  - *Asthma is an eosinophilic phenotype as defined by a baseline (pre- treatment) peripheral blood eosinophil level ≥ 150 cells/µL or peripheral blood eosinophil levels > 300 cells/mcL;* ***OR***
  - Patient is currently dependent on oral corticosteroids for the treatment of asthma; **AND**
- Asthma is inadequately controlled as shown by one of the following:
  - *Two* ~~one~~ more exacerbations requiring systemic corticosteroids within the past 12 months
  - ~~Any prior intubation for an asthma exacerbation~~
  - ~~Prior asthma-related hospitalization within the past 12 months~~
  - *Asthma-related emergency treatment (e.g., hospitalization, intensive care unit stay, or mechanical ventilation in the past 12 months;*
  - *Patient is currently dependent on oral corticosteroids for the treatment of asthma;* ***AND***
- Patient is currently being treated with ONE of the following, unless there is a contraindication:
  - Combination therapy including BOTH of the following:
    - One medium or high dose inhaled corticosteroid (ICS); **AND**
    - One additional asthma controller medication [e.g., LABA, leukotriene antagonist, theophylline]; **OR**
  - One maximally dosed combination inhaled ICS/ LABA *or ICS/LAMA/LABA product*; **AND**
- Will be used as adjunct therapy along with above asthma treatment; **AND**
- Prescribed by, or in consultation with, a pulmonologist, allergist, or immunologist

Renewal Criteria:

- Documentation of a positive clinical response (e.g., reduction in exacerbations, improvement in forced FEV1, decreased use of rescue medications); **AND**
- Patient is being treated with ONE of the following, unless there is a contraindication:
  - Combination therapy including both a high-dose ICS and an additional asthma controller medication
  - One maximally dosed combination inhaled ICS/ LABA *or ICS/LAMA/LABA* product

Eosinophilic granulomatosis with polyangiitis (EGPA)

Initial Criteria (6-month duration):

- *Patient is ≥ 18 years of age;* ***AND***
- *Diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA);* ***AND***
- *Patient is currently taking standard therapy [i.e., systemic glucocorticoids (e.g., prednisolone, prednisone) with or without immunosuppressive therapy (e.g., cyclophosphamide, rituximab)]*
- *One of the following:*
  - *Patient has relapsing disease (defined as a relapse requiring additional or dose escalation of corticosteroids or immunosuppressant, or hospitalization)*
  - *Refractory disease as defined as failure to attain remission within the prior 6 months following induction treatment with standard therapy regimens;* ***AND***
- *Prescribed by, or in consultation with, a pulmonologist, rheumatologist, allergist, or immunologist*

Renewal Criteria:

- *Documentation of positive clinical response to therapy (e.g., reduced frequency or severity of relapses, reduction or discontinuation of corticosteroids or immunosuppressants)*

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for NUCALA

Current Criteria:

Asthma

Initial Criteria (6-month duration):

- Patient is ≥ 6 years old; **AND**
- One of the following:
  - Patient is currently dependent on oral corticosteroids for the treatment of asthma; **OR**
  - Nucala will be used to treat eosinophilic asthma as defined by one of the following:
    - Baseline (pre-treatment) peripheral blood eosinophil level > 150 cells per microliter
    - Peripheral blood eosinophil levels > 300 cells/microliter within the past 12 months; **AND**
      - Asthma is inadequately controlled as shown by one of the following:
        - ≥ 1 asthma exacerbation requiring systemic corticosteroid within the past 12 months
        - Any prior intubation for an asthma exacerbation
        - Prior asthma-related hospitalization within the past 12 months; **AND**
- Patient is currently being treated with ONE of the following, unless there is a contraindication:
  - Combination therapy including both of the following:
    - One high dose inhaled corticosteroid (ICS)
    - One additional asthma controller medication [e.g., LABA, leukotriene antagonist, theophylline]; **OR**
  - One maximally dosed combination inhaled corticosteroid (ICS)/ LABA) product (e.g., Advair [fluticasone propionate/salmeterol], Dulera [mometasone/formoterol], Symbicort [budesonide/formoterol]); **AND**
- Nucala will be used as adjunct therapy along with above asthma treatment; **AND**
- Prescribed by, or in consultation with, a pulmonologist, allergist, or immunologist

Renewal Criteria:

- Documentation of a positive clinical response (e.g., reduction in exacerbations, improvement in FEV1, decreased use of rescue medications); **AND**
- Patient is being treated with ONE of the following, unless there is a contraindication:
  - Combination therapy including both a high-dose ICS and an additional asthma controller medication
  - One maximally dosed combination inhaled corticosteroid (ICS)/ LABA) product

Eosinophilic granulomatosis with polyangiitis (EGPA) Diagnosis

Initial Criteria (6-month duration):

- Patient's disease has relapsed or is refractory to standard of care therapy (i.e., systemic corticosteroid treatment with or without immunosuppressive therapy); **AND**
- Trial and failure, or contraindication, to treatment with azathioprine, cyclophosphamide, or methotrexate; **AND**
- Patient is currently receiving corticosteroid therapy (e.g., prednisolone, prednisone); **AND**
- Prescribed by, or in consultation with, a pulmonologist, rheumatologist, allergist, or immunologist

Renewal Criteria:

- Documentation of positive clinical response to therapy (e.g., increase in remission time)

Hypereosinophilic syndrome (HES) Diagnosis

Initial Criteria (6-month duration):

- Patient is ≥ 12 years of age; **AND**
- Patient has had HES for ≥ 6-month; **AND**
- There is no identifiable non-hematologic secondary cause (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy, etc.); **AND**

- Patient does not have FIP1L1-PDGFRα kinase-positive HES; **AND**
- Prescribed by, or in consultation with a pulmonologist, rheumatologist, allergist, or immunologist; **AND**
- Patient has tried and failed Gleevec (imatinib) **Renewal Criteria:**
- Documentation of positive clinical response to therapy

Chronic rhinosinusitis with nasal polyps (CRSwNP) Diagnosis

Initial Criteria (6-month duration):

- Patient is ≥ 18 years of age; **AND**
- One of the following:
  - Presence of bilateral nasal polyps
  - Patient has previously required surgical removal of bilateral nasal polyps; **AND**
- Documentation of inadequate response, intolerance, or contraindication to BOTH of the following:
  - Nasal corticosteroid spray
  - Oral corticosteroid; **AND**
- Must be used in combination with intranasal corticosteroid, unless contraindication or intolerance; **AND**
- Prescribed by, or in consultation with, an allergist, immunologist, otolaryngologist, or pulmonologist

Renewal Criteria:

- Documentation of positive clinical response to therapy; **AND**
- Will continue to use in combination with intranasal corticosteroids

Proposed Criteria:

Asthma

Initial Criteria: (6-month duration)

- Patient is ≥ 6 years old; **AND**
- *Diagnosis of moderate to severe asthma; **AND***
- One of the following:
  - ~~Dupixent will be used to treat eosinophilic asthma as defined by one of the following:~~
    - ~~Baseline (pre-treatment) peripheral blood eosinophil level > 150 cells per microliter~~
    - ~~Peripheral blood eosinophil levels > 300 cells/microliter within the past 12 months; **OR**~~
  - *Asthma is an eosinophilic phenotype as defined by a baseline (pre- treatment) peripheral blood eosinophil level ≥ 150 cells/µL or peripheral blood eosinophil levels > 300 cells/mcL; **OR***
  - Patient is currently dependent on oral corticosteroids for the treatment of asthma; **AND**
- Asthma is inadequately controlled as shown by one of the following:
  - *Two* ~~one~~ more exacerbations requiring systemic corticosteroids within the past 12 months
  - ~~Any prior intubation for an asthma exacerbation~~
  - ~~Prior asthma-related hospitalization within the past 12 months~~
  - *Asthma-related emergency treatment (e.g., hospitalization, intensive care unit stay, or mechanical ventilation in the past 12 months;*
  - *Patient is currently dependent on oral corticosteroids for the treatment of asthma; **AND***
- Patient is currently being treated with ONE of the following, unless there is a contraindication:
  - Combination therapy including BOTH of the following:
    - One medium or high dose inhaled corticosteroid (ICS); **AND**
    - One additional asthma controller medication [e.g., LABA, leukotriene antagonist, theophylline]; **OR**
  - One maximally dosed combination inhaled ICS/ LABA *or ICS/LAMA/LABA product*; **AND**
- Will be used as adjunct therapy along with above asthma treatment; **AND**
- Prescribed by, or in consultation with, a pulmonologist, allergist, or immunologist

Renewal Criteria:

- Documentation of a positive clinical response (e.g., reduction in exacerbations, improvement in forced FEV1, decreased use of rescue medications); **AND**
- Patient is being treated with ONE of the following, unless there is a contraindication:
  - Combination therapy including both a high-dose ICS and an additional asthma controller medication
  - One maximally dosed combination inhaled ICS/ LABA *or ICS/LAMA/LABA* product

Eosinophilic granulomatosis with polyangiitis (EGPA) ~~Diagnosis~~

Initial Criteria (6-month duration):

- *Patient is ≥ 18 years of age;* ***AND***
- *Diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA);* ***AND***
- *Patient is currently taking standard therapy [i.e., systemic glucocorticoids (e.g., prednisolone, prednisone) with or without immunosuppressive therapy (e.g., cyclophosphamide, rituximab)]*
- ~~Trial and failure, or contraindication, to treatment with azathioprine, cyclophosphamide, or methotrexate;~~ ~~**AND**~~
- ~~Patient is currently receiving corticosteroid therapy (e.g., prednisolone, prednisone);~~ ~~**AND**~~
- ~~Patient's disease has relapsed or is refractory to standard of care therapy (i.e., corticosteroid treatment with or without immunosuppressive therapy):~~ ~~**AND**~~
- *One of the following:*
  - *Patient has relapsing disease (defined as a relapse requiring additional or dose escalation of corticosteroids or immunosuppressant, or hospitalization);* ***OR***
  - *Refractory disease as defined as failure to attain remission within the prior 6 months following induction treatment with standard therapy regimens*; **AND**
- Prescribed by, or in consultation with, a pulmonologist, rheumatologist, allergist, or immunologist

Renewal Criteria:

- Documentation of positive clinical response to therapy (e.g., *reduced frequency or severity of relapses, reduction or discontinuation of corticosteroids or immunosuppressants* ~~increase in remission time~~)

Hypereosinophilic Syndrome (HES)

Initial Criteria (6-month duration):

- Patient is ≥ 12 years of age; **AND**
- Patient has had HES for ≥ 6-month; **AND**
- There is no identifiable non-hematologic secondary cause (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy, etc.); **AND**
- Patient does not have FIP1L1-PDGFRα kinase-positive HES; **AND**
- *Baseline (pre-Nucala treatment) blood eosinophil level ≥1000 cells/µL (documentation required);* ***AND***
- ~~Patient has tried and failed Gleevec (imatinib):~~ ~~**AND**~~
- *Patient is currently receiving a stable dose of background HES therapy (e.g., oral corticosteroid, immunosuppressor, or cytotoxic therapy);* ***AND***
- Prescribed by, or in consultation with a pulmonologist, rheumatologist, allergist, or immunologist

Renewal Criteria:

- Documentation of positive clinical response to therapy

Chronic rhinosinusitis with nasal polyps (CRSwNP)

Initial Criteria (6-month duration):

- Patient is ≥ 18 years of age; **AND**
- Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) *confirmed by ONE of the following:*
  - *Presence of bilateral nasal polyps*
  - *Patient has previously required surgical removal of bilateral nasal polyps;* ***AND***
- ~~One of the following:~~
  - ~~Presence of bilateral nasal polyps~~
  - ~~Patient has previously required surgical removal of bilateral nasal polyps;~~ ~~**AND**~~
- ~~Documentation of inadequate response, intolerance, or contraindication to BOTH of the following:~~
  - ~~Nasal corticosteroid spray~~
  - ~~Oral corticosteroid;~~ ~~**AND**~~
- *One of the following:*
  - *Patient has required systemic corticosteroids for CRSwNP;* ***OR***
  - *Symptoms persist after trial of TWO of the following classes of agents:*
    - *Nasal saline irrigations*
    - *Intranasal corticosteroids*

- *Antileukotriene agents; **AND***

- Must be used in combination with intranasal corticosteroid, unless contraindication or intolerance; **AND**
- Prescribed by, or in consultation with, an allergist, immunologist, otolaryngologist, or pulmonologist

Renewal Criteria:

- Documentation of positive clinical response to therapy; **AND**
- Will continue to use in combination with intranasal corticosteroids

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for TEZSPIRE

Current Criteria:

Initial Criteria (6-month duration):

- Diagnosis of severe asthma; **AND**
- Patient is ≥ 12 years old; **AND**
- Asthma is inadequately controlled as shown by one of the following:
  - One or more asthma exacerbations requiring systemic corticosteroids within the past 12 months
  - Any prior intubation for an asthma exacerbation
  - Prior asthma-related hospitalization within the past 12 months; **AND**
- Patient is currently being treated with ONE of the following, unless there is a contraindication:
  - Combination therapy including both of the following:
    - One high-dose inhaled corticosteroid (ICS)
    - One additional asthma controller medication [e.g., long-acting beta-2 agonist LABA, leukotriene receptor antagonist, theophylline]; **OR**
  - One maximally dosed combination inhaled corticosteroid (ICS)/ LABA) product (e.g., Advair [fluticasone propionate/salmeterol], Dulera [mometasone/formoterol], Symbicort [budesonide/formoterol]); **AND**
- Tezspire will be used as adjunct therapy along with above asthma treatment; **AND**
- Prescribed by, or in consultation with, a pulmonologist, allergist, or immunologist

Renewal Criteria:

- Documentation of a positive clinical response (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications); **AND**
- Patient is being treated with ONE of the following, unless there is a contraindication:
  - Combination therapy including both a high-dose ICS and an additional asthma controller medication
  - One maximally dosed combination inhaled corticosteroid (ICS)/ LABA) product

Proposed Criteria:

Initial Criteria: (6-month duration)

- Patient is ≥ 12 years old; **AND**
- Diagnosis severe asthma; **AND**
- Asthma is inadequately controlled as shown by one of the following:
  - *Two* ~~one~~ more exacerbations requiring systemic corticosteroids within the past 12 months; **OR**
  - ~~Any prior intubation for an asthma exacerbation; **OR**~~
  - ~~Prior asthma-related hospitalization within the past 12 months; **OR**~~
  - *Asthma-related emergency treatment (e.g., hospitalization, intensive care unit stay, or mechanical ventilation in the past 12 months;* **OR**
  - *Patient is currently dependent on oral corticosteroids for the treatment of asthma; **AND***
- Patient is currently being treated with ONE of the following, unless there is a contraindication:
  - Combination therapy including BOTH of the following:
    - One medium or high dose inhaled corticosteroid (ICS); **AND**
    - One additional asthma controller medication [e.g., LABA, leukotriene antagonist, theophylline]; **OR**
  - One maximally dosed combination inhaled ICS/ LABA *or ICS/LAMA/LABA product*; **AND**

- Will be used as adjunct therapy along with above asthma treatment; **AND**
- Prescribed by, or in consultation with, a pulmonologist, allergist, or immunologist

Renewal Criteria:

- Documentation of a positive clinical response (e.g., reduction in exacerbations, improvement in forced FEV1, decreased use of rescue medications); **AND**
- Patient is being treated with ONE of the following, unless there is a contraindication:
  - Combination therapy including both a high-dose ICS and an additional asthma controller medication
  - One maximally dosed combination inhaled ICS/ LABA *or ICS/LAMA/LABA* product

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for XOLAIR

Current Criteria:

Moderate to Severe Allergic Asthma or Nonallergic Eosinophilic Asthma Diagnosis

Initial Criteria (6-month duration):

- Patient is ≥ 6 years old; **AND**
- Dose requested is consistent with corresponding weight and IgE level per manufacturer's dosing chart; **AND**
- One of the following:
  - Patient is currently dependent on oral corticosteroids for the treatment of asthma; **OR**
  - Xolair will be used to treat eosinophilic asthma as defined by one of the following:
    - Baseline (pre-treatment) peripheral blood eosinophil level > 150 cells per microliter
    - Peripheral blood eosinophil levels > 300 cells/microliter within the past 12 months; **OR**
  - Xolair will be used to treat persistent allergic asthma; **AND**
- Positive skin test or in vitro reactivity to a perennial aeroallergen; **AND**
- Asthma is inadequately controlled as shown by one of the following:
  - One or more asthma exacerbations requiring systemic corticosteroids within the past 12 months
  - Any prior intubation for an asthma exacerbation
  - Prior asthma-related hospitalization within the past 12 months; **AND**
- Patient is currently being treated with ONE of the following, unless there is a contraindication:
  - Combination therapy including both of the following:
    - One high dose inhaled corticosteroid (ICS)
  - One additional asthma controller medication [e.g., long-acting beta-2 agonist LABA, leukotriene receptor antagonist, theophylline]; **OR**
  - One maximally dosed combination inhaled corticosteroid (ICS)/ LABA) product (e.g., Advair [fluticasone propionate/salmeterol], Dulera [mometasone/formoterol], Symbicort [budesonide/formoterol]); **AND**
- Xolair will be used as adjunct therapy along with above asthma treatment; **AND**
- Prescribed by, or in consultation with, a pulmonologist, allergist, or immunologist

Renewal Criteria:

- Documentation of a positive clinical response (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications); **AND**
- Patient is being treated with ONE of the following, unless there is a contraindication:
  - Combination therapy including both a high-dose ICS and an additional asthma controller medication
  - One maximally dosed combination inhaled corticosteroid (ICS)/ LABA) product

Chronic Idiopathic Urticaria (CIU) Diagnosis

Initial Criteria (6-month duration):

- Patient is ≥ 12 years of age; **AND**
- Patient remains symptomatic despite a 2-week trial to BOTH the following taken in combination:
  - A second generation H1-antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine); **AND**
  - One of the following:
    - Different second generation H1-antihistamine (e.g., cetirizine, fexofenadine, levocetirizine)

- First generation H1-antihistamine (e.g., diphenhydramine, chlorpheniramine, hydroxyzine)
- H2-receptor antihistamine (e.g., famotidine, cimetidine, ranitidine)
- Leukotriene modifier (e.g., montelukast); **AND**

- Prescribed by, or in consultation with, an allergist, dermatologist, or immunologist

Renewal Criteria:

- Documentation of positive clinical response to therapy (e.g., reduction in exacerbations, itch severity, hives)

IgE-mediated food allergy

- Diagnosis of IgE-mediated food allergy; **AND**
- Patient has Type 1 allergic reactions, including anaphylaxis, to one or more of the following foods peanuts, milk, egg, wheat, cashew, hazelnut, and walnut documented by one of the following:
  - Skin puncture test
  - Allergen-specific IgE test; **AND**
- Xolair is to be used in combination with food allergen avoidance; **AND**
- Dose requested is consistent with corresponding weight and IgE level per manufacturer's dosing chart; **AND**
- Prescribed by, or in consultation with allergist or immunologist

Nasal polyps Diagnosis

Initial Criteria (6-month duration):

- Patient is ≥ 18 years of age; **AND**
- Patient has chronic rhinosinusitis; **AND**
- One of the following:
  - Presence of bilateral nasal polyps
  - Patient has previously required surgical removal of bilateral nasal polyps; **AND**
- Documentation of inadequate response, intolerance, or contraindication to BOTH of the following:
  - Nasal corticosteroid spray
  - Oral corticosteroid; **AND**
- Must be used in combination with intranasal corticosteroid, unless contraindication or intolerance; **AND**
- Prescribed by, or in consultation with, an allergist, immunologist, otolaryngologist, or pulmonologist

Renewal Criteria:

- Documentation of positive clinical response to therapy; **AND**
- Will continue to use in combination with intranasal corticosteroids

Proposed Criteria:

Asthma

Initial Criteria: (6-month duration)

- Patient is ≥ 6 years old; **AND**
- Diagnosis of moderate to severe persistent; **AND**
- Dose requested is consistent with corresponding weight and IgE level per manufacturer's dosing chart; **AND**
- *Baseline (pre-treatment) serum total IgE level greater than or equal to 30 IU/mL and less than or equal to 1300 IU/mL; **AND***
- ~~One of the following:~~
  - ~~Patient is currently dependent on oral corticosteroids for the treatment of asthma; **OR**~~
  - ~~Xolair will be used to treat eosinophilic asthma as defined by one of the following:~~
    - ~~Baseline (pre-treatment) peripheral blood eosinophil level > 150 cells per microliter~~
    - ~~Peripheral blood eosinophil levels > 300 cells/microliter within the past 12 months; **OR**~~
  - ~~Xolair will be used to treat persistent allergic asthma; **AND**~~
- Positive skin test or in vitro reactivity to a perennial aeroallergen; **AND**
- Asthma is inadequately controlled as shown by one of the following:
  - *Two* ~~one~~ more exacerbations requiring systemic corticosteroids within the past 12 months; **OR**
  - ~~Any prior intubation for an asthma exacerbation; **OR**~~
  - ~~Prior asthma-related hospitalization within the past 12 months; **OR**~~

- *Asthma-related emergency treatment (e.g., hospitalization, intensive care unit stay, or mechanical ventilation in the past 12 months*; **OR**
- *Patient is currently dependent on oral corticosteroids for the treatment of asthma; **AND***

- Patient is currently being treated with ONE of the following, unless there is a contraindication:
  - Combination therapy including BOTH of the following:
    - One medium or high dose inhaled corticosteroid (ICS); **AND**
    - One additional asthma controller medication [e.g., LABA, leukotriene antagonist, theophylline]; **OR**
  - One maximally dosed combination inhaled ICS/ LABA *or ICS/LAMA/LABA product*; **AND**
- Will be used as adjunct therapy along with above asthma treatment; **AND**
- Prescribed by, or in consultation with, a pulmonologist, allergist, or immunologist

Renewal Criteria:

- Documentation of a positive clinical response (e.g., reduction in exacerbations, improvement in forced FEV1, decreased use of rescue medications); **AND**
- Patient is being treated with ONE of the following, unless there is a contraindication:
  - Combination therapy including both a high-dose ICS and an additional asthma controller medication
- One maximally dosed combination inhaled ICS/ LABA *or ICS/LAMA/LABA* product

Chronic Urticaria

Initial Criteria (6-month duration):

- Patient is ≥ 12 years of age; **AND**
- Diagnosis of *chronic spontaneous idiopathic urticaria (CSU)* or chronic idiopathic urticaria(CIU); **AND**
- Patient remains symptomatic despite a 2-week trial to BOTH the following taken in combination:
  - A second generation H1-antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine); **AND**
  - One of the following:
    - Different second generation H1-antihistamine (e.g., cetirizine, fexofenadine, levocetirizine)
    - First generation H1-antihistamine (e.g., diphenhydramine, chlorpheniramine, hydroxyzine)
    - H2-receptor antihistamine (e.g., famotidine, cimetidine, ranitidine)
    - Leukotriene modifier (e.g., montelukast); **AND**
- Prescribed by, or in consultation with, an allergist, dermatologist, or immunologist

Renewal Criteria:

- Documentation of positive clinical response to therapy (e.g., reduction in exacerbations, itch severity, hives)

IgE-Mediated Food Allergy

- Diagnosis of IgE-mediated food allergy *confirmed by BOTH of the following:*
  - *History of type I allergic reactions; **AND***
  - *Food specific skin prick testing (SPT) or IgE antibody in vitro testing; **AND***
- ~~Patient has type 1 allergic reactions, including anaphylaxis, to one or more of the following foods peanuts, milk, egg, wheat, cashew, hazelnut, and walnut documented by one of the following:~~
  - ~~Skin puncture test~~
  - ~~Allergen-specific IgE test; **AND**~~
- Xolair is to be used in combination with food allergen avoidance; **AND**
- Dose requested is consistent with corresponding weight and IgE level per manufacturer's dosing chart; **AND**
- Prescribed by, or in consultation with allergist or immunologist

Chronic rhinosinusitis with nasal polyps (CRSwNP)

Initial Criteria (6-month duration):

- Patient is ≥ 18 years of age; **AND**
- *Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) confirmed by ONE of the following:*
  - *Presence of bilateral nasal polyps; **OR***
  - *Patient has previously required surgical removal of bilateral nasal polyps; **AND***
- ~~One of the following:~~
  - ~~Presence of bilateral nasal polyps; **OR**~~
  - ~~Patient has previously required surgical removal of bilateral nasal polyps; **AND**~~

- ~~Documentation of inadequate response, intolerance, or contraindication to BOTH of the following:~~
  - ~~Nasal corticosteroid spray~~
  - ~~Oral corticosteroid; **AND**~~
- *One of the following:*
  - *Patient has required systemic corticosteroids for CRSwNP; **OR***
  - *Symptoms persist after trial of two of the following classes of agents:*
    - *Nasal saline irrigations*
    - *Intranasal corticosteroids*
    - *Antileukotriene agents; **AND***
- Must be used in combination with intranasal corticosteroid, unless contraindication or intolerance; **AND**
- Prescribed by, or in consultation with, an allergist, immunologist, otolaryngologist, or pulmonologist

Renewal Criteria:

- Documentation of positive clinical response to therapy; **AND**
- Will continue to use in combination with intranasal corticosteroids

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• ADBRY (Initial month)	6 syringes/28 days
• ADBRY (Maintenance)	4 syringes/28 days
• CIBINQO	1/day
• DUPIXENT	2 syringes/28 days
• *EBGLYSS (Initial 2 months)*	*6 pens/56 days*
• *EBGLYSS (Maintenance)*	*1 pen/28 days*
• FASENRA (Initial – first 3 doses)	1/30 days
• FASENRA (Maintenance)	1/56 days
• NUCALA	3 pens or syringes/28 days
• TEZSPIRE	4 pens or syringes/28 days

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

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SEDATIVE HYPNOTIC AGENTS

Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred	
Sedative Hypnotic Agents [ID]	eszopiclone [QL] doxepin conc 10 mg/mL [QL] ROZEREM [QL] (ramelteon) zaleplon [QL] zolpidem [QL]	AMBIEN/ AMBIEN CR [QL] (zolpidem) BELSOMRA [QL] (suvorexant) DAYVIGO [PA, QL] (lemborexant) DORAL [PA, QL] (quazepam) doxepin [PA, QL] EDLUAR [PA, QL] (zolpidem) estazolam [PA, QL] flurazepam [PA, QL] HALCION [PA, QL] (triazolam) HETLIOZ caps & susp [PA, QL] (tasimelteon) LUNESTA [QL] (eszopiclone)	midazolam [QL] quazepam [PA, QL] QUVIVIQ [PA, QL] (daridorexant) ramelteon [QL] RESTORIL [PA, QL] (temazepam) SILENOR [PA, QL] (doxepin) tasimelteon [PA, QL] temazepam [PA, QL] triazolam [PA, QL] zolpidem ER [QL] zolpidem tartrate SL [QL]

Last Review Date: November 2022

Recent Significant Changes

- Drug Discontinuations: INTERMEZZO, 2022; ZOLPIMIST, 2024

Background

Insomnia is defined as a complaint of trouble initiating or maintaining sleep, which is associated with daytime consequences and is not attributable to environmental circumstances or inadequate opportunity to sleep. Insomnia is considered chronic when it has persisted for at least 3 months at a frequency of at least 3 times per week. Insomnia is considered short-term when the disorder meets symptom criteria but has persisted for less than 3 months. Occasional, short-term insomnia is thought to affect 30% to 50% of the population. Insomnia often occurs with comorbid disorders, including depression, anxiety, and substance abuse. Certain medical or psychiatric disorders may also increase the risk of insomnia.

The primary treatment goals are to improve sleep quality and quantity and to improve insomnia-related daytime impairments. General treatment measures for insomnia include treating comorbid medical and psychiatric conditions, modifying sleep-interfering medications and substances, and optimizing the sleep environment. Part of initial approach to treatment should include cognitive behavioral therapy. Zolpidem is the most widely prescribed hypnotic medication. Non-BZD sedative hypnotics used to treat insomnia are doxepin tablets (Silenor), daridorexant (Quviviq), eszopiclone (Lunesta), lemborexant (Dayvigo), ramelteon (Rozerem), suvorexant (Belsomra), tasimelteon (Hetlioz), and zaleplon (Sonata). Ramelteon and tasimelteon are melatonin receptor agonists that possess affinity for the melatonin MT1 and MT2 receptors vs. the MT3 receptor. Tasimelteon has a unique indication for treatment of Non-24-Hour Sleep-Wake Disorder (Non-24), a circadian rhythm sleep disorder found predominantly in the blind and characterized by excessive sleepiness during the day and an inability to sleep at night. Eszopiclone, zolpidem, and zaleplon act at the GABA receptor. Daridorexant, lemborexant, and suvorexant are orexin receptor antagonists.

All the agents in this review (with the exception of tasimelteon) have been shown to result in positive effects on sleep latency, total sleep time (TST) and/or wake time after sleep onset (WASO). The BZDs have been shown to be effective in improving sleep latency and TST. Other agents such as zaleplon and ramelteon are effective in reducing sleep latency, whereas medications such as eszopiclone and temazepam are more likely to improve sleep maintenance. Although a substantial number of FDA- and non-FDA-approved anxiolytics and sedative hypnotics are available, the focus of this review will be on BZDs and non-BZDs agents. Other classes of agents such as barbiturates, SNRIs, SSRIs, and TCAs are also utilized in these settings but will not be the focus of this review. Several BZDs and some non-BZDs have additional FDA-approved indications such as alcohol withdrawal, seizure disorder, muscle relaxation, and depression. These indications are outside the scope of this review, and therefore will not be addressed in this review.

Table 1. Medications Included Within Class Review

Drug	Generic Availability
Benzodiazepines	
estazolam	✔
flurazepam	✔
RESTORIL (temazepam)	✔
HALCION (triazolam)	✔
DORAL (quazepam)	✔
Non-benzodiazepines	
SILENOR (doxepin)†	✔
doxepin, oral concentrate	✔
LUNESTA (eszopiclone)	✔
DAYVIGO (lemborexant)	-
QUVIVIQ (daridorexant)	-
ROZEREM (ramelteon)	✔
BELSOMRA (suvorexant)	-
HETLIOZ (tasimelteon)	✔
HETLIOZ LQ (tasimelteon)	-
zaleplon	✔
AMBIEN, AMBIEN CR (zolpidem tartrate)	✔
EDLUAR (zolpidem tartrate)	-
zolpidem tartrate sublingual ‡	✔
zolpidem tartrate capsule §	-

† 3 and 6 mg tablets only. Doxepin capsules and oral solution are indicated for the treatment of various depression or anxiety disorders.
‡ Generic formulation is only available as 1.75 mg and 3.5 mg strengths.
§ Capsule formulation is only available 7.5 mg strengths. Use another immediate release product for 5 mg or 20 mg strength.

Table 2. FDA-Approved Indications

Indication	Benzodiazepines				Non-Benzodiazepines								
	estazolam	temazepam	triazolam	quazepam	daridorexant	doxepin	eszopiclone	lemborexant	ramelteon	suvorexant	tasimelteon	zaleplon	zolpidem
Short-term treatment of insomnia characterized by difficulties with sleep initiation/onset									✔				✔
Treatment of insomnia, characterized by difficulties with sleep maintenance						✔ ‡							
Treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance					✔			✔		✔			✔
Treatment of insomnia characterized by difficulty falling asleep, frequent nocturnal awakenings, and/or early morning awakenings	✔ *			✔									
Short-term treatment of insomnia		✔	✔									✔	
Treatment of insomnia							✔						
Treatment of non-24-hour sleep-wake disorder											✔		

Abbreviations: SL = sublingual; ODT = orally disintegrating tablet)
* Zolpidem is also indicated for treatment of insomnia when a middle of the night awakening is followed by difficult returning to sleep
‡ Doxepin 3 and 6 mg tablets only.

The Department of Veterans Affairs/Department of Defense (VA/DoD) guideline recommends cognitive behavioral therapy (strong recommendation) and suggests brief behavioral therapy (weak recommendation) for chronic insomnia disorder. Cognitive behavioral therapy should be the first-line treatment over pharmacotherapy. Low-dose doxepin (i.e., 3 mg or 6 mg) or non-BZD benzodiazepine receptor agonists (ie, zolpidem, zaleplon, eszopiclone) are the recommended pharmacotherapies for short-course treatment of chronic insomnia disorder. The guideline recommends against using BZDs and trazodone for treating chronic insomnia disorder. The evidence remains insufficient to make recommendations regarding ramelteon or suvorexant for chronic insomnia disorder.

American Academy of Sleep Medicine (AASM) Clinical Practice Guideline for the Pharmacologic Treatment of Chronic Insomnia in Adults makes recommendations for the treatment of sleep maintenance insomnia (vs. no treatment) in adults. The pharmacologic agents that are recommended include doxepin and suvorexant (both low quality of evidence). The pharmacologic agents that are not recommended include melatonin (very low quality of evidence), tiagabine or valerian (low quality of evidence), trazodone (moderate quality of evidence), tryptophan (high quality of evidence). Pharmacological recommendations for sleep onset and sleep maintenance insomnia (vs no treatment) in adults include eszopiclone and zolpidem (very low quality of evidence) and temazepam (moderate quality of evidence). The pharmacological agent not recommended for sleep onset and sleep maintenance insomnia is diphenhydramine (low quality of evidence).

For sleep onset insomnia (vs no treatment), the pharmacological recommended agents include ramelteon (very low quality of evidence), zaleplon (low quality of evidence), and triazolam (high quality of evidence). The agents not recommended for sleep onset insomnia are melatonin and tiagabine (very low quality of evidence), valerian (low quality of evidence), trazodone (moderate quality of evidence), and tryptophan (high quality of evidence).

American College of Physicians (ACP) Management of Chronic Insomnia Disorder in Adults recommends that all adults receive cognitive behavioral therapy for insomnia as the initial treatment for chronic insomnia disorder. ACP also recommends collaboration with the patient to determine whether a pharmacologic therapy should be initiated. Low-quality evidence shows that both eszopiclone and zolpidem improved global outcomes in the general population, and low- to moderate-quality evidence shows that eszopiclone, zolpidem, and doxepin improved sleep outcomes, such as SOL, TST, and WASO. Moderate-quality evidence shows that suvorexant improved treatment response and sleep outcomes. Low-quality evidence shows no statistically significant difference between ramelteon and placebo for sleep. Benzodiazepines and melatonin were not included in these guidelines. No one sedative hypnotic was recommended over another, due to insufficient evidence.

Doxepin is contraindicated in patients with untreated narrow angle glaucoma or severe urinary retention and in concomitant use with an MAOIs. Suvorexant, lemborexant, and daridorexant are contraindicated in patients with narcolepsy. Estazolam and triazolam are contraindicated with ketoconazole or itraconazole. Triazolam is also contraindicated with nefazodone and protease inhibitors. Quazepam is contraindicated in patients with sleep apnea or chronic pulmonary insufficiency. Zolpidem products, eszopiclone, and zaleplon are contraindicated in patients with a prior history of complex sleep behaviors.

Benzodiazepines carry a boxed warning for concomitant use with opioids, as it may result in profound sedation, respiratory depression, coma, and death. Zolpidem products, eszopiclone, and zaleplon carry a boxed warning for complex sleep behaviors such as sleepwalking, sleep-driving, and other activities, which may lead to serious injuries, including death. Daytime somnolence, sleepwalking, and “sleep-driving” are listed as warnings for the majority of benzodiazepines and non-benzodiazepines in this review. Withdrawal effects can be observed after continuous long-term therapy with benzodiazepines. Abrupt withdrawal or discontinuation should be avoided. Worsening of symptoms of depression/suicidal ideation is a warning with most benzodiazepines, doxepin, eszopiclone, zaleplon, zolpidem, lemborexant, suvorexant, and daridorexant. Caution is advised when using zolpidem, benzodiazepines, and orexin receptor antagonists in patients with compromised respiratory function.

Benzodiazepines should be used cautiously in the elderly (e.g., lowest possible dose with slow dose up-titration should be utilized. Additionally, benzodiazepines with a short half-life (e.g., oxazepam) are preferred over those with a long half-life in the elderly patient population. Zolpidem increases the risk of dizziness, drowsiness, and diarrhea in elderly patients. Elderly patients have a 2-fold exposure to tasimelteon compared with younger patients. With the non-benzodiazepines, differences in the reported AEs between elderly and younger patients were not noted; however, older patients may be at a higher risk for drowsiness, and consequently, falls.

Drowsiness, sedation, fatigue, cognitive impairment, and muscle weakness are the most frequent adverse events (AEs) with benzodiazepine use. Benzodiazepine use can lead to physiological dependence and tolerance, especially at higher doses and/or when given for a long duration. Treatment with benzodiazepines should be limited to short-term use whenever possible. Somnolence/sedation and other central nervous system (CNS)-related AEs have also been reported with the non-benzodiazepine sedative hypnotics. Concomitant use of alcohol and other CNS depressants can increase the risk of CNS depression. The concomitant use of benzodiazepines and opioids increases the risk of respiratory depression.

Clinical Rationale

The primary treatment goals are to improve sleep quality and quantity and to improve insomnia-related daytime impairments. General treatment measures for insomnia include treating comorbid medical and psychiatric conditions, modifying sleep-interfering medications and substances, and optimizing the sleep environment.

Recommendation

It is recommended that at least 2 agents, with different mechanism of actions, should be available for use. ~~It is recommended that the benzodiazepine sedative hypnotics should be subject to PA criteria.~~ Additionally, due to concerns regarding the use of psychotropic medications in patients with I/DD, these agents should be subject to PA in patients with an I/DD diagnosis without a concomitant mental health diagnosis.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for DAYVIGO

Current Criteria:

- Patient must 18 years of age or older; **AND**
- Diagnosis of insomnia characterized by difficulties with sleep onset and/or sleep maintenance; **AND**
- Medical documentation that rules out other insomnia related disorders (e.g., movement, breathing, psychiatric disorders and medication); **AND**
- Documented trial (at least 3 weeks) of non-pharmacological therapies (e.g., stimulus control, sleep restriction, sleep hygiene measures and relaxation therapy); **AND**
- Patient should not have any of the following diagnoses: Narcolepsy, COPD, moderate to severe OSA; **AND**
- Will not be given to patients with severe hepatic impairment, and baseline liver enzymes documentation required; **AND**
- Trial and failure, contraindication, or intolerance of 2 preferred agents; **AND**
- Patient should avoid concomitantly taking strong or moderate CYP3A inhibitors and inducers; **AND**
- Patients who are pregnant should be registered in the DAYVIGO pregnancy registry

Proposed Criteria:

- Patient must 18 years of age or older; **AND**
- Diagnosis of insomnia characterized by difficulties with sleep onset and/or sleep maintenance; **AND**
- ~~Medical documentation that rules out~~ *Narcolepsy and* other insomnia related disorders have been ruled out (e.g., movement, breathing, psychiatric disorders and medication); **AND**
- ~~Documented~~ *T*rial (at least 3 weeks) of non-pharmacological therapies (e.g., stimulus control, sleep restriction, sleep hygiene measures and relaxation therapy); **AND**

- ~~Patient should not have any of the following diagnoses: Narcolepsy, COPD, moderate to severe OSA;~~ **~~AND~~**
- ~~Will not be given to patients with severe hepatic impairment, and baseline liver enzymes documentation required;~~ **~~AND~~**
- Trial and failure, contraindication, or intolerance of 2 preferred agents; **AND**
- ~~Patient should avoid concomitantly taking strong or moderate CYP3A inhibitors and inducers;~~ **~~AND~~**
- Patients who are pregnant should be registered in the DAYVIGO pregnancy registry

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for QUVIVIQ

Current Criteria:

- Patient must 18 years of age or older; **AND**
- Diagnosis of insomnia characterized by difficulties with sleep onset and/or sleep maintenance; **AND**
- Medical documentation that rules out other insomnia related disorders have been ruled out (e.g., movement, breathing, psychiatric disorders and medication); **AND**
- Documented trial (at least 3 weeks) of non-pharmacological therapies (e.g., stimulus control, sleep restriction, sleep hygiene measures and relaxation therapy); **AND**
- Patient should not have any of the following diagnoses: Narcolepsy, COPD, moderate to severe OSA; **AND**
- Will not be given to patients with severe hepatic impairment, and baseline liver enzymes documentation required; **AND**
- Trial and failure, contraindication, or intolerance of 2 preferred agents; **AND**
- Patient should avoid concomitantly taking strong or moderate CYP3A inhibitors and strong or moderate CYP3A inducers; **AND**
- Concurrently not taking CNS stimulants, opiates, carisoprodol, meprobamate or barbiturates; **AND**
- Due to increased risk of dependency, patient does not have a history of alcohol or drug dependence/abuse; **AND**
- Patients who are pregnant should be registered in the Quviviq® pregnancy registry

Proposed Criteria:

- Patient must 18 years of age or older; **AND**
- Diagnosis of insomnia characterized by difficulties with sleep onset and/or sleep maintenance; **AND**
- ~~Medical documentation that rules out~~ *Narcolepsy and* other insomnia related disorders have been ruled out (e.g., movement, breathing, psychiatric disorders and medication); **AND**
- ~~Documented~~ Trial (at least 3 weeks) of non-pharmacological therapies (e.g., stimulus control, sleep restriction, sleep hygiene measures and relaxation therapy); **AND**
- Patient should not have any of the following diagnoses: Narcolepsy, COPD, moderate to severe OSA; **AND**
- ~~Will not be given to patients with severe hepatic impairment, and baseline liver enzymes documentation required;~~ **~~AND~~**
- Trial and failure, contraindication, or intolerance of 2 preferred agents; **AND**
- ~~Patient should avoid concomitantly taking strong or moderate CYP3A inhibitors and strong or moderate CYP3A inducers;~~ **~~AND~~**
- Concurrently not taking CNS stimulants, opiates, carisoprodol, meprobamate or barbiturates; **AND**
- Due to increased risk of dependency, patient does not have a history of alcohol or drug dependence/abuse; **AND**
- Patients who are pregnant should be registered in the Quviviq® pregnancy registry

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for DORAL, HALCION, RESTORIL

Current Criteria:

- Diagnosis of Insomnia; **AND**
- Medical documentation that rules out other insomnia related disorders (e.g., movement, breathing, psychiatric disorders & medication/substance use); **AND**
- Documented trial (at least 3 weeks) of non-pharmacological therapies (e.g., stimulus control, sleep restriction, sleep hygiene measures & relaxation therapy); **AND**
- Due to increased risk of toxicity:
  - Patient should not be pregnant **OR**
  - Concurrently taking CNS stimulants, opiates, carisoprodol, meprobamate or barbiturates; **AND**
- Due to increased risk of dependency, patient does not have a history of alcohol OR drug dependence/abuse; **AND**
- Clinically valid reason as why the generic cannot be used; **AND**
- Trial and failure, contraindication, or intolerance to 2 preferred agents
- **Note**: Caution is warranted if patient is concurrently taking CYP3A4 inhibitors [e.g., fluvoxamine, itraconazole, ketoconazole] as patient is at increased risk of toxicity.

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for doxepin (generic for SILENOR), SILENOR

Current Criteria:

- Documented trial/failure (defined as ≥ 1 week) at an appropriate dose of the doxepin mg/mL concentrated solution

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for EDLUAR

Current Criteria:

- Approved only for patients with difficulty swallowing/absorption

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for estazolam, flurazepam, quazepam, temazepam, triazolam

Current Criteria:

- Diagnosis of Insomnia; **AND**
- Medical documentation that rules out other insomnia related disorders (e.g., movement, breathing, psychiatric disorders and medication); **AND**
- Documented trial (at least 3 weeks) of non-pharmacological therapies (e.g., stimulus control, sleep restriction, sleep hygiene measures and relaxation therapy); **AND**

- Use of 2 preferred agents, unless patient has a contraindication or allergy; **AND**
- Due to increased risk of toxicity,
  - Patient should not be pregnant **OR**
  - Concurrently taking CNS stimulants, opiates, carisoprodol, meprobamate or barbiturates; **AND**
- Due to increased risk of dependency, does not have a history of alcohol or drug dependence/abuse; **AND**
- If request if for temazepam 7.5 or 22.5 mg, trial and failure of temazepam 15 mg and/or 30 mg strength

Note: Caution is warranted if patient is concurrently taking CYP3A4 inhibitors due to increased risk of toxicity.

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for HETLIOZ capsule, tasimelteon capsule

Current Criteria:

- Treatment of non-24-hour sleep wake disorder (non-24 or N24) in members who are unable to distinguish between light and darkness in both eyes; **OR**
- Treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in patients 16 years of age and older; **AND**
- Trial and failure or contraindication to melatonin; **AND**
- Will not take strong CYP1A2 inhibitors (e.g., fluvoxamine) or strong CYP3A4 inducers (e.g., rifampin); **AND**
- If request is for tasimelteon, clinically valid reason why preferred Hetlioz cannot be used

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for HETLIOZ suspension

Current Criteria:

- Treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS); **AND**
- Patient is at least 3 years of age but not greater than 15 years of age; **AND**
- Trial and failure or contraindication to melatonin; **AND**
- Patient is unable to swallow/absorb medications through the GI tract; **AND**
- Patient will not take strong CYP1A2 inhibitors (e.g., fluvoxamine) or strong CYP3A4 inducers (e.g., rifampin)

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• AMBIEN (zolpidem)	14/30 days*
• AMBIEN CR (zolpidem ER)	14/30 days*
• BELSOMRA	14/30 days*
• DAYVIGO	14/30 days*
• DORAL (quazepam)	14/30 days*
• EDLUAR	14/30 days*
• estazolam	14/30 days*

- flurazepam 14/30 days*
- HALCION (triazolam) 14/30 days*
- HETLIOZ (tasimelteon) suspension 5 mL per day, 158 mL/60 days*
- HETLIOZ capsule 30/60 days*
- LUNESTA (eszopiclone) 14/30 days*
- QUVIVIQ 14/30 days*
- RESTORIL (temazepam) 14/30 days*
- ROZEREM (ramelteon) 14/30 days*
- SILENOR (doxepin) 14/30 days*
- zaleplon 14/30 days*

*For children, larger quantities may be approved as medically necessary.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- Ambien tablets (zolpidem tartrate) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis US LLC; February 2022.
- Ambien CR extended-release tablets (zolpidem tartrate) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis US LLC; February 2022.
- Belsomra (suvorexant) [prescribing information]. Rahway, NJ: Merck Sharp & Dohme LLC; February 2023.
- DayVigo (lemborexant) [prescribing information]. Nutley, NJ: Eisai Inc; December 2023.
- Doral (quazepam) [prescribing information]. Atlanta, GA: Galt Pharmaceuticals LLC; January 2023.
- Doxepin hydrochloride capsules, USP [prescribing information]. Bedminster, NJ: Alembic Pharmaceuticals Inc; September 2021.
- Drugs@FDA: FDA approved drug products. FDA Web site. https://www.accessdata.fda.gov/scripts/cder/daf/. Accessed August 6, 2024.
- Edluar (zolpidem tartrate) sublingual tablets [prescribing information]. Somerset, NJ: Meda Pharmaceuticals Inc; August 2022.
- Estazolam [prescribing information]. East Windsor, NJ: Novitium Pharma LLC; November 2022.
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- Flurazepam hydrochloride [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals Inc; February 2021.
- Gliatto MF. Generalized anxiety disorder. Am Fam Physician. 2000;62(7):1591-1600.
- Halcion (triazolam) [prescribing information]. New York, NY: Pharmacia & Upjohn Co; January 2023.
- Hetlioz (tasimelteon) [prescribing information]. Washington, DC: Vanda Pharmaceuticals; December 2020.
- Intermezzo tablets (zolpidem tartrate) [prescribing information]. Stamford, CT: Purdue Pharma LP; August 2019.
- Lunesta (eszopiclone) [prescribing information]. Wixom, MI: Waylis Therapeutics LLC; July 2023.
- Midazolam [package insert]. Lake Forest, IL: Hospira Inc; September 2009.
- Orange Book: Approved drug products with therapeutic equivalence evaluations. Food and Drug Administration Web site. https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm. Accessed August 6, 2024.
- Qaseem A, Kangsara D, Forceia MA, Cooke M, Denberg TD. Management of chronic insomnia disorder in adults: A clinical practice guideline from the American College of Physicians. Ann Intern Med. 2016;165:125-133.
- Quviviq (daridorexant) [prescribing information]. Radnor, PA: Idorsia Pharmaceuticals US Inc; November 2023.
- Restoril (temazepam) [prescribing information]. Webster Groves, MO: SpecGx LLC; January 2023.
- Sateia MJ, Buysse DJ, Krystal AD, Neubauer DN, Heald JL. Clinical practice guidelines for the pharmacologic treatment of chronic insomnia in adults: An American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2017;13(2):307-349.
- Silenor (doxepin) [prescribing information]. Brentwood, TN: Currax Pharmaceuticals LLC; December 2022.
- Temazepam [prescribing information]. Elizabeth, NJ: Actavis Elizabeth; June 2012.
- Triazolam [prescribing information]. Morgantown, WV: Greenstone LLC; February 2023.
- Veteran's Affairs/Department of Defense (VA/DoD) clinical practice guidelines - the management of chronic insomnia disorder and obstructive sleep apnea. Department of Veterans Affairs Web site. October 2019. https://www.healthquality.va.gov/guidelines/CD/insomniap. Accessed August 6, 2024.
- Zaleplon capsules [prescribing information]. Princeton, NJ: Bionpharma Inc; June 2023.
- Zolpidem. Lexi-Drugs. UpToDate Lexidrug. Waltham, MA: UpToDate Inc. http://online.lexi.com. Accessed November 14, 2014.
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ABBREVIATED DRUG CLASS REVIEWS

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ACNE AGENTS, TOPICAL

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	PREFERRED	NON-PREFERRED
Acne Agents, Topical (covered for patients < 21 years old only)	benzoyl peroxide (2.5%, 5%, 10% excluding cleanser, gel, microspheres, & towelettes) QL (OTC) clindamycin (excluding foam, lotion, & 75 mL bottle of gel) QL clindamycin/benzoyl peroxide gel QL erythromycin (excluding swab & gels) QL sodium sulfacetamide/sulfur QL	ACZONE PA, QL (dapsone) AMZEEQ PA, QL (minocycline) benzoyl peroxide (excluding preferred products) QL CABTREO PA, QL (adapalene/benzoyl peroxide/clindamycin) clindamycin (excluding preferred products) PQL dapsone PA, QL dermatological kits PA, QL erythromycin/benzoyl peroxide QL erythromycin swab & gel QL sulfacetamide susp PQL WINLEVI PA, QL (clascoterone) All branded single agent and combination products of benzoyl peroxide, clindamycin, erythromycin, and sodium sulfacetamide

Last Review Date: November 2022

Recent Significant Changes

- No significant updates since last review

Recommendation

It is recommended that at least two topical antibiotic agents indicated for acne be available for use, which should include components of one combination product.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for ACZONE

Current Criteria:

- Patient is at least 12 years of age and less than 21 years of age; **AND**
- Patient has a diagnosis of acne vulgaris; **AND**
- Clinically valid reason why generic dapsone gel cannot be used

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for AMZEEQ

Current Criteria:

- Diagnosis of non-nodular moderate to severe acne vulgaris; **AND**
- Patient is at least 9 years of age and less than 21 years of age; **AND**
- Trial and failure, contraindication, or intolerance to ALL the following:
  - 2 preferred agents; **AND**
  - minocycline capsules; **AND**

- Prescriber must provide peer-reviewed medical literature documenting why the requested drug for the requested indication is the only appropriate choice versus the preferred agents

Proposed Criteria:
Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for CABTREO

Current Criteria:
- Patient is at least 12 years of age and less than 21 years of age; **AND**
- Patient has a diagnosis of acne vulgaris; **AND**
- Provider must provide peer-reviewed medical literature documenting why the requested drug for the requested indication is the only appropriate choice versus the preferred agents

Proposed Criteria:
Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for dapsone gel

Current Criteria:
- Patient is at least 12 years of age and less than 21 years of age; **AND**
- Patient has a diagnosis of acne vulgaris; **AND**
- Clinically valid reason why the preferred agents cannot be used

Proposed Criteria:
Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for dermatological kits

Current Criteria:
- Trial and failure of 3 preferred agents; **AND**
- Trial and failure of the individual components of the kit

Proposed Criteria:
Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for WINLEVI

Current Criteria:
- Diagnosis of acne vulgaris; **AND**
- Patient is at least 12 years of age and less than 21 years of age; **AND**

- Trial and failure, contraindication, or intolerance of 2 preferred agents; **AND**
- Prescriber provides peer-reviewed medical literature documenting why the requested drug for the requested indication is the only appropriate choice versus the preferred agents

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• ACZONE	1 package/Rx
• AMZEEQ	1 package/28 days
• benzoyl peroxide	1 package/Rx
• benzoyl peroxide 2.5%, 5%, 10%	1 package/Rx
• CABTREO	1 package/Rx
• clindamycin phosphate	1 package/Rx
• clindamycin	1 package/Rx
• clindamycin/benzoyl peroxide gel	1 package/Rx
• dapsone gel	1 package/Rx
• dermatological kits	1 package/Rx
• erythromycin	1 package/Rx
• erythromycin swab & gel	1 package/Rx
• erythromycin/benzoyl peroxide	1 package/Rx
• sodium sulfacetamide/sulfur	1 package/Rx
• sulfacetamide suspension	1 package/Rx
• WINLEVI	1 tube/30 days
• All branded single agent and combination products of benzoyl peroxide, clindamycin, erythromycin, and sodium sulfacetamide	1 package/Rx

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- Aczone 5% gel (dapsone) [prescribing information]. Exton, PA: Alrmirall LLC; July 2019.
- Aczone 7.5% gel (dapsone) [prescribing information]. Malvern, PA: Almirall LLC; August 2021.
- Amzeeq (minocycline) [prescribing information]. Scottsdale, AZ: Journey Medical Corporation; January 2023.
- Benzoyl Peroxide (benzoyl peroxide USP) [prescribing information]. Livonia, MI: Rugby Laboratories; December 2019.
- Cabtreo (clindamycin, adapalene, and benzoyl peroxide) [prescribing information]. Bridgewater, NJ: Bausch Health US LLC; October 2023.
- Clindamycin Phosphate (topical) [prescribing information]. Durham, NC: Encube Ethicals Inc; January 2020.
- Epiduo (adapalene and benzoyl peroxide) [prescribing information]. Fort Worth, TX: Galderma; February 2018.
- Ery 2% Pads (erythromycin) [prescribing information]. Allegan, MI: Padagis; February 2022.
- Erygel (erythromycin) [prescribing information]. Newtown, PA: Prestium Pharma; June 2018.
- Erythromycin [prescribing information]. Basking Ridge, NJ: Micro Labs USA Inc; April 2021.
- Sulfacetamide (Topical). *Lexi-Drugs*. UpToDate Lexidrug. Waltham, MA: UpToDate Inc. http://online.lexi.com. Accessed July 22, 2014.
- Sulfur and Sulfacetamide. *Lexi-Drugs*. UpToDate Lexidrug. Waltham, MA: UpToDate Inc. https://online.lexi.com. Accessed April 16, 2014.
- Winlevi (clascoterone) [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries Inc; December 2022.

AGENTS FOR BURNS, TOPICAL

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred
Topical Agents for Burns	silver sulfadiazine QL SSD QL (silver sulfadiazine)	mafenide pack QL SILVADENE QL (silver sulfadiazine) SULFAMYLON QL (mafenide)

Last Review Date: November 2022

Recent Significant Changes

- No significant updates since last review

Recommendation

It is recommended that at least one topical agent for burn treatment is available for use.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

- silver sulfadiazine 1 package/Rx
- SSD 1 package/Rx
- mafenide 1 package/Rx
- SILVADENE 1 package/Rx
- SULFAMYLON 1 package/Rx

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- Silvadene (silver sulfadiazine) [prescribing information]. New York, NY: Pfizer; October 2016.
- Silver sulfadiazine [prescribing information]. Peapack, NJ: Greenstone LLC; October 2016.
- Sulfamylon (mafenide) cream [prescribing information]. East Brunswick, NJ: Rising Pharma Holdings Inc; August 2020.
- Sulfamylon (mafenide) powder for solution [prescribing information]. Rockford, IL: Mylan Institutional Inc; June 2018.

AGENTS FOR ROSACEA, TOPICAL

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred
Topical Agents for Rosacea *	azelaic acid FINACEA foam QL (azelaic acid) metronidazole cream QL metronidazole gel QL metronidazole lotion QL	brimonidine gel QL ivermectin cream QL NORITATE cream QL (metronidazole 1%) RHOFADE PA, QL (oxymetazoline)

- Topical agents for rosea are covered for recipients < 21 years old only

Last Review Date: November 2022

Recent Significant Changes

- Drug Discontinuations
  - METROGEL KIT, 2012

Recommendation

It is recommended that at least 2 agents, with different mechanism of actions, should be available for use.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for RHOFADE

Current Criteria:

- Patient age < 21 years of age; **AND**
- Patient has a diagnosis rosacea or erythema; **AND**
- Trial and failure, or contraindication, of 2 of the following: brimonidine, ivermectin, tetracycline, minocycline, doxycycline, erythromycin, clindamycin, benzoyl peroxide; **AND**
- Trial and failure of 2 preferred topical agents for rosacea

Proposed Criteria:

- Patient age < 21 years of age; **AND**
- Patient has a diagnosis *persistent facial erythema associated with rosacea;* ~~rosacea or erythema~~; **AND**
- Trial and failure, or contraindication, of 2 of the following: brimonidine, ivermectin, tetracycline, minocycline, doxycycline, erythromycin, clindamycin, benzoyl peroxide; **AND**
- Trial and failure of 2 preferred topical agents for rosacea

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• FINACEA	50 g/Rx
• metronidazole cream, lotion, gel	60 g/Rx
• brimonidine gel	30 g/Rx
• ivermectin cream	45 g/Rx
• METROLOTION	60 g/Rx
• NORITATE cream	60 g/Rx
• RHOFADE	30 g/30 days

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- Finacea (azelaic acid) gel [prescribing information]. Madison, NJ: LEO Pharma Inc; May 2021.
- Ivermectin 0.5% lotion [prescribing information]. Hawthorne, NY: Taro Pharmaceuticals USA Inc; November 2020.
- MetroLotion (metronidazole) 0.75% lotion [prescribing information]. Fort Worth, TX: Galderma Laboratories, L.P.; February 2017.
- MetroNIDAZOLE (Topical). Lexi-Drugs. UpToDate Lexidrug. Waltham, MA: UpToDate Inc. http://online.lexi.com. Accessed March 10, 2014.
- Noritate (metronidazole) 1% cream [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; June 2020.
- Rhofade (oxymetazoline hydrochloride) [prescribing information]. San Antonio, TX: DPT Laboratories, Ltd; November 2019.
- Zilxi (minocycline) [prescribing information]. Bridgewater, NJ: VYNE Pharmaceuticals Inc; September 2022.

ANESTHETICS, TOPICAL

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred	
Anesthetics, Topical	lidocaine (excluding lotion, soln, kits) QL lidocaine patch 5% PA, QL lidocaine viscous lidocaine/prilocaine QL ZTLIDO PA, QL (lidocaine, patch)	hydrocortisone/pramoxine lidocaine brand products (ZTLIDO excluded) lidocaine lotion and soln lidocaine kits PA lidocaine/prilocaine brand products	lidocaine/hydrocortisone PA,QL PLIAGLIS QL (lidocaine/tetracaine) PRAMOSONE 2.5%-1% lotion QL (pramoxine/hydrocortisone)

Last Review Date: November 2022

Recent Significant Changes

- Drug Discontinuations
  - lidocaine/tetracaine cream, 2024 (brand PLIAGLIS is still available)
  - Novacort gel, 2023

Recommendation

~~The topical anesthetics include medications for a variety of indications. With the exception of lidocaine patches, they are often used to alleviate itching and pain caused by insect bites, minor burns, sunburns, atopic dermatitis, or eczema. Additionally, these agents are commonly used to provide an anesthetic effect during minor surgical procedures and diagnostic tests. The variety of products, dosage forms, and indications present makes direct, head-to-head comparisons of these agents difficult. Additionally, clinical guidelines for the use of topical anesthetics are lacking; therefore, it is difficult to determine therapeutic alternatives in this category. Based on their FDA-approved indications and place in therapy, it is thought that all topical anesthetics (with the exception of lidocaine patches) are similar in safety and efficacy. Therefore, it is recommended at least one topical anesthetic be available for use. The topical lidocaine patch has a unique indication for the treatment of pain associated with postherpetic neuralgia. Guidelines from the American Academy of Neurology (AAN) recommend the use of topical lidocaine, as well as oral medications such as tricyclic antidepressants, gabapentin, pregabalin, and opioids, for the treatment of pain associated with PHN, but do not indicate that topical lidocaine patches are recommended over oral therapies. In addition, there are no head-to-head trials evaluating lidocaine patches against the oral medications that are also indicated for the treatment of pain associated with PHN.~~ Due to their ~~high cost and~~ limited *FDA approved* indications, it is recommended that topical lidocaine patches be subject to clinical criteria in order to ensure appropriate use.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for lidocaine patch 5%

Current Criteria:

- Diagnosis of post-herpetic neuralgia

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for ZTLIDO

Current Criteria:

- Diagnosis of post-herpetic neuralgia

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for lidocaine/hydrocortisone

Current Criteria:

- Diagnosis of FDA-approved indication; **AND**
- Clinically valid reason why the preferred topical anesthetics cannot be used

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for lidocaine kits

Current Criteria:

- Diagnosis of FDA-approved indication; **AND**
- Clinically valid reason why the preferred topical anesthetics cannot be used; **AND**
- For combination kits, trial and failure of individual agents

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• lidocaine (excluding lotion/solution)	1 tube/Rx
• lidocaine patch 5%	*3* ~~2~~/day
• lidocaine/prilocaine	30 g/Rx
• ZTLIDO	*3* ~~2~~/day
• lidocaine/hydrocortisone	1 package/Rx
• PLIAGLIS	1 package/Rx
• PRAMOSONE 2.5-1% lotion	1 package/Rx

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- Lidocaine (Topical). Lexi-Drugs. UpToDate Lexidrug. Waltham, MA: UpToDate Inc. http://online.lexi.com. Accessed March 27, 2015.Novacort (hydrocortisone/pramoxine) [prescribing information]. Chicago, IL: Novum Pharma, LLC; November 2018.
- Pliaglis (lidocaine/tetracaine) [prescribing information]. Phoenix, AZ: Oba Pharmaceuticals, Inc; September 2020.
- Pramosone ointment (hydrocortisone/pramoxine) [prescribing information]. Roswell, GA: Sebela Pharmaceuticals; February 2015.
- ZTlido (lidocaine) [prescribing information]. Palo Alto, CA: Scilex Pharmaceuticals Inc; April 2021.

ANTIBIOTICS, TOPICAL

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred
Antibiotics, Topical	gentamicin cream gentamicin ointment mupirocin ointment QL	mupirocin cream QL

Last Review Date: November 2022

Recent Significant Changes

- Discontinued Drugs:
  - CENTANY ointment, 2023
  - XEPI cream, 2024

Recommendation

~~The topical antibacterial agents for skin and soft tissue infections are approved for the treatment and/or prevention of various superficial skin infections and impetigo. Clinical trials have demonstrated efficacy for the treatment and eradication of various organisms but have not yet demonstrated a clear role of the agents in the prevention of infections. Current clinical guidelines from IDSA, AAFP, all recommend topical mupirocin as first line treatment for impetigo and the ISPD guidelines recommend mupirocin for prevention of catheter site infections. Therefore,~~ It is recommended that at least one mupirocin agent be available for use.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

- mupirocin ointment 44 g/Rx
- mupirocin cream 30g/Rx

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- Gentamicin ointment [prescribing information]. Buena, NJ: Teligent Pharma Inc; April 2018.
- Gentamicin sulfate cream [prescribing information]. Buena, NJ: Teligent Pharma Inc; September 2021.
- Mupirocin (USP, 2%) ointment [prescribing information]. Allegan, MI: Padagis; January 2022.
- Mupirocin (USP, 2%) cream [prescribing information]. Memphis, TN: Northstar RxLLC; November 2020.

ANTINEOPLASTICS, TOPICAL

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred
Antineoplastics, Topical	CARAC [QL] (fluorouracil cream, 0.5%) diclofenac 3% gel [PA, QL] fluorouracil 5% cream imiquimod [QL] TARGRETIN gel [QL] (bexarotene)	bexarotene gel [QL] EFUDEX [QL] (fluorouracil) fluorouracil 0.5% cream HYFTOR [PA, QL] (sirolimus) VALCHLOR [PA, QL] (mechlorethamine) ZYCLARA [PA, QL] (imiquimod)

Last Review Date: November 2022

Recent Significant Changes

- No significant changes since last review

Recommendation

It is recommended that at least one agent for each unique indication be available for use.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for diclofenac 3% gel

Current Criteria:

- Diagnosis of actinic keratosis

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for HYFTOR

Current Criteria:

Initial Criteria (4-month duration):

- Diagnosis of facial angiofibroma associated with tuberous sclerosis complex; **AND**
- Patient is 6 years of age or older; **AND**
- Prescribed by or in consultation with a dermatologist or neurologist; **AND**
- Patient is not a candidate for laser therapy or surgical treatments

Renewal Criteria:

- Documentation of positive clinical response to therapy (e.g., improvement in size or redness of facial angiofibroma)

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for VALCHLOR

Current Criteria:

- Diagnosis of stage IA or IB mycosis fungoides -type cutaneous T-cell lymphoma; **AND**
- Patient has received skin directed therapy

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for ZYCLARA

Current Criteria:

- Diagnosis of actinic keratosis; **OR**
- Diagnosis of basal cell carcinoma

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• CARAC	1 package/Rx
• diclofenac 3% gel	1 package/Rx
• imiquimod	1 package/Rx
• TARGRETIN	1 package/Rx
• bexarotene	1 package/Rx
• EFUDEX	1 package/Rx
• HYFTOR	30 g/month
• VALCHLOR	1 package/Rx
• ZYCLARA	1 package/Rx

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- Carac (fluorouracil 0.5% cream) [prescribing information]. Bridgewater, NJ: Bausch Health US LLC; May 2022.
- Efudex solutions and cream (fluorouracil) [prescribing information]. Sugar Land, TX: Mylan Institutional Inc; October 2021.
- Fluorouracil topical solution (2% and 5%) [prescribing information]. Madisonville, LA Solubiomix LLC; September 2017.
- Hyftor (sirolimus topical) [prescribing information]. Bethesda, MD: Nobelpharma America LLC; March 2022.
- Imiquimod cream 5% [prescribing information]. Melville, NY: Fougera Pharmaceuticals Inc; July 2015.
- Targretin (bexarotene) [prescribing information]. San Antonio, TX DPT Laboratories Ltd; June 2020.
- Valchlor (mechlorethamine) [prescribing information]. Iselin, NJ: Helsinn Therapeutics (U.S.), Inc; January 2020.
- Zyclara (imiquimod) [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; June 2020.

ANTIPRURITICS/ANTIHISTAMINES, TOPICAL

Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred	
Antipruritics/ Antihistamines, Topical	N/A	doxepin cream PA, QL PRUDOXIN PA, QL (doxepin)	ZONALON PA, QL (doxepin)

Last Review Date: November 2022

Recent Significant Changes

- No significant updates since last review

Recommendation

It is recommended that topical doxepin be reserved for patients who have failed first line therapy and be subject to clinical criteria.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for doxepin cream, PRUDOXIN, ZONALON

Current Criteria:

- Patient moderate pruritus due to various forms of eczematous dermatitis, including atopic dermatitis and lichen simplex chronicus; **AND**
- Inadequate response, intolerance, or contraindication to BOTH of the following:
  - A topical corticosteroid; **AND**
  - An oral antihistamine (first or second generation) or a topical antihistaminic agent

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

- doxepin cream 45 g/90 days
- PRUDOXIN 45 g/90 days
- ZONALON 45 g/90 days

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- Lexicomp. (n.d.). Testosterone: Drug information. UpToDate. Accessed October 1, 2024, from https://www.uptodate.com/contents/doxepin-topical-drug-information
- Prudoxin (doxepin hydrochloride) 5% cream [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals; June 2017.
- Zonalon (doxepin hydrochloride) 5% cream [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals; June 2017.
- Zonalon (doxepin hydrochloride) 5% cream [product monograph]. Montreal, Quebec, Canada: Valeant Canada LP; March 2013.

PEDICULOCIDES/SCABICIDES

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred	
Pediculocides/ Scabicides	NATROBA [QL] (spinosad) permethrin [QL] VANALICE [QL] (pyrethrins/ piperonyl butoxide)	CROTAN [PA, QL] (crotamiton) ivermectin lotion [QL] malathion [QL]	OVIDE [QL] (malathion) SKLICE [QL] (ivermectin) spinosad [QL]

Last Review Date: November 2022

Recent Significant Changes

- No significant updates since last review

Recommendation

It is recommended that at least permethrin and one non-permethrin antiparasitic agent is available. Further, recommend that at least one ovicidal or ovotoxic agent should be available for use. ~~Lindane should be subject to prior authorization as a result of safety concerns.~~

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for CROTAN

Current Criteria:

- Patient is being treated for scabies; **AND**
- Patient has tried and failed permethrin (unless patient has a contraindication)

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• NATROBA (Spinosad)	2 bottles/Rx
• permethrin	2 tubes/Rx
• VANALICE	1 bottle/Rx
• CROTAN	1 bottle/Rx
• OVIDE (malathion)	2 bottles/Rx
• SKLICE (ivermectin lotion)	1 tube/Rx

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- Crotan (crotamiton) [prescribing information]. Charleston, SC: Marnell Pharmaceuticals LLC; received December 2021.
- Ivermectin 0.5% lotion [prescribing information]. Hawthorne, NY: Taro Pharmaceuticals USA Inc; November 2020.
- Natroba (spinosad) [prescribing information]. Carmel, IN: ParaPRO; April 2021.
- Ovide 0.5% (malathion lotion) [prescribing information]. Hawthorne, NY: Taro Pharmaceuticals USA Inc; February 2017.
- Permethrin cream 5% [prescribing information]. Parsippany, NJ: Actavis; December 2019.
- Permethrin lotion [prescribing information]. Lincolnton, NC: Actavis; August 2008.
- Sklice (ivermectin) [prescribing information]. Atlanta, GA: Arbor Pharmaceuticals; May 2021.

RETINOIDS, ORAL

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred	
Retinoids, Oral	N/A	ABSORICA [PA] (isotretinoin) ABSORICA LD [PA] (isotretinoin, micronized) ACCUTANE [PA] (isotretinoin) AMNESTEEM [PA] (isotretinoin)	CLARAVIS [PA] (isotretinoin) isotretinoin [PA] ZENATANE [PA] (isotretinoin)

Last Review Date: November 2022

Recent Significant Changes

- Drug Discontinuations
  - MYORISAN, 2024

Recommendation

Note: previously, the Committee recommended that at least one oral retinoid have preferred status on the PDL and that clinical criteria be removed as all providers must be enrolled in the iPledge program to prescribe these agents. TennCare decided that, based on their significant side effect profile, the agents would remain as non-preferred and continue to be subject to clinical criteria to help ensure appropriate use.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for ABSORICA, ABSORICA LD, ACCUTANE, AMNESTEEM, CLARAVIS, isotretinoin, ZENATANE

Current Criteria:

- Diagnosis of chronic myelogenous leukemia, head or neck cancer, ichthyosis, keratosis follicularis, neuroblastoma, or pityriasis rubra pilaris will be reviewed on a case-by-case basis; **OR**
- Patient is 20 years of age or younger and has a diagnosis of severe recalcitrant nodular acne

Note: Will not be covered for acne or rosacea for recipients ≥ 21 years of age)

Note: Active registration and compliance with the iPLEDGE program is required.

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- Absorica/Absorica LD (isotretinoin) [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries Inc; April 2022.
- Accutane (isotretinoin) [prescribing information]. Scottsdale, AZ: JG Pharma, Inc; July 2020.
- Amnesteem (isotretinoin) [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals Inc; August 2022.
- Claravis (isotretinoin) [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA Inc; August 2022.
- Zenatane (isotretinoin) [prescribing information]. Princeton, NJ: Dr. Reddy's Laboratories Inc; September 2022.

RETINOIDS, TOPICAL

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred	
Retinoids, Topical	adapalene PA ≥ 21, QL adapalene/benzoyl peroxide PA ≥ 21, QL tazarotene cream PA ≥ 21, QL tretinoin cream PA ≥ 21, QL	ALTRENO PA, QL (tretinoin) ATRALIN PA, QL (tretinoin) ARAZLO PA, QL (tazarotene) clindamycin/tretinoin PA, QL FABIOR PA, QL (tazarotene)	RETIN-A PA, QL (tretinoin) RETIN-A MICRO PA, QL (tretinoin) tretinoin gel PA, QL ZIANA PA (clindamycin/ tretinoin)

Last Review Date: November 2022

Recent Significant Changes

- Discontinued drugs:
  - Avita, 2023

Recommendation

Therefore, it is recommended at least two topical retinoids be available for use, one of which should be tazarotene. In order to prevent use of topical retinoids for the mitigation of fine wrinkles, it is recommended that the topical retinoids be subject to clinical criteria to ensure medical necessity.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for adapalene, adapalene/benzoyl peroxide, tretinoin cream, ATRALIN, clindamycin/tretinoin, RETIN-A, RETIN-A MICRO, tretinoin gel, ZIANA

Current Criteria:

- Patient is < 21 years old; **AND**
  - Diagnosis of acne, keratosis follicularis, verruca plana, or actinic keratosis; **OR**
- Patient is ≥ 21 years old: **AND**
  - Diagnosis of keratosis follicularis (1 year approval duration); **OR**
  - Diagnosis of verruca plana (2-month approval duration); **OR**
  - Diagnosis of actinic keratosis for the prevention of future lesions (1 year approval duration); **AND**
- If request is for a non-preferred agent, trial and failure of TWO preferred agents

Note: Will not be covered for patients > 21 years old with a diagnosis of acne

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for tazarotene cream, FABIOR

Current Criteria:

- Diagnosis of psoriasis; **AND**
  - Trial and failure, contraindication, or intolerance to at least one topical steroid; **OR**
- Diagnosis of acne in patients less than 21 years of age

Proposed Criteria:
Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for ALTRENO, ARAZLO

Current Criteria:
- Patient is ≥ 9 years of age but less than 21 years of age; **AND**
- Diagnosis of acne vulgaris in children 9 years and older; **AND**
- Trial and failure, contraindication, or intolerance of 2 preferred agents; **AND**
- Clinically valid reason why the requested drug is the only appropriate choice vs the preferred agents; **AND**
- If request is for ARAZLO, patient is not pregnant

Proposed Criteria:
Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• adapalene	1 package/Rx
• tazarotene cream	1 package/Rx
• tretinoin cream	1 package/Rx
• adapalene/benzoyl peroxide	1 package/Rx
• ALTRENO	1 package/Rx
• ATRALIN	1 package/Rx
• ARAZLO	1 package/28 days
• clindamycin/tretinoin	1 package/Rx
• FABIOR	1 package/Rx
• RETIN-A	1 package/Rx
• RETIN-A MICRO	1 package/Rx
• tretinoin gel	1 package/Rx

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- Adapalene Topical Solution (adapalene) [prescribing information]. Doylestown, PA: Rochester Pharmaceuticals; July 2021.[PubMed 12814337]
- Aklief (trifarotene) [prescribing information]. Fort Worth, TX: Galderma Laboratories LP; January 2022.
- Altreno (tretinoin) [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; March 2020.
- Atralin gel (tretinoin) [prescribing information]. Bridgewater, NJ: Bausch Health US; February 2024.
- Avita cream (tretinoin) [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals; June 2018.
- Epiduo Forte (adapalene and benzoyl peroxide) [prescribing information]. Fort Worth, TX: Galderma Laboratories LP; April 2022.
- Fabior (tazarotene) [prescribing information]. Greenville, NC: Mayne Pharma; June 2018.
- Retin-A cream, gel (tretinoin) [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; September 2019.
- Retin-A Micro gel (tretinoin) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; October 2017.
- Tazarotene. Lexi-Drugs. UpToDate Lexidrug. Waltham, MA: UpToDate Inc. https://online.lexi.com. Accessed March 24, 2014.
- Tazorac cream (tazarotene) [prescribing information]. Exton, PA: Almirall, LLC; August 2019.
- Tazorac gel (tazarotene) [prescribing information]. Exton, PA: Almirall, LLC; August 2019.
- Tretinoin (topical). Lexi-Drugs [database online]. UpToDate Lexidrug. Waltham, MA: UpToDate Inc http://online.lexi.com. Accessed March 11, 2014.
- Ziana (clindamycin phosphate and tretinoin) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; March 2017.

TOPICAL STEROIDS: LEAST POTENT

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred
Topical Steroids: Least Potent	hydrocortisone 0.5% cream and ointment (Rx & OTC) QL hydrocortisone 1% cream, lotion, gel, and ointment (Rx & OTC) QL hydrocortisone 2.5% cream, lotion, and ointment QL	TEXACORT 2.5% solution (hydrocortisone)

Last Review Date: November 2022

Recent Significant Changes

- No significant changes since last review

Recommendation

It is recommended at least seven topical steroids be available for use, reflective of at least one agent in each potency group.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

- hydrocortisone 0.5% cream and ointment 1 package/Rx
- hydrocortisone 1% cream, lotion, gel, and ointment 1 package/Rx
- hydrocortisone 2.5% cream, lotion, and ointment 1 package/Rx

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- Hydrocortisone cream [prescribing information]. Melville, NY: Fougera; December 2011.
- Hydrocortisone gel [prescribing information]. Melville, NY: Fougera; December 2011.
- Hydrocortisone lotion [prescribing information]. Melville, NY: Fougera; October 2015.
- Hydrocortisone ointment [prescribing information]. Melville, NY: Fougera; December 2011.
- Texacort (hydrocortisone) [prescribing information]. San Antonio, TX: Mission Pharmacal Company; received August 2019.

TOPICAL STEROIDS: MILD

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred
Topical Steroids: Mild	alclometasone 0.05% cream and ointment desonide 0.05% cream and ointment QL fluocinolone 0.01% cream, oil, and soln QL	DERMA-SMOOTHE/FS OIL (fluocinolone) SYNALAR 0.01% soln QL (fluocinolone)

Last Review Date: November 2022

Recent Significant Changes

- No significant changes since last review

Recommendation

It is recommended at least seven topical steroids be available for use, reflective of at least one agent in each potency group.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• desonide 0.05% cream, ointment	1 package/Rx
• fluocinolone 0.01% cream, oil, solution	1 package/Rx
• desonide 0.05% ointment	1 package/Rx
• SYNALAR 0.01% solution	1 package/Rx

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- Alclometasone dipropionate cream [prescribing information]. Hawthorne, NY: Taro Pharmaceuticals Inc; October 2015.
- Derma-Smoothe/FS body oil (fluocinolone acetonide) [prescribing information]. Sanford, FL: Hill Dermaceuticals Inc; October 2013.
- Derma-Smoothe/FS scalp oil (fluocinolone acetonide) [prescribing information]. Sanford, FL: Hill Dermaceuticals Inc; January 2014.
- Desonide [prescribing information]. Hawthorne, NY: Taro; October 2015.
- Synalar topical solution (fluocinolone acetonide) [prescribing information]. Fairfield, NJ: Medimetriks Pharmaceuticals, Inc; June 2018.

TOPICAL STEROIDS: LOWER MID-STRENGTH

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred
Topical Steroids: Lower Mid-Strength	betamethasone dipropionate 0.05% lotion QL betamethasone valerate 0.1% cream QL CLODERM 0.1% cream fluticasone propionate 0.05% cream LOCOID LIPOCREAM QL (hydrocortisone butyrate hydrophilic lipo base cream 0.1%)	clocortolone 0.1% cream and pump QL desonide 0.05% lotion QL fluocinolone acetonide 0.025% cream fluticasone propionate 0.05% lotion hydrocortisone butyrate 0.1% cream, lotion, ointment, soln QL hydrocortisone valerate 0.2% cream QL LOCOID QL (hydrocortisone butyrate lotion 0.1%) PANDEL 0.1% cream QL (hydrocortisone probutate)

Last Review Date: November 2022

Recent Significant Changes

- Discontinued Drugs:
  - CAPEX shampoo, 2024
  - clocortolone 0.1% pump, 2020
  - fluocinolone acetonide 0.01% shampoo, 2001
  - prednicarbate 0.1% cream and ointment, 2023

Recommendation

It is recommended at least seven topical steroids be available for use, reflective of at least one agent in each potency group.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• betamethasone dipropionate 0.05% lotion	1 package/Rx
• betamethasone valerate 0.1% cream	1 package/Rx
• clocortolone 0.1% cream and pump	1 package/Rx
• desonide 0.05% lotion	1 package/Rx
• hydrocortisone 0.1% cream, lotion, ointment, solution	1 package/Rx
• hydrocortisone valerate 0.2% cream	1 package/Rx
• LOCOID LIPOCREAM and LOCOID lotion	1 package/Rx
• PANDEL 0.1% cream	1 package/Rx

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- Betamethasone dipropionate cream, lotion, ointment [prescribing information]. South Plainfield, NJ: G & W Laboratories; January 2016.
- Betamethasone valerate cream, lotion, ointment [prescribing information]. Melville, NY: Fougera; July 2013.
- Cloderm (clocortolone pivalate) [prescribing information]. Charleston, SC: EPI Health LLC; November 2018.
- Desonide [prescribing information]. Hawthorne, NY: Taro; October 2015.
- Fluticasone [prescribing information]. Melville, NY: E. Fougera & Co; July 2018.
- Hydrocortisone ointment [prescribing information]. Melville, NY: Fougera; December 2011.
- Hydrocortisone valerate [prescribing information]. South Plainfield, NJ: Cosette Pharmaceuticals Inc; May 2020.
- Locoid (hydrocortisone) lotion [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals; October 2014.
- Pandel (hydrocortisone) [prescribing information]. Baudette, MN: ANI Pharmaceuticals Inc; September 2021.

TOPICAL STEROIDS: MID-STRENGTH

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred
Topical Steroids: Mid-Strength	mometasone furoate 0.1% cream and soln (lotion) triamcinolone acetonide 0.1% cream QL	fluocinolone acetonide 0.025% ointment flurandrenolide 0.5% cream and lotion hydrocortisone valerate 0.2% ointment QL KENALOG aerosol spray (triamcinolone acetonide) triamcinolone spray

Last Review Date: November 2022

Recent Significant Changes

- Drug Discontinuations
  - flurandrenolide ointment, 2023

Recommendation

It is recommended at least seven topical steroids be available for use, reflective of at least one agent in each potency group.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

- triamcinolone acetonide 0.1% cream 1 package/Rx
- hydrocortisone valerate 0.2% ointment 1 package/Rx

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- Fluocinolone acetonide [prescribing information]. Ferndale, MI: Ferndale Laboratories Inc; October 2022.
- Flurandrenolide. Lexi-Drugs. UpToDate Lexidrug. Waltham, MA: UpToDate Inc. http://online.lexi.com. Accessed July 24, 2014.
- Hydrocortisone valerate [prescribing information]. South Plainfield, NJ: Cosette Pharmaceuticals Inc; May 2020.
- Kenalog spray (triamcinolone acetonide) [prescribing information]. Jacksonville, FL: Ranbaxy; August 2012.
- Mometasone furoate cream [prescribing information]. Brampton, Ontario, Canada: Padagis; February 2021.
- Mometasone furoate solution [prescribing information]. Yeruham, Israel: Padagis; April 2023.
- Triamcinolone (topical). Lexi-Drugs. UpToDate Lexidrug. Waltham, MA: UpToDate Inc. http://online.lexi.com. Accessed November 17, 2015.

TOPICAL STEROIDS: UPPER MID-STRENGTH

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred
Topical Steroids: Upper Mid-Strength	betamethasone valerate 0.1% ointment QL fluticasone propionate 0.005% ointment QL triamcinolone acetonide 0.025% cream, lotion, ointment QL triamcinolone acetonide 0.05% ointment QL triamcinolone acetonide 0.1% lotion and ointment QL triamcinolone acetonide 0.5% cream and ointment QL	amcinonide 0.1% cream and lotion QL betamethasone dipropionate 0.05% cream QL betamethasone valerate 0.12% foam QL desoximetasone 0.05% cream QL fluocinonide 0.05% emulsified base cream QL

Last Review Date: November 2022

Recent Significant Changes

- Discontinued Drug:
  - SERNIVO, 2023

Recommendation

It is recommended at least seven topical steroids be available for use, reflective of at least one agent in each potency group.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• betamethasone valerate 0.1% ointment	1 package/Rx
• fluticasone propionate 0.005% ointment	1 package/Rx
• triamcinolone acetonide 0.025% cream, lotion, ointment	1 package/Rx
• triamcinolone acetonide 0.05% ointment	1 package/Rx
• triamcinolone acetonide 0.1% lotion and ointment	1 package/Rx
• triamcinolone acetonide 0.5% cream and ointment	1 package/Rx
• amcinonide 0.1% cream and lotion	1 package/Rx
• betamethasone dipropionate 0.05% cream	1 package/Rx
• betamethasone valerate 0.12% foam	1 package/Rx

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- Amcinonide cream [prescribing information]. Fairmont, WI: INA Pharmaceuticals Inc; May 2023.
- Amcinonide lotion [prescribing information]. Melville, NY: Fougera Pharmaceuticals; December 2013.
- Betamethasone dipropionate cream [prescribing information]. South Plainfield, NJ: G & W Laboratories; January 2016.
- Betamethasone valerate foam [prescribing information]. Orlando, FL: Ingenus Pharmaceuticals, LLC; December 2019.
- Betamethasone valerate ointment [prescribing information]. Melville, NY: Fougera; July 2013.
- Desoximetasone [prescribing informaiton]. Hawthorne, NY: TaroPharma; September 2015.
- Fluocinonide emulsified cream [prescribing information]. Hawthorne, NY: Taro Pharmaceuticals USA Inc; November 2017.
- Fluticasone ointment [prescribing information]. Bronx, NY: Perrigo; May 2018.
- Triamcinolone (topical). *Lexi-Drugs*. UpToDate Lexidrug. Waltham, MA: UpToDate Inc. http://online.lexi.com. Accessed November 17, 2015.

TOPICAL STEROIDS: POTENT

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred
Topical Steroids: Potent	betamethasone dipropionate, augmented 0.05% cream QL betamethasone dipropionate, augmented 0.05% lotion QL fluocinonide 0.05% cream and ointment QL fluocinonide 0.05% soln mometasone furoate 0.1% ointment	APEXICON E 0.05% cream QL (diflorasone) betamethasone dipropionate 0.05% ointment QL desoximetasone 0.05% gel and ointment QL desoximetasone 0.25% cream, ointment, spray QL diflorasone diacetate 0.05% cream and ointment QL HALOG 0.1% ointment, cream, and soln QL (halcinonide) TOPICORT 0.05% gel and ointment (desoximetasone) TOPICORT 0.25% cream and ointment (desoximetasone)

Last Review Date: November 2022

Recent Significant Changes

- No significant changes since last review

Recommendation

It is recommended at least seven topical steroids be available for use, reflective of at least one agent in each potency group.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• betamethasone dipropionate, augmented 0.05% cream	1 package/Rx
• APEXICON E 0.05% cream	1 package/Rx
• betamethasone dipropionate, augmented 0.05% lotion	1 package/Rx
• betamethasone dipropionate, augmented 0.05% ointment	1 package/Rx
• desoximetasone 0.05% gel and ointment	1 package/Rx
• desoximetasone 0.25% cream, ointment, spray	1 package/Rx
• diflorasone diacetate 0.05% cream and ointment	1 package/Rx
• fluocinonide 0.05% cream, gel, and ointment	1 package/Rx
• HALOG 0.1% ointment and cream	1 package/Rx
• HALOG solution	120 mL per 30 days

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- ApexiCon E Cream (diflorasone) [prescribing information]. Baudette, MN: ANI Pharmaceuticals Inc; September 2021.
- Betamethasone dipropionate cream, lotion, ointment [prescribing information]. South Plainfield, NJ: G & W Laboratories; January 2016.
- Diflorasone diacetate ointment [prescribing information]. Brockton, MA: Lyne Laboratories Inc; October 2020.
- Fluocinonide cream, gel, and ointment [prescribing information]. Hawthorne, NY: Taro Pharmaceuticals USA Inc; November 2017.
- Fluocinonide solution [prescribing information]. Durham, NC: Encube Ethicals Inc; November 2021.
- Halog solution (halcinonide) [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc; July 2019.
- Mometasone furoate ointment [prescribing information]. Yeruham, Israel: Padagis; January 2023.
- Topicort cream and gel [prescribing information]. Hawthorne, NY: Taro Pharmaceuticals; September 2015.
- Topicort ointment [prescribing information]. Hawthorne, NY: Taro Pharmaceuticals; April 2015.
- Topicort topical spray (desoximetasone) [prescribing information]. Hawthorne, NY: Taro Pharmaceuticals; October 2021.

TOPICAL STEROIDS: SUPER POTENT

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred
Topical Steroids: Super Potent	clobetasol propionate 0.05% cream, gel, ointment, lotion and soln QL clobetasol propionate emollient base 0.05% cream QL clobetasol propionate 0.05% foam, shampoo, and spray QL fluocinonide 0.1% cream QL	BRYHALI lotion PA, QL (halobetasol propionate lotion 0.01%) betamethasone dipropionate, augmented 0.05% gel, and ointment QL clobetasol propionate emollient base 0.05% foam QL CLODAN (clobetasol propionate shampoo 0.05%) DIPROLENE 0.05% ointment (betamethasone propionate) halobetasol propionate 0.05% cream, foam, ointment QL LEXETTE PA, QL (halobetasol propionate foam 0.05%) TOVET (clobetasol propionate emollient foam 0.05%) QL ULTRAVATE 0.05% lotion QL (halobetasol propionate) VANOS 0.1% cream (fluocinonide)

Last Review Date: November 2022

Recent Significant Changes

- Drug Discontinuations
  - CLODAN KIT, 2024
  - ULTRAVATE cream and ointment, 2021

Recommendation

It is recommended at least seven topical steroids be available for use, reflective of at least one agent in each potency group.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for BRYHALI LOTION, LEXETTE

Current Criteria:

- Diagnosis of an FDA-approved indication; **AND**
- Clinically valid reason why a preferred agent cannot be used

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• clobetasol propionate 0.05% cream, gel, ointment, lotion, soln	1 package/Rx
• clobetasol propionate emollient base 0.05% cream	1 package/Rx
• BRYHALI LOTION	200 g/28 days
• betamethasone dipropionate, augmented 0.05% gel, ointment	1 package/Rx
• clobetasol propionate 0.05% foam, shampoo, spray	1 package/Rx
• clobetasol propionate emollient base 0.05% foam	1 package/Rx
• fluocinonide 0.1% cream	1 package/Rx
• halobetasol propionate 0.05% cream, foam, ointment	1 package/Rx

- LEXETTE 100 g/Rx
- TOVET 1 package/Rx
- ULTRAVATE 0.05% lotion 1 package/Rx

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- Betamethasone dipropionate gel [prescribing information]. Madisonville, LA: Solubiomix LLC; September 2017.
- Betamethasone dipropionate ointment [prescribing information]. Allegan, MI: Padagis; August 2021.
- Bryhali (halobetasol) lotion [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; June 2020.
- Clobetasol propionate emollient cream [prescribing information]. Melville, NY: Fougera Pharmaceuticals Inc; September 2018.
- Clobetasol propionate gel [prescribing information]. Buena, NJ: Teligent Pharma Inc; February 2017.
- Clobetasol Propionate Topical Solution, USP (0.05%) [prescribing information]. Morton Grove, IL: Morton Grove Pharmaceuticals Inc; May 2018.
- Clobex lotion (clobetasol) [prescribing information]. Fort Worth, TX: Galderma Laboratories; July 2014.
- Clobex shampoo (clobetasol) [prescribing information]. Dallas, TX: Galderma Laboratories LP; January 2023.
- Clobex spray (clobetasol) [prescribing information]. Dallas, TX: Galderma Laboratories LP; February 2023.
- Clodan Kit (clobetasol) [prescribing information]. Fairfield, NJ: Medimetriks Pharmaceuticals; February 2016.
- Clodan shampoo (clobetasol) [prescribing information]. Fairfield, NJ: Medimetriks Pharmaceuticals; February 2017.
- Diprolene (betamethasone dipropionate ointment) [prescribing information]. Jersey City, NJ: Organon LLC; February 2022.
- Fluocinonide cream[prescribing information]. Hawthorne, NY: Taro Pharmaceuticals USA Inc; November 2017.
- Halobetasol propionate cream 0.05% [prescribing information]. Melville, NY: E. Fougera & Co; January 2020.
- Halobetasol propionate foam [prescribing information]. Greenville, NC: Mayne Pharma; May 2021.
- Halobetasol propionate ointment [prescribing information]. Buena, NJ: Teligent Pharma Inc; February 2020.
- Lexette (halobetasol) [prescribing information]. Greenville, NC: Mayne Pharma; May 2021.
- Tovet (clobetasol) [prescribing information]. Fairfield, NJ: Medimetriks Pharmaceuticals Inc; April 2022.
- Ultravate (halobetasol propionate) lotion [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries Inc; September 2020.
- Vanos (fluocinonide) cream [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; May 2017.

AGENTS FOR NEUROPATHIC PAIN AND FIBROMYALGIA

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred	
Agents for Neuropathic Pain & Fibromyalgia	duloxetine 20, 30, & 60 mg QL gabapentin caps QL gabapentin soln PA HORIZANT PA, QL (gabapentin enacarbil) lidocaine patch 5% PA, QL pregabalin caps and soln PA	CYMBALTA QL (duloxetine) DRIZALMA SPRINKLE QL (duloxetine, DR) duloxetine 40 mg PA, QL gabapentin tabs PA, QL GRALISE PA, QL (gabapentin) LYRICA caps and soln (pregabalin)	LYRICA CR PA, QL (pregabalin) NEURONTIN caps and tabs QL (gabapentin) NEURONTIN soln PA (gabapentin) pregabalin ER PA, QL SAVELLA PA, QL (milnacipran)

Last Review Date: November 2022

Recommendation

It is recommended that at least two agents be available for the treatment of neuropathic pain.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for gabapentin solution

Current Criteria:

- One of the following:
  - Patient is less than 12 years of age; **OR**
  - Inability to swallow solid oral dosage forms; **AND**
    - Inability to open capsule and empty contents in food and drink

Proposed Criteria:

- One of the following:
  - Patient is less than 12 years of age; **OR**
  - Inability to swallow solid oral dosage forms; ~~**AND**~~
    - ~~Inability to open capsule and empty contents in food and drink~~

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for HORIZANT

Current Criteria:

- Diagnosis of post-herpetic neuralgia; **OR**
- Diagnosis of Restless Leg Syndrome

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for lidocaine patch 5%

Current Criteria:

- Diagnosis of post-herpetic neuralgia

Proposed Criteria:
Same as current

COMMITTEE VOTE
APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for pregabalin capsules

Current Criteria:
- Diagnosis of neuropathic pain; **OR**
- Diagnosis of post-herpetic neuralgia; **OR**
- Diagnosis of fibromyalgia; **OR**
- Diagnosis of seizure disorder

Proposed Criteria:
Same as current

COMMITTEE VOTE
APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for pregabalin solution

Current Criteria:
- Patient is less than 12 years of age; **OR**
- Inability to swallow solid oral dosage forms

Proposed Criteria:
Same as current

COMMITTEE VOTE
APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for duloxetine 40 mg

Current Criteria:
- Clinically valid reason why the preferred duloxetine strengths (20 mg, 30 mg, 60 mg) cannot be used

Proposed Criteria:
Same as current

COMMITTEE VOTE
APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for NEURONTIN SOLUTION

Current Criteria:
- One of the following:
  - Patient is less than 12 years of age; **OR**
  - Inability to swallow solid oral dosage forms; **AND**
    - Inability to open capsule and empty contents in food and drink

Proposed Criteria:
Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for gabapentin tablets

Current Criteria:

- Documented allergy or contraindication to an inactive ingredient in the capsule that is NOT present in the tablets

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for GRALISE

Current Criteria:

- Clinically valid reason why the preferred gabapentin agents cannot be used

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for LYRICA CR, pregabalin CR

Current Criteria:

- Diagnosis of postherpetic neuralgia OR neuropathic pain associated with-diabetic peripheral neuropathy; **AND**
- Trial and failure, contraindication, or intolerance to a tricyclic antidepressant OR gabapentin; **AND**
- Clinically valid reason why immediate-release pregabalin cannot be used

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for SAVELLA

Current Criteria:

- Patient has a diagnosis of fibromyalgia accompanied by fatigue; **AND**
- Patient is 18 years of age or older; **AND**
- Patient MUST have tried and failed, or have contraindication, or intolerance to duloxetine

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• DRIZALMA SPRINKLE	2/day
• gabapentin 100 mg capsules	6/day
• gabapentin 300 mg capsules	12/day
• gabapentin 400 mg capsules	9/day
• HORIZANT	1/day
• lidocaine 5% patch	2/day
• CYMBALTA	2/day
• duloxetine 40 mg	2/day
• gabapentin solution	72 mL/day
• gabapentin 600 mg tablets	6/day
• GRALISE	3/day
• LYRICA CR 330 mg	2/day
• NEURONTIN 100 mg capsules	6/day
• NEURONTIN 300 mg capsules	12/day
• NEURONTIN 400 mg capsules	9/day
• NEURONTIN solution	72 mL/day
• NEURONTIN 600 mg tablets	6/day
• pregabalin CR 330 mg	2/day
• SAVELLA	2/day
• LYRICA CR 82.5 mg, 165 mg	1/day
• pregabalin CR 82.5 mg, 165 mg	1/day
• gabapentin 800 mg tablets	4.5/day
• NEURONTIN 800 mg tablets	4.5/day
• duloxetine 20, 30, 60 mg	2/day

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- Gabapentin. *Lexi-Interact*. UpToDate Lexidrug. Waltham, MA: UpToDate Inc. http://online.lexi.com. Accessed December 19, 2014.
- Gralise (gabapentin) [prescribing information]. Newark, CA: Depomed, Inc; April 2023.
- Horizant (gabapentin enacarbil) [prescribing information]. Woburn, MA: Azurity Pharmaceuticals Inc; August 2022.
- Lyrica (pregabalin) [prescribing information]. New York, NY: Parke-Davis; December 2023.
- Neurontin (gabapentin) [prescribing information]. New York, NY: Parke-Davis; July 2022.
- Savella (milnacipran) [prescribing information]. Madison, NJ: Allergan USA Inc; December 2023.

AGENTS FOR RESTLESS LEG SYNDROME (RLS)

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred
Agents for RLS	HORIZANT [PA, QL] (gabapentin) pramipexole [QL] ropinirole	NEUPRO [PA] (rotigotine, transdermal) REQUIP (ropinirole)

Last Review Date: November 2022

Recent Significant Changes

- No significant changes since last review

Recommendation

It is recommended to include at least one alpha2-delta calcium channel ligands (e.g., gabapentin, gabapentin enacarbil) and at least one dopamine agonist.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for HORIZANT

Current Criteria:

- Diagnosis of Restless Leg Syndrome; **OR**
- Diagnosis of post-herpetic neuralgia

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for NEUPRO

Current Criteria:

- Diagnosis of Parkinson's Disease or Restless Leg Syndrome; **AND**
- Trial and failure, contraindication, or intolerance to pramipexole and ropinirole; **OR**
- Inability to swallow

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

- pramipexole 3/day
- HORIZANT 1/day (max daily gabapentin dose: 3600 mg)

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- Horizant (gabapentin enacarbil) [prescribing information]. Woburn, MA: Azurity Pharmaceuticals Inc; August 2022.
- Neupro (rotigotine) [prescribing information]. Smyrna, GA: UCB Inc; July 2021.
- Pramipexole [package insert], Bridgewater, NJ: Alembic Pharmaceuticals; January 2021.
- Requip (ropinirole) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; July 2021.

ALZHEIMER'S: NMDA ANTAGONISTS

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred	
NMDA Antagonists	memantine tabs [QL]	memantine ER [PA, QL] memantine soln [PA, QL] NAMENDA TITRATION PAK [PA, QL] (memantine)	NAMENDA XR [PA, QL] (memantine) NAMZARIC [PA, QL] (memantine/donepezil)

Last Review Date: November 2022

Recent Significant Changes

- Discontinued Drugs:
  - NAMENDA IR, 2023

Recommendation

It is recommended memantine be available for use.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for memantine ER, memantine solution, NAMENDA XR and titration pack

Current Criteria:

- Diagnosis of moderate to severe Alzheimer's disease

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for NAMZARIC

Current Criteria:

- Diagnosis of moderate to severe dementia associated with Alzheimer's disease; **AND**
- Concomitantly taking donepezil and memantine (immediate release or extended release) (≥10 mg/day on both agents); **AND**
- Clinical reason why recipient is unable to take the components individually

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• memantine tablets 5 mg, 10 mg	2/day
• NAMENDA (memantine) titration pack	1 titration pack/month
• NAMENDA XR (memantine ER)	1/day
• memantine solution	10 mL/day
• NAMZARIC	1/day

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- Namenda (memantine) [prescribing information]. Madison, NJ: Allergan USA Inc; November 2018.
- Namenda XR (memantine) [prescribing information]. Madison, NJ: Allergan USA Inc; November 2019.
- Memantine. Lexi-Drugs. UpToDate Lexidrug. Waltham, MA: UpToDate Inc. http://online.lexi.com. Accessed August 28, 2014.
- Namzaric (memantine hydrochloride and donepezil hydrochloride) [prescribing information]. Madison, NJ: Allergan USA, Inc; January 2019.

CHOLINERGIC MUSCLE STIMULANTS

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred
Cholinergic Muscle Stimulants	MESTINON solution (pyridostigmine) MESTINON 180 MG ER TABS (pyridostigmine ER) pyridostigmine 60 mg tabs pyridostigmine 180 mg ER tabs	MESTINON 60 mg tabs (pyridostigmine) pyridostigmine solution

Last Review Date: November 2022

Recent Significant Changes

- No significant updates since last review

Recommendation

It is recommended that at least pyridostigmine be available for use in patients with myasthenia gravis.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- Mestinon (pyridostigmine) [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; December 2020.

MOVEMENT DISORDERS

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred		Non-Preferred
Movement Disorders	AUSTEDO [PA, QL] (deutetrabenazine) AUSTEDO XR [PA, QL] (deutetrabenazine)	INGREZZA [PA, QL] (valbenazine) tetrabenazine [PA]	Xenazine [PA] (tetrabenazine)

Last Review Date: August 2023

Recent Significant Changes

- No significant changes since last review

Recommendation

It is recommended to include deutetrabenazine or valbenazine as alternative options on the PDL subject to prior authorization criteria.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for XENAZINE

Current Criteria:

- Diagnosis of chorea associated with Huntington's disease

Proposed Criteria:

- Diagnosis of chorea associated with Huntington's disease; **AND**
- *Clinically valid reason why preferred generic tetrabenazine cannot be used*

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for AUSTEDO, AUSTEDO XR

Current Criteria:

Diagnosis of tardive dyskinesia:

- Patient age ≥ 18 years; **AND**
- Documentation that AIMS test has been completed (e.g., score or copy of AIMS assessment); **AND**
- Prescribed by, or in consultation with, a neurologist or psychiatrist (or other mental health provider), provided patient has reasonable access; **AND**
- Documentation or claims history of current or former chronic patient use of a dopamine antagonist (e.g., antipsychotic, metoclopramide, prochlorperazine, droperidol, promethazine)

Diagnosis of chorea related to Huntington's Disease:

- Physician is experienced in the treatment of Huntington's Disease or is in a Center of Excellence for Huntington's Disease; **AND**
- Patient does not have a history of untreated or inadequately treated depression or suicidal ideation due to a boxed warning that it increases the risk of depression and suicidal thoughts and behavior

Patients meeting any of the following criteria will NOT be approved:

- Concurrent therapy with tetrabenazine, reserpine, or MAOIs
- Hepatic impairment
- Hypersensitivity to the active ingredient
- Pregnancy

Proposed Criteria:
Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for INGREZZA

Current Criteria:
Diagnosis of tardive dyskinesia:
- Patient age ≥ 18 years; **AND**
- Documentation that AIMS test has been completed (e.g., score or copy of AIMS assessment); **AND**
- Prescribed by, or in consultation with, a neurologist or psychiatrist (or other mental health provider), provided patient has reasonable access; **AND**
- Documentation or claims history of current or former chronic patient use of a dopamine antagonist (e.g., antipsychotic, metoclopramide, prochlorperazine, droperidol, promethazine)

Diagnosis of chorea related to Huntington's Disease:
- Physician is experienced in the treatment of Huntington's Disease or is in a Center of Excellence for Huntington's Disease; **AND**
- Patient does not have a history of untreated or inadequately treated depression or suicidal ideation due to a boxed warning that it increases the risk of depression and suicidal thoughts and behavior

Patients meeting any of the following criteria will NOT be approved:
- Concurrent use of MAOIs or strong CYP3A4 inducers s
- Hypersensitivity to the active ingredient
- Pregnancy

Proposed Criteria:
Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for tetrabenazine

Current Criteria:
- Diagnosis of chorea associated with Huntington's disease

Proposed Criteria:
Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• AUSTEDO	4/day	• INGREZZA 40 mg	2/day
• AUSTEDO XR	1/day	• INGREZZA 60 mg, 80 mg	1/day

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- Austedo and Austedo XR (deutetrabenazine) [prescribing information]. Parsippany, NJ: Teva Neuroscience Inc; May 2024.
- Ingrezza (valbenazine) [prescribing information]. San Diego, CA: Neurocrine Biosciences Inc; April 2024.
- Xenazine (tetrabenazine) tablets [prescribing information]. Deerfield, IL: Lundbeck; June 2022.

SKELETAL MUSCLE RELAXANTS

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred	
Skeletal Muscle Relaxants	baclofen tabs cyclobenzaprine methocarbamol tizanidine tabs	AMRIX [PA, QL] (cyclobenzaprine ER) baclofen soln [PA, QL] baclofen susp [PA, QL] carisoprodol [PA, QL] chlorzoxazone cyclobenzaprine 7.5mg cyclobenzaprine ER [PA, QL] Dantrium dantrolene	FLEQSUVY [PA, QL] (baclofen susp) LORZONE (chlorzoxazone) LYVISPAH [PA, QL] (baclofen granules packet) metaxalone NORGESIC FORTE [PA] (orphenadrine/ASA/caffeine) orphenadrine SOMA [PA, QL] (carisoprodol) tizanidine caps ZANAFLEX (tizanidine)

Last Review Date: November 2022

Recent Significant Changes

- Drug Discontinuations
  - carisoprodol/ASA/codeine, 2024
  - SKELAXIN, 2024

Recommendation

It is recommended that one spasticity agent and three spasmodic agents be available.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for AMRIX, cyclobenzaprine ER

Current Criteria:

- Diagnosis of an FDA-approved indication; **AND**
- Provider must provide peer-reviewed medical literature documenting why the requested drug for the requested indication is the only appropriate choice versus the preferred cyclobenzaprine

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for baclofen solution

Current Criteria:

- Diagnosis of spasticity with flexor spasms and concomitant pain, clonus, and/or muscular rigidity (e.g., multiple sclerosis, spinal cord injury, other spinal cord disease); **AND**
- Documented inability to swallow baclofen tablets

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for baclofen suspension, FLEQSUVY, LYVISPAH

Current Criteria:

- Diagnosis of spasticity with flexor spasms and concomitant pain, clonus, and/or muscular rigidity (e.g., multiple sclerosis, spinal cord injury, other spinal cord disease); **AND**
- Documented inability to swallow baclofen tablets; **AND**
- Trial and failure of baclofen solution

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for carisoprodol, SOMA

Current Criteria:

- Patient is 16 years of age or older; **AND**
- Contraindication, drug to drug interaction, or history of toxic side effects that will cause immediate or long-term damage with ALL preferred skeletal muscle relaxants; **AND**
- Patient does not have a history of, or received treatment for, drug dependency or drug abuse; **AND**
- Prescriber must have checked the Tennessee Controlled Substance Database for this patient within the last 30 days; **AND**
- Patient is not concurrently utilizing any other opioid therapy

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for NORGESIC FORTE

Current Criteria:

- Diagnosis of an FDA-approved indication; **AND**
- Provider must provide peer-reviewed medical literature documenting why the requested drug for the requested indication is the only appropriate choice versus the preferred agents

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• AMRIX	1/day
• baclofen solution	16 mL/day
• baclofen suspension	16 mL/day
• carisoprodol	4/day
• cyclobenzaprine ER	1/day
• FLEQSUVY	16 mL/day
• LYVISPAH	4 packets/day
• SOMA	4/day

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

References

- Amrix (cyclobenzaprine) [prescribing information]. Vandalia, OH: Adare Pharmaceuticals Inc; August 2021.
- Baclofen [prescribing information]. Minneapolis, MN: Upsher-Smith Laboratories Inc. September 2009.
- Carisoprodol/aspirin/codeine phosphate [prescribing information]. Orlando, FL: Ingenus Pharmaceuticals; September 2019.
- Chlorzoxazone [prescribing information]. East Brunswick, NJ: Rising Pharmaceuticals Inc; February 2023.
- Cyclobenzaprine [prescribing information]. East Windsor, NJ: Aurobindo Pharma USA Inc; July 2021.
- Dantrium (dantrolene sodium) capsules [prescribing information]. Chestnut Ridge, NY: Par Pharmaceutical; May 2017.
- Dantrolene sodium capsules [prescribing information]. Indianapolis, IN: Major Pharmaceuticals; October 2020.
- Fleqsuvy (baclofen) [prescribing information]. Woburn, MA: Azurity Pharmaceuticals Inc; February 2023.
- Lorzone (chlorzoxazone) [prescribing information]. Alpharetta, GA: Vertical Pharmaceuticals LLC; November 2021.
- Lyvispah (baclofen) [prescribing information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; April 2023.
- Metaxalone 400 mg tablet [prescribing information]. Hauppauge, NY: ScieGen Pharmaceuticals Inc; September 2021.
- Methocarbamol tablet, USP [package insert]. Edison, NJ: AustarPharma LLC; March 2022.
- Norgesic and Norgesic Forte tablets (orphenadrine citrate, aspirin and caffeine) [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; April 2021.
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DISEASE MODIFYING ANTI-RHEUMATIC DRUGS (DMARDS)

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred		Non-Preferred	
DMARDs	hydroxychloroquine leflunomide methotrexate tabs/inj RIDAURA (auranofin)	sulfasalazine QL sulfasalazine EC QL	ARAVA (leflunomide) AZULFIDINE QL (sulfasalazine) AZULFIDINE EN QL (sulfasalazine) JYLAMVO PA (methotrexate, soln) OTREXUP PA, QL (methotrexate, inj)	PLAQUENIL (hydroxychloroquine) RASUVO PA, QL (methotrexate, inj) SOVUNA (hydroxychloroquine) TREXALL (methotrexate) XATMEP PA (methotrexate, soln)

Note: Injectable agents for the treatment of RA are located under Immunomodulators.

Last Review Date: August 2023

Recent Significant Changes

- Discontinued Drug: REDITREX, 2023

Recommendation

It is recommended that at least methotrexate, leflunomide, sulfasalazine and hydroxychloroquine be available for use.

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for JYLAMVO

Current Criteria:

- Dosing that will not allow the use of preferred methotrexate tablets; **OR**
- Patient is unable to swallow methotrexate tablets

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for OTREXUP, RASUVO

Current Criteria:

- One of the following:
  - Diagnosis of Rheumatoid Arthritis (RA) or polyarticular Juvenile Idiopathic Arthritis (pJIA); **AND**
    - Trial and failure of TWO preferred DMARD agents
  - Diagnosis of psoriasis; **AND**
    - Trial and failure of TWO topical antipsoriatic agents; **AND**
    - Clinically valid reason why oral methotrexate cannot be used; **AND**
- One of the following:
  - Patient has an allergy or contraindication to benzoyl alcohol or preservative in injectable methotrexate that is not in requested agent
  - Patient has dexterity issues and is without assistance to a caregiver who can administer the requested agent

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for XATMEP

Current Criteria:

- Age ≤12 years; **AND**
- One of the following:
  - Dosing that will not allow the use of preferred methotrexate tablets
  - Patient is unable to swallow methotrexate tablets

Proposed Criteria:

Same as current

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Quantity Limits

• sulfasalazine	8/day
• sulfasalazine EC	8/day
• AZULFIDINE	8/day
• AZULFIDINE EN	8/day
• OTREXUP	4 syringes/28 days
• RASUVO	4 injections/28 days

COMMITTEE VOTE

APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

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Low Utilization and/or Low-Cost Drug Classes

Identified drug classes have been reviewed but will not be included in the drug class reviews based on low utilization and/ or low-cost of the drug class. These classes have no professional guideline updates and do not have prior authorization criteria changes.

- **Dermatologics**
  - Antipsoriatics, Oral
  - Anti-seborrheic Agents
  - Emollients
  - Genital Warts
  - Keratolytic Agents
  - Antivirals, Topical
- **Central Nervous System**
  - Alzheimer's: Cholinesterase Inhibitors
  - Analeptics
  - Miscellaneous CNS Agents