TennCare Pharmacy Advisory Committee (PAC) Meeting Minutes

November 9, 2023

Members in attendance: Chair Edward Capparelli, MD, Vice-Chair Joel Phares, MD, James Johns, MD, Karen Rhea, MD, Elizabeth Close, MD, Danielle Sims (Patient Health Advocate), Eleanor Twigg, PharmD, Toie Alston, PharmD, Renee Williams-Clark, PharmD (TennCare Chief Pharmacy Officer, Ex Officio Member)

Non-members present from TennCare: Cooper Lloyd, MD (Associate Medical Director), Lorraine Buerhaus, DPh (Director of CoverRx and CoverKids), Tracey Lovett, PharmD (Director of Clinical Pharmacy), Lora Underwood, PharmD (Director of Pharmacy Operations) Joshua Lager, PharmD

Non-members present from OptumRx: Chrysa Bright, PharmD (Account Director), Jill LeCheminant, PharmD (PDL Pharmacist), Samantha Watlington, PharmD (PDL Pharmacist), Amanda Kiriakopoulos, PharmD (FFS Medicaid Associate Director), Chelsea Faw, PharmD (TennCare Associate Director), Kimberly Barnes, PharmD (DUR Pharmacist), Tasha Bedwell, PharmD (Provider Liaison), Samantha Boldin, PharmD (Provider Liaison)

WELCOME AND INTRODUCTIONS

The meeting was called to order by Dr. Capparelli. Dr. Capparelli stated that Committee members are volunteers, have been appointed according to Public Act (TCA 71-5-2401) which established the PAC, and have signed conflict of interest statements. Dr. Capparelli confirmed that a quorum had been established. Members of the Committee, TennCare Team, and OptumRx Account Team were introduced.

Dr. Close joined the meeting before the TennCare pharmacy update and introduced herself to the committee. Dr. Close is a family medicine doctor located in Chattanooga, TN.

APPROVAL OF MINUTES FROM PREVIOUS MEETING

Meeting minutes from the previous PAC meeting held August 10, 2023, were reviewed by the Committee. A motion to approve the minutes was made by Dr. Phares, seconded by Dr. Rhea, and was unanimously carried.

AUTO-EXEMPT SUBCOMITTEE UPDATE

The auto-exempt list identifies drugs and supplies that do not count toward an enrollee's monthly drug limit. Dr. Watlington reported that Abilify Asimtufii, Perseris, Uzedy, Amjevita, Arcalyst, Atorvaliq, Opvee, Tafinlar tablet for oral suspension, Mekinist oral solution, and Liqrev were added to the auto exempt list during the third quarter of 2023.

FOLLOW-UP ITEMS FROM PREVIOUS MEETING

Dr. Watlington reviewed all follow up items from the previous meeting. A note was added to Cablivi criteria to approve the medication if started as an inpatient hospital regimen to prevent disruption in therapy as patient transition to a home/outpatient setting. Dr. Watlington reviewed Sunlenca's PA criteria for all three MCOs. The PA criteria for Sunlenca was similar between the MCOs and TennCare; therefore, no coordination issues found for patients using the pharmacy and medical benefit to obtain this medication. Dr. Watlington reported that brand Symbicort will be available for the next three years per the manufacturer. Dr. Watlington stated that Daliresp and the generic are dispensed in a bottle of 28 tablets that is not split or broken at the pharmacy. Dr. Watlington also reported Daybue has not being studied in patients less than 2 years of age.

Dr. Capparelli inquired about the formulary status of brand Symbicort and the generic. Dr. Watlington answered brand Symbicort is preferred, and the generic is nonpreferred.

TENNCARE PHARMACY UPDATE

Dr. Renee Williams-Clark provided an update on the cost of dispensing survey results. TennCare reimburses pharmacies based on both the ingredient cost of the drug and a professional dispensing fee. TennCare partners with Mercer to conduct surveys of pharmacies in the network to determine the cost to dispense a single

prescription. Mercer surveyed 1,800 pharmacies and received about 60% complete response rate from those pharmacies. Dr. Renee Williams-Clark stated TennCare is confident the results reflect the cost of dispensing prescriptions in the state of Tennessee. Low volume pharmacies, which dispense on average less than 65,000 prescriptions annually, dispensing fee will increase from $11.98 to $13.16. High volume pharmacies, which dispense more than 65,000 prescriptions annually, dispensing fee will increase from $8.37 to $9.02. Long term care and 340B pharmacies dispensing fee will increase from $13.16 to $16.92. Specialty pharmacy's new dispensing fee will increase from $45.94 to $52.46 for non-blood factor prescriptions. Dr. Williams-Clark stated TennCare will submit survey updates to CMS who will review and approve within 90 days. The dispensing fee changes were effective 11/1/23.

Dr. Capparelli inquired what happens if CMS does not approve the dispensing fee recommendations. Dr. Williams-Clark stated TennCare would have to default back to previous rate or CMS may ask TennCare to conduct another survey. Dr. Williams-Clark noted CMS has approved TennCare dispensing fee recommendations the last three times.

TENNCARE UPDATE

Dr. Lloyd provided updates regarding renewal of eligibility, the adult dental benefit, and lactation benefit. She noted that during the public health emergency the membership grew by 25% to about 1.8 million Tennesseans. Renewals were restarted in April 2023 and will take 1 year to complete. Dr. Lloyd noted 868,000 members have gone through the renewal process to date. 183,000 members (38%) were auto renewed by pulling data from other resources. 31% of members were ineligible for renewal. 24% of members were terminated due to not responding to the renewal package, which is better than the national average. Dr. Lloyd stated 37% who did not respond have gained health insurance through a third party. She also noted there is a 90-day reconsideration period. Dr. Lloyd stated that on January 1 of this year TennCare extended dental care to all adult members, and 650,000 members are eligible for dental care. The dental benefit manager is DentaQuest. Members are eligible for regular exams, X-rays, cleanings, fillings, crowns, dentures, extractions, root canals, and more. Dr. Lloyd shared a member's story of the positive impact of the dental benefit. Dr. Lloyd stated on June 1 of this year, TennCare is now offering lactation services. Members can receive lactation services during pregnancy and through the extended postpartum period. The lactation services can be delivered in one-on-one settings, small groups, or telehealth. There is no limit in the number of visits the member can participate in.

Dr. Capparelli inquired about the subgroup of women that have recently delivered with a substance use problem. He noted that pregnancy coverage was extended to one year after delivering. He expressed that addiction is a chronic disease that is not always solved in 12 months or less. Dr. Lloyd agreed this is an important subgroup of women and some women will have TennCare coverage after 12 months depending on income levels.

PUBLIC TESTIMONY

Public testimony speakers were allowed a maximum of five minutes to address the Committee.

The following individuals provided public testimony:

- Shawn Hayes provided public testimony regarding Joenja on behalf of Pharming.
- Frances Davis provided public testimony regarding Veozah on behalf of Astellas Pharmaceuticals.
- Chad Sanders provided public testimony regarding Bylvay on behalf of Ipsen Biopharmaceutical.
- Lauren Devine provided public testimony regarding Tyvaso DPI on behalf of United Therapeutics.
- Kyle Swift rescinded his public testimony regarding Eliquis on behalf of Pfizer.

DRUG UTILIZATION REVIEW (DUR) INITIATIVE

Dr. Watlington provided an overview of the DUR initiative GLP-1 agonist utilization in non-diabetic member. Dr. Watlington stated the diabetic GLP-1 (e.g., Ozempic, Victoza, Trulicity) are first line treatments for Type 2 Diabetes patients and do not have compendia support or indication for obesity. Most non-diabetic members are

utilizing GLP-1 agonist for weight loss, which is a non-covered benefit for adults under TennCare. Dr. Watlington stated a review of class data showed 2,000 members are utilizing GLP-1 without a diagnosis of Type 2 Diabetes and without claims for any antidiabetic medications. Dr. Watlington stated the goal was to edit the PA criteria for GLP-1 agonists to decrease inappropriate utilization by requiring prescribers to submit ICD-10 codes, requirement of lab documentation to confirm diagnosis, and additional of renewal criteria.

Dr. Rhea asked if weight gain from psychotherapeutic medications can be considered for the prior authorization criteria. Dr. Underwood stated weight loss is not a covered benefit for adults under TennCare.

Dr. Close asked how increased risk or high risk for ASCVD will be evaluated by the PA team. Dr. Watlington responded that since the renewal criteria requires submission of medical records, a clinical pharmacist will review every PA for GLP-1 agonists. Dr. Close also stated the GLP-1 agonists have several drug shortages and asked if more GLP-1s can be moved to preferred status. Dr. Lovett responded that the new agents are non-preferred due to cost, and most are currently on backorder as well. Dr. Williams-Clark also stated due to waiver for Medicare and Medicaid it excludes drugs used for treatment of weight loss or anorexia and several other excluded products.

A motion to approve the prior authorization criteria was made by Dr. Johns, seconded by Dr. Phares, and unanimously carried.

ARCALYST

New: New Drug Review

PDL Placement:

	Preferred	Non-Preferred	
Immunomodulators	ENBREL PA, QL (etanercept)	ACTEMRA PA, QL (tocilizumab)	SILIQ PA, QL (brodalumab)
	HUMIRA PA, QL (adalimumab)	ACTIMMUNE (interferon gamma-1b)	SIMPONI PA, QL (golimumab)
	KINERET PA, QL (anakinra)	ARCALYST PA, QL (rilonacept)	SKYRIZI PA, QL (risankizumab)
	OTEZLA PA, QL (apremilast)	BENLYSTA PA, QL (adalimumab)	SOTYKTU PA, QL (deucravacitinib)
	ORENCIA PA, QL (abatacept)	CIMZIA PA, QL (belimumab)	STELARA PA, QL (syringes only)
	OTEZLA PA, QL (apremilast)	COSENTYX PA, QL (secukinumab)	(ustekinumab)
	TALTZ PA, QL (ixekizumab)	ENSPRYNG PA, QL (satralizumab)	TAVNEOS PA, QL (avacopan)
		KEVZARA PA, QL (sarilumab)	TREMFYA PA, QL (guselkumab)

Prior Authorization criteria for ARCALYST

Interim 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 meets all of the following:
  - 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**

Quantity Limits

- ARCALYST 8 vials per month

COMMITTEE VOTE

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

Discussion and Approval:

A motion to approve the prior authorization criteria and quantity limits was made by Dr. Johns, seconded by Dr. Rhea, and unanimously carried.

CAFFEINE CITRATE ORAL SOLUTION

New: New Formulation Review

PDL Placement:

	Preferred	Non-Preferred
Analeptics	N/A	caffeine citrate oral solution [PA]

Prior Authorization Criteria for caffeine citrate oral solution

Interim Criteria: (2-month duration)

- Diagnosis of apnea in premature infants (between 28 and <33 weeks gestational age); **AND**
- Infant does not have renal impairment, hepatic impairment, or cardiovascular disease; **AND**
- Prescriber must attest that they are aware of the risks of fatal necrotizing enterocolitis in premature infants; **AND**
- Prescribed by, or in consultation with, a board-certified neonatologist

Proposed Criteria: (2-month duration)

- Diagnosis of apnea in premature infants (born between 28 and <33 weeks gestational age); **AND**
- *Patient is continuing therapy from an inpatient hospital stay (to facilitate transition to outpatient for completion of therapy);* **AND**
- Infant does not have renal impairment, hepatic impairment, or cardiovascular disease; **AND**
- Prescriber must attest that they are aware of the risks of fatal necrotizing enterocolitis in premature infants *and will monitor patient to avoid serious toxicity*; **AND**
- Prescribed by, or in consultation with, a board-certified neonatologist

COMMITTEE VOTE:

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

Discussion and Approval:

A motion to approve the prior authorization criteria with modifications made by Dr. Johns, seconded by Dr. Close, and unanimously carried.

Dr. Capparelli asked why the PA duration was for only 2 months. Dr. Watlington stated the average duration of therapy is 60 days. Patients should not be using more than 2 months after discharge. Dr. Johns suggested updating criteria point 4 to state “will monitor patient for efficacy and to avoid serious toxicity” to highlight the main concern is efficacy of this medication for apnea.

FILSPARI

New: New Drug Review

PDL Placement:

	Preferred	Non-Preferred	
IgA Nephropathy (IgAN)	N/A	FILSPARI (sparsentan) PA, QL	Tarpeyo (budesonide DR cap) PA, QL

Prior Authorization criteria for FILSPARI

Interim Criteria:

Initial Criteria: (6-month duration)

- Patient has diagnosis of biopsy proven Primary IgA nephropathy; **AND**
- Patient is at risk of rapid disease progression (e.g., urine protein-to-creatine ratio (UPCR) ≥ 1.5 g/g); **AND**
- Filspari will be used to reduce proteinuria; **AND**
- Patient has tried and failed max tolerated doses of a preferred angiotensin II receptor blocker or ACE inhibitor minimum duration of 90 days; **AND**
- Prescriber and patient have met the requirements of Filspari REMS Program

Renewal Criteria:

- Patient continues to meet initial criteria; **AND**
- Patient has positive clinical response to Filspari therapy (e.g., reduction of proteinuria from baseline, decreased UPCR)

Proposed Criteria:

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

- Patient has diagnosis of biopsy proven Primary IgA nephropathy; **AND**
- Patient is at risk of rapid disease progression (e.g., urine protein-to-creatine ratio (UPCR) ≥ 1.5 g/g *or proteinuria >0.75 to 1 g/day despite ≥ 90 days of optimized supportive care*); **AND**
- Filspari will be used to reduce proteinuria; **AND**
- Patient has tried and failed max tolerated doses of a preferred angiotensin II receptor blocker or ACE inhibitor minimum duration of 90 days; **OR**
  - *Patient is currently experiencing rapid disease progression; **AND***
- *Use of renin-angiotensin-aldosterone system (RAAS) inhibitors (e.g., ACE inhibitors, ARBs), endothelin receptor antagonists (e.g., Letairis, Opsumit, Tracleer), and aliskiren will be discontinued prior to initiating treatment; **AND***
- Prescriber and patient have met the requirements of Filspari REMS Program

Renewal Criteria:

- ~~Patient continues to meet initial criteria; **AND**~~
- Patient has positive clinical response to Filspari therapy (e.g., reduction of proteinuria from baseline, decreased UPCR)

COMMITTEE VOTE

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

Quantity Limits

- FILSPARI 1/day

COMMITTEE VOTE

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

Discussion and Approval:

A motion to approve the prior authorization criteria and quantity limits was made by Dr. Phares, seconded by Dr. Alston, and unanimously carried.

JOENJA

New: New Drug Review

PDL Placement:

	Preferred	Non-Preferred
Activated PI3K Delta Syndrome (APDS)	N/A	JOENJA (leniolisib) PA ,QL

Prior Authorization criteria for JOENJA

Interim Criteria:

Initial Criteria (6-month duration)

- Patient is ≥ 12 years of age; **AND**
- Patient weighs at least 45 kg; **AND**
- Diagnosis of activated phosphoinositide 3-kinase delta syndrome (APDS); **AND**
- Diagnosis has been confirmed by the presence of an APDS-associated genetic variant in either PIK3CD or PIK3R1; **AND**
- Documentation of other clinical findings and manifestations consistent with APDS (e.g., recurrent respiratory tract infections and viral infections, lymphadenopathy, hepatosplenomegaly, autoimmune cytopenia); **AND**
- Prescribed by, or in consultation with, hematologist, allergist, or immunologist; **AND**
- For patients with reproductive potential, the prescriber attests to ALL of the following:
  - Patient is not pregnant prior to initiation of therapy
  - Patient has been counseled on potential risk during pregnancy
  - Patient has been advised to use effective contraception during treatment and for 1 week after the last dose

Renewal Criteria

- Disease response to therapy and tolerability compared to baseline (e.g., decreased lymph node size, increased functional B cell counts, decreased infections/hospitalizations, and decreased utilization of immunoglobulin replacement therapy)

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Quantity Limits

- JOENJA 2/day

COMMITTEE VOTE

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

Discussion and Approval:

A motion to approve the prior authorization criteria and quantity limits with modifications made by Dr. Rhea, seconded by Dr. Phares, and unanimously carried.

Dr. Close suggested adding a fourth bullet to the last criteria, stating “Patient has been advised to not breastfeed during treatment and for 1 week after the last dose”. Dr. Rhea also agreed with this addition.

ORSERDU

New: New Drug Review

PDL Placement:

	Preferred		Non-Preferred
Oncology Agents*	Anastrozole [PA]	KISQALI/FEMARA [PA, QL] (letrozole/ribociclib)	ARIMIDEX (anastrozole)
	exemestane	letrozole	FEMARA (letrozole)
	FARESTON (toremifene)	SOLTAMOX (tamoxifen)	ORSERDU (ELACESTRANT) [PA, QL]
	IBRANCE (palbociclib)	tamoxifen	
	KISQALI [PA, QL] (ribociclib)	VERZENIO (abemaciclib)	

* Table does not include all oncology agents. Oncology agents with the same indication as ORSERDU are included.

Prior Authorization criteria for ORSERDU

Interim Criteria:

Initial Criteria: (6-month duration)

- Patient has hormone receptor-positive, HER2-negative advanced breast; **AND**
- Patient has received at least one endocrine based regimen; **AND**
- Patient has ESR1 mutation detected by FDA-approved test; **AND**
- If female, patient is postmenopausal; **AND**
- Orserdu will be used as monotherapy; **AND**
- Prescribed by, or in consultation with, an oncologist; **AND**
- Patient must not be pregnant or breastfeeding; **AND**
- Females of reproductive potential and males undergoing treatment with female partners of reproductive age should be advised to use effective contraception during treatment and for 1 week after the final dose

Renewal Criteria:

- Patient continues to meet initial criteria; **AND**
- Patient has positive disease response defined as disease stabilization or decrease in size of tumor or tumor spread; **AND**
- Patient does not have unacceptable toxicity (e.g., dyslipidemia, musculoskeletal pain)

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Quantity Limits

- ORSERDU 345 mg MDD=1; 86 mg MDD=3

COMMITTEE VOTE

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

Discussion and Approval:

A motion to approve the prior authorization criteria and quantity limits was made by Dr. Rhea, seconded by Dr. Johns, and unanimously carried.

PYRUKYND

New: New Drug Review

PDL Placement:

	Preferred	Non-Preferred
Pyruvate Kinase (PK) Deficiency	N/A	Pyrukynd [PA, QL] (mitapivat)

Prior Authorization criteria for PYRUKYND

Interim Criteria:

Initial Criteria: (6-month duration)

- Patient has diagnosis of hemolytic anemia with pyruvate kinase (PK) deficiency; **AND**
- Patient has at least 2 variant alleles in the PK liver and red blood cell gene of which at least 1 was a missense variant; **AND**
- One of the following:
  - History of 6 transfusions within the past year; **OR**
  - Both of the following:
    - Hemoglobin (Hb) < 10 g/dL;
    - No more than 4 transfusion in a 52-week period and no transfusion in a 3-month period prior to treatment; **AND**
- Prescribed by or in consultation with a hematologist

Renewal Criteria:

- Documentation of positive clinical response to therapy as evidenced by one of the following:
  - Hemoglobin increase ≥ 1.5 g/dL from baseline
  - Reduction in the number of red blood cell units transfused from baseline

Proposed Criteria:

Initial Criteria: (6-month duration)

- Patient has diagnosis of hemolytic anemia with pyruvate kinase (PK) deficiency*;* **AND**
- Patient has at least 2 variant alleles in the PK liver and red blood cell gene of which at least 1 was a missense variant; **AND**
- *Hemoglobin is <10 g/dL;* ***AND***
- One of the following:
  - *Patient has symptomatic anemia*
  - *Patient is transfusion dependent;* ***AND***
  - ~~History of 6 transfusions within the past year;~~ ~~**OR**~~
  - ~~Both of the following:~~
    - ~~Hemoglobin (Hb) < 10 g/dL;~~
    - ~~No more than 4 transfusion in a 52-week period and no transfusion in a 3-month period prior to treatment;~~ ~~**AND**~~
- Prescribed by, or in consultation with, a hematologist

Renewal Criteria:

- Documentation of positive clinical response to therapy as evidenced by one of the following:
  - Hemoglobin increase ≥ 1.5 g/dL from baseline
  - Reduction in the number of red blood cell units transfused from baseline

COMMITTEE VOTE

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

Quantity Limits

- PYRUKYND 2 tablets/day

COMMITTEE VOTE

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

Discussion and Approval:

A motion to approve the prior authorization criteria and quantity limits was made by Dr. Rhea, seconded by Dr. Johns, and unanimously carried.

Dr. Close asked what would be considered as transfusion dependent to meet the PA criteria. Dr. Watlington stated the criteria would only require prescriber attestation that the member is transfusion dependent. Dr. Close agreed prescriber attestation is appropriate.

REZLIDHIA

New: New Drug Review

PDL Placement:

	Preferred	Non-Preferred
Oncology Agents*	N/A	REZLIDHIA [PA,QL] (olutasidenib) TIBSOVO [PA, QL] (ivosidenib)

* Table does not include all oncology agents. Oncology agents with the same indication as REZLIDHIA are included.

Prior Authorization criteria for REZLIDHIA

Interim Criteria:

Initial Criteria: (6-month duration)

- Patient has diagnosis of relapsed or refractory acute myeloid leukemia (AML); **AND**
- Patient has an isocitrate dehydrogenase-1 (IDH1) mutation, as detected by an FDA-approved test

Renewal Criteria:

- Patient continues to meet initial criteria; **AND**
- Patient demonstrates disease stabilization or improvement as evidenced by complete remission, complete remission with partial hematologic recovery, or reduction in red blood cell (RBC) and/or platelet transfusions from baseline; **AND**
- Patient does not have unacceptable toxicity (hepatoxicity, differentiation syndrome)

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Quantity Limits

- REZLIDHIA 60 tablets per 30 days

COMMITTEE VOTE

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

Discussion and Approval:

A motion to approve the prior authorization criteria and quantity limits was made by Dr. Phares, seconded by Dr. Alston, and unanimously carried.

VEOZAH

New: New Drug Review

PDL Placement:

	Preferred	Non-Preferred
Neurokinin 3 (NK3) Antagonists	N/A	VEOZAH PA, QL

Prior Authorization criteria for VEOZAH

Interim Criteria:

- Diagnosis of moderate to severe vasomotor symptoms due to menopause; **AND**
- Trial and failure, contraindication, or intolerance to TWO of the following:
  - Gabapentin
  - Menopausal hormone therapy (e.g., estrogen monotherapy or estrogen + progesterone)
  - Oxybutynin
  - SSRI (e.g., paroxetine, escitalopram, citalopram)
  - SNRI (e.g., venlafaxine and desvenlafaxine)

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Quantity Limits

- VEOZAH 1/day

COMMITTEE VOTE

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

Discussion and Approval:

A motion to approve the prior authorization criteria and quantity limits was made by Dr. Close, seconded by Dr. Phares, and unanimously carried.

VOWST

New: New Drug Review

PDL Placement:

	Preferred	Non-Preferred
Fecal Microbiota	N/A	VOWST [PA, QL] (fecal microbiota spores)

Prior Authorization criteria for VOWST

Interim Criteria:

Criteria: (2-month duration)

- Patient is ≥ 18 years old; **AND**
- Treatment is to prevent the recurrence of *Clostridioides difficile* infection (CDI); **AND**
- Patient has had three or more episodes of CDI within the past year; **AND**
- Submission of medical records (e.g., chart notes, lab test) of a positive *C. difficile* stool test with toxin A/B results within the previous 30 days; **AND**
- Patient has or will complete a full treatment course with ONE of the following antibiotic therapies 2 to 4 days prior to initiating Vowst:
  - Fidaxomicin
  - Vancomycin; **AND**
- Prescriber by or in consultation with an infectious disease specialist or gastroenterologist; **AND**
- The agent will not to be used in combination with other products for prevention of CDI, such as Zinplava or Rebyota

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Quantity Limits

- VOWST 12 capsules/year

COMMITTEE VOTE

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

Discussion and Approval:

A motion to approve the prior authorization criteria and quantity limits was made by Dr. Phares, seconded by Dr. Twigg, and unanimously carried.

STANDARD DRUG CLASS REVIEWS

DIURETICS: POTASSIUM SPARING

Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred	
Diuretics: Potassium Sparing	**amiloride** **spironolactone**	ALDACTONE (spironolactone tab) CAROSPIR PA, QL (spironolactone suspension) DYRENIUM (triamterene) **eplerenone PA**	INSPRA PA (eplerenone) KERENDIA PA, QL (finerenone) **triamterene**

Recommendation

It is recommended that at least 2 agents are available, one of which should be spironolactone.

COMMITTEE VOTE

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

Prior Authorization criteria for CAROSPIR

Current Criteria:

- One of the following:
  - Diagnosis of hypertension
  - Diagnosis of heart failure
  - Diagnosis of edema associated with hepatic cirrhosis; **AND**
- Patient does not have Addison's disease; **AND**
- Serum potassium is < 5.5 mEq/L; **AND**
- Patient cannot be receiving concomitant treatment with eplerenone; **AND**
- Patient is unable to swallow solid dosage forms

Note: PA not required for patients < 6 years of age

Proposed Criteria:

- One of the following:
  - Diagnosis of hypertension
  - Diagnosis of heart failure
  - Diagnosis of edema associated with hepatic cirrhosis; **AND**
- ~~Patient does not have Addison's disease; **AND**~~
- ~~Serum potassium is < 5.5 mEq/L; **AND**~~
- ~~Patient cannot be receiving concomitant treatment with eplerenone; **AND**~~
- Patient is unable to swallow solid dosage forms

Note: PA not required for patients < 6 years of age

COMMITTEE VOTE

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

Prior Authorization criteria for eplerenone, INSPRA

Current Criteria:

- One of the following:
  - Patient has a diagnosis of hypertension, **OR**
  - Patient has a diagnosis of congestive heart failure (post-acute myocardial infarction); **AND**
- Trial and failure, contraindication, or intolerance of spironolactone preferred agents; **AND**
- Serum potassium is < 5.5 mEq/L; **AND**
- Creatine clearance is > 30 ml/min; **AND**
- Patient cannot be receiving concomitant treatment with strong CYP3A4 inhibitors

Proposed Criteria:

- One of the following:
  - Patient has a diagnosis of hypertension; **OR**
  - Patient has a diagnosis of congestive heart failure (post-acute myocardial infarction); **AND**
- Trial and failure, contraindication, or intolerance of spironolactone preferred agents; ~~**AND**~~
- ~~Serum potassium is < 5.5 mEq/L; **AND**~~
- ~~Creatine clearance is > 30 ml/min; **AND**~~
- ~~Patient cannot be receiving concomitant treatment with strong CYP3A4 inhibitors~~

COMMITTEE VOTE

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

Prior Authorization criteria for KERENDIA

Current Criteria:

- Adults 18 years of age or older; **AND**
- Patient has a diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D); **AND**
- Currently taking the maximum tolerated dose of an ACE inhibitor or ARB, unless contraindicated or intolerant; **AND**
- Currently taking an antidiabetic agent (e.g., insulin, metformin, GLP-1 receptor agonist, SGLT2 inhibitor); **AND**
- Patient does not have adrenal insufficiency; **AND**
- eGFR is ≥ 25 mL/min/1.73 m^2; **AND**
- Serum potassium is ≤ 5.5 mEq/L; **AND**
- Patient does not have a diagnosis of chronic heart failure (NYHA class II to IV) with reduced ejection fraction; **AND**
- Patient cannot be receiving concomitant treatment with strong CYP3A4 inhibitors

Proposed Criteria:

- Adults 18 years of age or older; **AND**
- Patient has a diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D); **AND**
- Currently taking the maximum tolerated dose of an ACE inhibitor or ARB, unless contraindicated or intolerant; **AND**
- Currently taking an antidiabetic agent (e.g., insulin, metformin, GLP-1 receptor agonist, SGLT2 inhibitor); ~~**AND**~~
- ~~Patient does not have adrenal insufficiency; **AND**~~
- ~~eGFR is ≥ 25 mL/min/1.73m2); **AND**~~
- ~~Serum potassium is ≤ 5.5 mEq/L; **AND**~~
- ~~Patient does not have a diagnosis of chronic heart failure (NYHA class II to IV) with reduced ejection fraction; **AND**~~
- ~~Patient cannot be receiving concomitant treatment with strong CYP3A4 inhibitors~~

COMMITTEE VOTE

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

Quantity Limits

• CAROSPIR	15 mL/day
• KERENDIA	1/day

COMMITTEE VOTE

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

Discussion and Approval:

A motion to approve all prior authorization criteria and quantity limits with modifications to the class recommendation and eplerenone prior authorization criteria was made by Dr. Johns, seconded by Dr. Phares, and unanimously carried.

Dr. Johns stated eplerenone has less gynecomastia side effect and is only $5 to $10 more than spironolactone. Dr. Johns noted that several compendia can be used to support off label use. There are guidelines and randomized double blind, placebo-controlled studies showing improved function in boys with Duchenne's Muscular Dystrophy treated with eplerenone.

Dr. Johns suggested updating the class recommendation to state "It is recommended that spironolactone and eplerenone be available." Dr. Johns noted both medications have mortality benefits for heart failure patients not just for heart failure patients post-acute MI. Dr. Johns also suggested removing PA criteria from eplerenone because there is no safety, efficacy, or cost reason for PA criteria. Dr. Capparelli asked if the proposed update to the class recommendation would eliminate amiloride being available for use. Dr. Lovett responded that the proposed updated class recommendation would not remove amiloride being available for use.

ANTICOAGULANTS, ORAL

Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred		Non-Preferred
Anticoagulants, Oral	ELIQUIS QL (apixaban) JANTOVEN (warfarin) PRADAXA ~~PA~~, QL (dabigatran)	warfarin XARELTO QL (rivaroxaban)	dabigatran PA, QL SAVAYSA PA, QL (edoxaban) XARELTO suspension PA (rivaroxaban)

Recommendation

It is recommended warfarin *and target specific oral anticoagulants (TSOAC)* should be available for all indications. ~~and all other oral anticoagulants should be subject to prior authorization.~~

COMMITTEE VOTE

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

Prior Authorization criteria for PRADAXA

Current Criteria:

- Diagnosis of non-valvular atrial fibrillation, deep vein thrombosis, OR pulmonary embolism; **AND**
  - Patient does NOT have moderate to severe mitral stenosis, mechanical prosthetic or bioprosthetic heart valve; **OR**
- Diagnosis of thromboprophylaxis following hip replacement surgery (duration of 35 days); **OR**
- Diagnosis of deep vein thrombosis in patients in patients 8 to 18 years of age; **AND**
  - Patient has been treated with a parenteral anticoagulant for at least 5 days; **OR**
  - Pradaxa will be utilized to reduce the risk or recurrence after previous treatment

Proposed Criteria:

Remove PA Criteria

COMMITTEE VOTE

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

Prior Authorization criteria for SAVAYSA

Current Criteria:

- Diagnosis of non-valvular atrial fibrillation; **AND**
  - Documentation that CrCl NOT ≥ 95 mL/min as calculated by Cockcroft-Gault equation; **AND**
  - Contraindication, drug-drug interaction, or adverse reaction to Xarelto and Pradaxa; **OR**
- Diagnosis of deep vein thrombosis or pulmonary embolism; **AND**
  - Patient has received 5-10 days of initial therapy with a parenteral anticoagulant; **AND**
  - Contraindication, drug-drug interaction, or adverse reaction to Xarelto and Pradaxa

Proposed Criteria:

Remove PA Criteria

COMMITTEE VOTE

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

Prior Authorization criteria for dabigatran

Current Criteria:

- Clinically valid reason why the preferred Pradaxa cannot be used

Proposed Criteria:
Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for XARELTO SUSPENSION

Current Criteria:
- Patient is unable to swallow solid dosage forms

Proposed Criteria:
Same as current

COMMITTEE VOTE

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

Quantity Limits

• ELIQUIS	2/day
• PRADAXA	2/day
• XARELTO 2.5 mg	2/day
• XARELTO 10 mg, 20 mg	1/day
• XARELTO 15 mg	2/day
• dabigatran	2/day
• SAVAYSA	1/day

COMMITTEE VOTE

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

Discussion and Approval:

A motion to approve the class recommendation, all prior authorization criteria, and quantity limits with modification to Savaysa prior authorization criteria was made by Dr. Phares, seconded by Dr. Johns, and unanimously carried.

Dr. Phares suggested leaving in criteria point “Documentation that CrCl NOT ≥ 95 mL/min as calculated by Cockcroft-Gault equation” for Savaysa due safety concerns instead of removing all prior authorization criteria. In the clinical trial, patients with CrCl > 95 had decreased efficacy due to increased clearance of the drug. Dr. Phares also noted CrCl has to be calculated by the Cockcroft-Gault equation and EGFR cannot be used. Dr. Watlington stated there was no utilization for Savaysa but understands the safety concern. Dr. Johns also stated he agreed the safety criteria should remain in the prior authorization criteria.

PULMONARY ARTERIAL HYPERTENSION (PAH) AGENTS

Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred	
Pulmonary Arterial Hypertension (PAH) Agents	ALYQ PA, QL (tadalafil) ambrisentan PA, QL bosentan PA, QL sildenafil PA, QL (generic REVATIO) tadalafil PA, QL (generic ADCIRCA) TYVASO PA, QL (treprostinil) VENTAVIS PA, QL (iloprost)	ADCIRCA PA, QL (tadalafil) ADEMPAS PA, QL (riociguat) LETAIRIS PA, QL (ambrisentan) LIQREV PA, QL (sildenafil) OPSUMIT PA, QL (macitentan) ORENITRAM ER PA, QL (treprostinil) REVATIO PA, QL (sildenafil)	REVATIO suspension PA, QL (sildenafil) sildenafil suspension PA, QL TADLIQ PA, QL (tadalafil) TRACLEER tabs PA, QL (bosentan) TRACLEER soluble tabs PA, QL (bosentan) TYVASO DPI PA, QL (treprostinil) UPTRAVI PA, QL (selexipag)

Recommendation

It is recommended that at least one phosphodiesterase-5 enzyme (PDE5) inhibitor agent, at least one endothelin receptor antagonist (ERA), and at least one prostacyclin analog be available for individuals with a diagnosis of PAH. It is recommended that *sildenafil and tadalafil* ~~REVATIO~~ be subject to clinical criteria in order to ensure it is being used for PAH.

COMMITTEE VOTE

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

Prior Authorization criteria for bosentan

Current Criteria:

- Diagnosis of one of the following:
  - Pulmonary Arterial Hypertension (PAH)/ Elevated Pulmonary Vascular Resistance or Primary Pulmonary Hypertension (PPH)
  - Diagnosis of congenital heart disease with elevated pulmonary vascular resistance; **AND**
- A WHO Functional Class (FC) I-IV or age less than 11 years

Proposed Criteria:

- Diagnosis of one of the following:
  - Pulmonary Arterial Hypertension (PAH)/Elevated Pulmonary Vascular Resistance or Primary Pulmonary Hypertension (PPH)
  - Diagnosis of congenital heart disease with elevated pulmonary vascular resistance; ~~**AND**~~
- ~~A WHO Functional Class (FC) I-IV or age less than 11 years~~

COMMITTEE VOTE

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

Prior Authorization criteria for TYVASO

Current Criteria:

- Diagnosis of ONE of the following:
  - Pulmonary Arterial Hypertension (PAH)/Elevated Pulmonary Vascular Resistance or Primary Pulmonary Hypertension (PPH)
  - Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability
  - Congenital heart disease with elevated pulmonary vascular resistance; **AND**
- A WHO Functional Class (FC) II-IV or age less than 11 years

Proposed Criteria:

- Diagnosis of ONE of the following:

- Pulmonary Arterial Hypertension (PAH)/Elevated Pulmonary Vascular Resistance or Primary Pulmonary Hypertension (PPH)
- Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability
- Congenital heart disease with elevated pulmonary vascular resistance; ~~**AND**~~

- ~~A WHO Functional Class (FC) II-IV or age less than 11 years~~

COMMITTEE VOTE

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

Prior Authorization criteria for ADCIRCA, LETAIRIS, REVATIO, TRACLEER TABS

Current Criteria:

- Diagnosis of ONE of the following:
  - Diagnosis of Pulmonary Arterial Hypertension (PAH)/Elevated Pulmonary Vascular Resistance or Primary Pulmonary Hypertension (PPH)
  - Diagnosis of congenital heart disease with elevated pulmonary vascular resistance; **AND**
- Trial of ONE preferred agent with persistent signs or symptoms; **AND**
- A WHO Functional Class (FC) I-IV or age less than 11 years

Proposed Criteria:

- Diagnosis of ONE of the following:
  - Diagnosis of Pulmonary Arterial Hypertension (PAH)/Elevated Pulmonary Vascular Resistance or Primary Pulmonary Hypertension (PPH)
  - Diagnosis of congenital heart disease with elevated pulmonary vascular resistance; **AND**
- ~~Trial of ONE preferred agent with persistent signs or symptoms; **AND**~~
- ~~A WHO Functional Class (FC) I-IV or age less than 11 years~~
- *Clinically valid reason why the preferred generic cannot be used*

COMMITTEE VOTE

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

Prior Authorization criteria for ADEMPAS

Current Criteria:

- Diagnosis of ONE of the following:
  - Pulmonary Arterial Hypertension (PAH)/ Elevated Pulmonary Vascular Resistance
  - Primary Pulmonary Hypertension (PPH)
  - Congenital heart disease with elevated pulmonary vascular resistance; **AND**
- Trial of ONE preferred agent with persistent signs or symptoms; **AND**
- One of the following:
  - A WHO Functional Class (FC) I-IV or age less than 11 years; **OR**
  - Patient has a diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH) that is inoperable, or patient has residual post-pulmonary endarterectomy hypertension

Note: Use of Adempas® is contraindicated in patients also taking PDE-5 inhibitors

Proposed Criteria:

- ~~Diagnosis of~~ ONE of the following:
  - *Diagnosis of* Pulmonary Arterial Hypertension (PAH)/ Elevated Pulmonary Vascular Resistance or Primary Pulmonary Hypertension (PPH)
  - *Diagnosis of* congenital heart disease with elevated pulmonary vascular resistance; **AND**
    - Trial of ONE preferred agent with persistent signs or symptoms; ~~**AND**~~ ***OR***
- ~~One of the following:~~ *Diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH) with one of the following:*
  - ~~A WHO Functional Class (FC) I-IV or age less than 11 years; **OR**~~

- ~~Patient has a diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH)~~ *Patient has disease* that is inoperable
- Patient has residual post-pulmonary endarterectomy hypertension

Note: Use of Adempas is contraindicated in patients also taking PDE-5 inhibitors

COMMITTEE VOTE

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

Prior Authorization criteria for LIQREV, REVATIO SUSPENSION, sildenafil suspension, TADLIQ

Current Criteria:

- Diagnosis of ONE of the following:
  - Diagnosis of Pulmonary Arterial Hypertension (PAH)/ Elevated Pulmonary Vascular Resistance or Primary Pulmonary Hypertension (PPH)
  - Diagnosis of congenital heart disease with elevated pulmonary vascular resistance; **AND**
- Patient has one of the following:
  - Patient is unable to swallow tablets
  - Dosing that will not allow the use of preferred sildenafil tablets to be crushed;
  - Patient is < 6 years of age

Proposed Criteria:

- Diagnosis of ONE of the following:
  - Diagnosis of Pulmonary Arterial Hypertension (PAH)/ Elevated Pulmonary Vascular Resistance or Primary Pulmonary Hypertension (PPH)
  - Diagnosis of congenital heart disease with elevated pulmonary vascular resistance; **AND**
- Patient has one of the following:
  - Patient is unable to swallow tablets
  - ~~Dosing that will not allow the use of preferred sildenafil tablets to be crushed;~~
  - Patient is < 6 years of age
  - *Clinically valid reason why a preferred tablet formulation cannot be used*

COMMITTEE VOTE

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

Prior Authorization criteria for OPSUMIT, ORENITRAM ER, UPTRAVI

Current Criteria:

- Diagnosis of ONE of the following:
  - Diagnosis of Pulmonary Arterial Hypertension (PAH)/Elevated Pulmonary Vascular Resistance or Primary Pulmonary Hypertension (PPH)
  - Diagnosis of congenital heart disease with elevated pulmonary vascular resistance; **AND**
- Trial of ONE preferred agent with persistent signs or symptoms; **AND**
- A WHO Functional Class (FC) I-IV or age less than 11 years

Proposed Criteria:

- Diagnosis of ONE of the following:
  - Diagnosis of Pulmonary Arterial Hypertension (PAH)/Elevated Pulmonary Vascular Resistance or Primary Pulmonary Hypertension (PPH)
  - Diagnosis of congenital heart disease with elevated pulmonary vascular resistance; **AND**
- Trial of ONE preferred agent with persistent signs or symptoms; ~~**AND**~~
- ~~A WHO Functional Class (FC) I-IV or age less than 11 years~~

COMMITTEE VOTE

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

Prior Authorization criteria for TRACLEER SOLUBLE TABS

Current Criteria:

- Diagnosis of one of the following:
  - Pulmonary Arterial Hypertension (PAH)/ Elevated Pulmonary Vascular Resistance or Primary Pulmonary Hypertension (PPH)
  - Diagnosis of congenital heart disease with elevated pulmonary vascular resistance; **AND**
- A WHO Functional Class (FC) I-IV or age less than 11 years; **AND**
- Patient is unable to swallow solid dosage forms

Proposed Criteria:

- Diagnosis of one of the following:
  - Pulmonary Arterial Hypertension (PAH)/ Elevated Pulmonary Vascular Resistance or Primary Pulmonary Hypertension (PPH)
  - Diagnosis of congenital heart disease with elevated pulmonary vascular resistance; **AND**
- ~~A WHO Functional Class (FC) I-IV or age less than 11 years; **AND**~~
- Patient is unable to swallow solid dosage forms

COMMITTEE VOTE

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

Prior Authorization criteria for TYVASO DPI

Current Criteria:

Initial Criteria:

- One of the following:
  - Diagnosis of pulmonary arterial hypertension (PAH)/Elevated pulmonary vascular resistance or Primary pulmonary hypertension
  - Diagnosis of pulmonary hypertension associated with interstitial lung disease; **AND**
- Diagnosis is confirmed by diagnostic test(s) (e.g., right heart catheterization, doppler echocardiogram, computerized tomography imaging); **AND**
- Prescribed by, or in consultation with, a pulmonologist or cardiologist

Renewal Criteria:

- Documentation of positive clinical response to therapy

Proposed Criteria:

Initial Criteria:

- One of the following:
  - Diagnosis of pulmonary arterial hypertension (PAH)/Elevated pulmonary vascular resistance or Primary pulmonary hypertension
  - Diagnosis of pulmonary hypertension associated with interstitial lung disease; **AND**
- *Clinically valid reason why the preferred Tyvaso inhalation solution cannot be used*
- ~~Diagnosis is confirmed by diagnostic test(s) (e.g., right heart catheterization, doppler echocardiogram, computerized tomography imaging); **AND**~~
- ~~Prescribed by or in consultation with a pulmonologist or cardiologist~~

~~**Renewal Criteria:**~~

- ~~Documentation of positive clinical response to therapy~~

COMMITTEE VOTE

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

Prior Authorization criteria for Alyq, sildenafil, ambrisentan, tadalafil, VENTAVIS

Current Criteria:

- Diagnosis of Pulmonary Arterial Hypertension (PAH)/ Elevated Pulmonary Vascular Resistance or Primary Pulmonary Hypertension (PPH); **OR**
- Diagnosis of congenital heart disease with elevated pulmonary vascular resistance

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Quantity Limits

• ALYQ (tadalafil)	2/day	• REVATIO tab (sildenafil)	3/day
• bosentan	2/day	• REVATIO (sildenafil) suspension	6 mL/day
• TYVASO	2.9 mL/day	• TADLIQ	10 mL/day
• VENTAVIS	3mL/day	• TRACLEER tabs	2/day
• ADCIRCA (tadalafil)	2/day	• TRACLEER tabs, soluble	2.9 mL/day
• ADEMPAS	3/day	• TYVASO DPI, single cartridges	4/day
• LETAIRIS (ambrisentan)	1/day	• TYVASO DPI, combo cartridges	8/day
• LIQREV	240 mg/day	• TYVASO DPI, kits	2/year
• OPSUMIT	1/day	• UPTRAVI	2/day
• ORENITRAM ER	3/day	• UPTRAVI, titration pack	1 pack/Rx

COMMITTEE VOTE

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

Discussion and Approval:

A motion to approve the class recommendation, all prior authorization criteria and quantity limits was made by Dr. Johns, seconded by Dr. Phares, and unanimously carried.

LIPOTROPICS: OMEGA-3 FATTY ACIDS

Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred
Omega-3 Fatty Acids	LOVAZA [PA] (omega-3 fatty acids) omega-3 acid ethyl esters [PA] VASCEPA [PA, QL] (icosapent ethyl)	icosapent ethyl [PA, QL]

Recommendation

~~Given that clinical guidelines consider fibrates the first-line treatment agent for patients with severe hypertriglyceridemia and state that non-statin therapies do not provide acceptable atherosclerotic cardiovascular disease (ASCVD) risk reduction benefits compared to their potential for adverse effects,~~ It is recommended the omega-3 fatty acids agents should be subject to prior authorization *to ensure appropriate use for hypertriglyceridemia*.

COMMITTEE VOTE

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

Prior Authorization criteria for VASCEPA, icosapent ethyl

Current Criteria:

- Diagnosis of Severe Hypertriglyceridemia (TG level is above 500 mg/dl); **OR**
- Patient is on maximally tolerated statin, with or without ezetimibe, AND has triglyceride levels between 135 and 499mg/dL; **AND**
- One of the following:
  - ≥45 years old with clinical ASCVD, **OR**
  - ≥50 years of age with type 2 diabetes and at least 1 additional risk factor from the following:
    - Cigarette smoker or stopped smoking within 3 months
    - Hypertension (≥140 mmHg systolic or ≥90 mmHg diastolic) or on antihypertensive medication,
    - HDL-C ≤40 mg/dL for men or ≤50 mg/dL for women
    - Hs-CRP >3.0 mg/L
    - Renal dysfunction: Creatinine clearance >30 and <60 mL/min
    - Retinopathy
    - Micro-or macro-albuminuria
    - ABI<0.9 without symptoms of intermittent claudication

Proposed Criteria:

Initial criteria:

- Diagnosis of Severe Hypertriglyceridemia (TG level is above 500 mg/dl); **OR**
- Patient is on maximally tolerated statin, ~~with or without ezetimibe,~~ AND has triglyceride levels *>135* ~~between 135 and 499mg/dL;~~ **AND**
- ~~One of the following:~~
  - ~~≥45 years old with clinical ASCVD, **OR**~~
  - ~~≥50 years of age with type 2 diabetes and at least 1 additional risk factor from the following:~~
    - ~~Cigarette smoker or stopped smoking within 3 months~~
    - ~~Hypertension (≥140 mmHg systolic or ≥90 mmHg diastolic) or on antihypertensive medication,~~
    - ~~HDL-C ≤40 mg/dL for men or ≤50 mg/dL for women~~
    - ~~Hs-CRP >3.0 mg/L~~
    - ~~Renal dysfunction: Creatinine clearance >30 and <60 mL/min~~
    - ~~Retinopathy~~
    - ~~Micro-or macro-albuminuria~~
    - ~~ABI<0.9 without symptoms of intermittent claudication~~

- *If the request is for the generic icosapent ethyl, clinically valid reason as to why the preferred Brand Vascepa cannot be used*

Renewal Criteria

- *Documentation of positive clinical response (e.g., reduction in TG from baseline)*

COMMITTEE VOTE

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

Prior Authorization criteria for LOVAZA, omega-3 acid ethyl esters

Current Criteria:

- Diagnosis of Severe Hypertriglyceridemia (TG level is above 500 mg/dl); **OR**
- Patient is on maximally tolerated statin, with or without ezetimibe, AND has triglyceride levels between 135 and 499mg/dL; **AND**
- One of the following:
  - ≥45 years old with clinical ASCVD, **OR**
  - ≥50 years of age with type 2 diabetes and at least 1 additional risk factor from the following:
    - Cigarette smoker or stopped smoking within 3 months
    - Hypertension (≥140 mmHg systolic or ≥90 mmHg diastolic) or on antihypertensive medication,
    - HDL-C ≤40 mg/dL for men or ≤50 mg/dL for women
    - Hs-CRP >3.0 mg/L
    - Renal dysfunction: Creatinine clearance >30 and <60 mL/min
    - Retinopathy
    - Micro-or macro-albuminuria
    - ABI<0.9 without symptoms of intermittent claudication

Proposed Criteria:

Initial Criteria:

- Diagnosis of Severe Hypertriglyceridemia (TG level is above 500 mg/dl); ~~***AND***~~
- ~~Patient is on maximally tolerated statin, with or without ezetimibe, AND has triglyceride levels > between 135 and 499mg/dL; **AND**~~
- ~~One of the following:~~
  - ~~≥45 years old with clinical ASCVD, **OR**~~
  - ~~≥50 years of age with type 2 diabetes and at least 1 additional risk factor from the following:~~
    - ~~Cigarette smoker or stopped smoking within 3 months~~
    - ~~Hypertension (≥140 mmHg systolic or ≥90 mmHg diastolic) or on antihypertensive medication,~~
    - ~~HDL-C ≤40 mg/dL for men or ≤50 mg/dL for women~~
    - ~~Hs-CRP >3.0 mg/L~~
    - ~~Renal dysfunction: Creatinine clearance >30 and <60 mL/min~~
    - ~~Retinopathy~~
    - ~~Micro-or macro-albuminuria~~
    - ~~ABI<0.9 without symptoms of intermittent claudication~~

Renewal Criteria

- *Documentation of positive clinical response (e.g. reduction in TG from baseline)*

COMMITTEE VOTE

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

Quantity Limits

• icosapent ethyl 0.5 g	2/day	• omega-3 acid ethyl esters	4/day
• icosapent ethyl 1 g	4/day	• VASCEPA 0.5 g	2/day
• LOVAZA	4/day	• VASCEPA 1 g	4/day

COMMITTEE VOTE

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

Discussion and Approval:

A motion to approve the class recommendation, all prior authorization criteria and quantity limits was made by Dr. Close, seconded by Dr. Rhea, and unanimously carried.

Dr. Capparelli states the lab reporting he has seen for triglycerides will not report a value greater than 400. Dr. Capparelli asked the committee if anyone else has the same problem. Dr. Close stated she receives quantitative lab values for greater than 400 for triglycerides. Dr. Capparelli stated he will review his lab reports from the vendor he uses.

~~LIPOTROPICS: PCSK-9 INHIBITORS~~ *ANTIHYPERLIPIDEMIC AGENTS*

Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred
Antihyperlipidemic Agents	PRALUENT PA, QL (alirocumab) REPATHA PA, QL (evolocumab)	JUXTAPID PA, QL (lomitapide) NEXLETOL PA, QL (bempedoic acid) NEXLIZET PA, QL (bempedoic acid/ezetimibe)

Recommendation

Familial Hypercholesterolemia Agents:
PCSK9 inhibitors and lipotropics bempedoic acid and lomitapide should be considered as adjunct therapy for patients with familial hypercholesterolemia (FH) or clinical atherosclerotic cardiovascular disease (ASCVD) who are unable to reach their LDL-C goals with maximally tolerated statin therapy. These agents should be subject to prior authorization to ensure appropriate use.

~~**PSK9 Inhibitor Class**:~~
~~PCSK9 inhibitors should be considered as adjunct therapy to treatment with statins in patients with familial hypercholesterolemia (FH) or clinical cardiovascular disease who are unable to reach their LDL-C goals with maximally tolerated statin therapy. PSCK-9 inhibitors should remain available with clinical criteria.~~

COMMITTEE VOTE
APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for PRALUENT, REPATHA

Current Criteria:

Initial Criteria: (3-month duration)

- Age ≥ 18 years if diagnosis is atherosclerotic cardiovascular disease (ASCVD) or primary hyperlipidemia (including heterozygous familial hypercholesterolemia (HeFH)), **OR**
  - **For evolocumab**, ≥ 10 years if diagnosed with homozygous familial hypercholesterolemia (HoFH); **AND**
- Diagnosis of atherosclerotic cardiovascular disease (ASCVD), primary hyperlipidemia or heterozygous familial hypercholesterolemia (HeFH) as confirmed by genotyping or by clinical criteria ("definite FH" using either the Simon Broome or WHO/Dutch Lipid Network criteria), **OR**
  - **For evolocumab only**, ≥ 10 years and HoFH as confirmed by either:
    - Documented DNA test for functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality; **OR**
    - A history of an untreated LDL-C concentration > 500 mg/dL and triglycerides < 300 mg/dL and both parents with documented untreated TC > 250 mg/dL; **AND**
- All secondary causes of hyperlipidemia have been addressed including diet, other diseases, and concomitant drugs; **AND**
- Prior treatment history with highest available dose or maximally-tolerated dose of high intensity statin (atorvastatin or rosuvastatin) AND ezetimibe (or a clinically valid reason why the patient cannot take ezetimibe) for at least three continuous months with failure to reach target LDL- C (at least 50% reduction from baseline OR if no baseline is available: 70 mg/dL for patients with clinical ASCVD and <100 mg /dL for patients with primary hyperlipidemia, including HeFH, and no history of clinical ASCVD); **AND**
  - If the patient is not able to use a maximum dose of atorvastatin or rosuvastatin due to muscle symptoms, documentation of a causal relationship must be established between statin use and muscle symptoms; **AND**
  - Documentation must demonstrate that the patient experienced pain, tenderness, stiffness, cramping, weakness, and/or fatigue and all the following:
    - Muscle symptoms resolve after discontinuation of statin; **AND**

- Muscle symptoms occurred when re-challenged at a lower dose of the same statin; **AND**
- Muscle symptoms occurred after switching to an alternative statin; **AND**
- Documentation ruling out non-statin causes of muscle symptoms (e.g., hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders, such as polymyalgia rheumatica, steroid myopathy, vitamin D deficiency, or primary muscle disease); **OR**

○ The patient has been diagnosed with statin-induced rhabdomyolysis
- The diagnosis should be supported by acute neuromuscular illness or dark urine AND an acute elevation in creatine kinase (usually >5,000 IU/L or five times the upper limit of normal); **AND**
- If the patient failed to reach target LDL-C (at least 50% reduction from baseline OR if no baseline is available: <70 mg/dL for patients with clinical ASCVD and <100 mg/dL for patients with primary hyperlipidemia, including HeFH, and no history of clinical ASCVD), adherence to maximally-tolerated statin and ezetimibe has been verified using pharmacy claims data (or a clinically valid reason why the patient cannot take ezetimibe) and the patient is determined to be compliant for at least three consecutive months prior to the lipid panel demonstrating suboptimal reduction; **AND**
- Maximally tolerated statin will continue to be used in conjunction with a PCSK9 inhibitor; **AND**
- Patient has not had a prior trial and failure of an alternative PCSK9 inhibitor; **AND**
- Request is being made for the lowest approved dose to adequately treat the patient; **AND**
- Requests for an escalated dose must contain a lipid panel documenting suboptimal reduction in LDL-C after at least 4 weeks at the lower dose.

Renewal Criteria: (6-month duration)
- Lipid panel showing an ongoing reduction in LDL-C compared to the labs prior to initiating a PCSK9 inhibitor; **AND**
- Continued adherence to maximally tolerated statin dose established prior to the original PCSK9 inhibitor approval

Proposed Criteria:

Initial Criteria: (*6* ~~3~~-month duration)
- ~~Age ≥ 18 years if diagnosis is atherosclerotic cardiovascular disease (ASCVD) or primary hyperlipidemia (including heterozygous familial hypercholesterolemia (HeFH)), **OR**~~
  - ~~**For evolocumab**, ≥ 10 years if diagnosed with homozygous familial hypercholesterolemia (HoFH); **AND**~~
- ~~Diagnosis of atherosclerotic cardiovascular disease (ASCVD), primary hyperlipidemia or heterozygous familial hypercholesterolemia (HeFH) as confirmed by genotyping or by clinical criteria ("definite FH" using either the Simon Broome or WHO/Dutch Lipid Network criteria), **OR**~~
  - ~~**For evolocumab only**, ≥ 10 years and HoFH as confirmed by either:~~
    - ~~Documented DNA test for functional mutation(s) in both LDL receptor alleles or alleles known to affect LDL receptor functionality; **OR**~~
    - ~~A history of an untreated LDL-C concentration > 500 mg/dL and triglycerides < 300 mg/dL and both parents with documented untreated TC > 250 mg/dL; **AND**~~
- ~~All secondary causes of hyperlipidemia have been addressed including diet, other diseases, and concomitant drugs; **AND**~~
- ~~Prior treatment history with highest available dose or maximally tolerated dose of high intensity statin (atorvastatin or rosuvastatin) AND ezetimibe (or a clinically valid reason why the patient cannot take ezetimibe) for at least three continuous months with failure to reach target LDL- C (at least 50% reduction from baseline OR if no baseline is available: 70 mg/dL for patients with clinical ASCVD and <100 mg /dL for patients with primary hyperlipidemia, including HeFH, and no history of clinical ASCVD); **AND**~~
  - ~~If the patient is not able to use a maximum dose of atorvastatin or rosuvastatin due to muscle symptoms, documentation of a causal relationship established between statin use and muscle symptoms; **AND**~~
  - ~~Documentation must demonstrate that the patient experienced pain, tenderness, stiffness, cramping, weakness, and/or fatigue and all the following:~~
    - ~~Muscle symptoms resolve after discontinuation of statin; **AND**~~
    - ~~Muscle symptoms occurred when re-challenged at a lower dose of the same statin; **AND**~~
    - ~~Muscle symptoms occurred after switching to an alternative statin; **AND**~~

- ~~Documentation ruling out non-statin causes of muscle symptoms (e.g., hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders, such as polymyalgia rheumatica, steroid myopathy, vitamin D deficiency, or primary muscle disease); **OR**~~
- ~~The patient has been diagnosed with statin-induced rhabdomyolysis~~
  - ~~The diagnosis should be supported by acute neuromuscular illness or dark urine AND an acute elevation in creatine kinase (usually >5,000 IU/L or five times the upper limit of normal); **AND**~~
  - ~~If the patient failed to reach target LDL-C (at least 50% reduction from baseline OR if no baseline is available: <70 mg/dL for patients with clinical ASCVD and <100 mg/dL for patients with primary hyperlipidemia, including HeFH, and no history of clinical ASCVD), adherence to maximally-tolerated statin and ezetimibe has been verified using pharmacy claims data (or a clinically valid reason why the patient cannot take ezetimibe) and the patient is determined to be compliant for at least 3 consecutive months prior to the lipid panel demonstrating suboptimal reduction; **AND**~~
  - ~~Maximally tolerated statin will continue to be used in conjunction with a PCSK9 inhibitor; **AND**~~
  - ~~Patient has not had a prior trial and failure of an alternative PCSK9 inhibitor; **AND**~~
  - ~~Request is being made for the lowest approved dose to adequately treat the patient; **AND**~~
  - ~~Requests for an escalated dose must contain a lipid panel documenting suboptimal reduction in LDL-C after at least 4 weeks at the lower dose.~~

Primary and Secondary CVD Prevention

- *Patient age ≥ 18 years; **AND***
- *Patient has history of ONE of the following:*
  - *History of MI*
  - *Stroke*
  - *Unstable angina*
  - *Symptomatic peripheral artery disease*
  - *Primary Hyperlipidemia (including heterozygous familial hypercholesterolemia (HeFH))*
  - *Baseline LDL-C ≥ 190; **AND***
- *Documented current LDL-C (within 3 months); **AND***
- *Patient specific target LDL-C is provided; **AND***
- *Failure to reach patient specific LDL target despite a ≥ 3-month trial (supported by claims history or clinical documentation) of concurrent therapy with both the following, unless contraindicated or intolerance:*
  - *High-intensity statin atorvastatin/rosuvastatin*
  - *Ezetimibe; **AND***
- *Agent will be used in combination with other lipid lowering therapies, unless documented intolerance*

Diagnosis of heterozygous familial hypercholesterolemia (HeFH) or homozygous familial hypercholesterolemia (HoFH)

- *If request is for Repatha, patient age ≥10 years; **AND***
- *If request is for Praluent, patient age ≥18 years; **AND***
- *Diagnosis of ONE of the following:*
  - *Heterozygous familial hypercholesterolemia (HeFH)*
  - *Homozygous familial hypercholesterolemia (HoFH); **AND***
- *Diagnosis has been confirmed by ONE of the following:*
  - *Presence of a mutation in LDL receptor, ApoB, PCSK9 gene*
  - *Clinical criteria using either the Simon Broome or WHO/Dutch Lipid Network criteria; **AND***
- *Documented current LDL-C (within 3 months); **AND***
- *Patient specific target LDL-C is provided; **AND***
- *Failure to reach patient specific LDL target despite a ≥ 3-month trial (supported by claims history or clinical documentation)of concurrent therapy with both the following, unless contraindicated or intolerance:*
  - *High-intensity statin atorvastatin/rosuvastatin*
  - *Ezetimibe; **AND***
- *Agent will be used in combination with other lipid lowering therapies, unless documented intolerance*

Renewal Criteria:

- ~~Lipid panel showing an ongoing reduction in LDL-C compared to the labs prior to initiating a PCSK9 inhibitor; **AND**~~

- ~~Continued adherence to maximally tolerated statin dose established prior to the original PCSK9 inhibitor approval~~
- *Documentation of a positive clinical response to therapy (e.g. LDL reduction from baseline, patient has meet LDL-C target)*

COMMITTEE VOTE

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

Prior Authorization criteria for JUXTAPID

Current Criteria:

- Diagnosis of Homozygous Familial Hypercholesterolemia(HoFH); **AND**
- Member will be concurrently taking other lipid-lowering medications; **AND**
- Trial and failure, contraindication, or intolerance to Repatha; **AND**
- If female, documentation patient is not currently pregnant; **AND**
- Patient is not concomitantly taking strong or moderate inhibitors of cytochrome P450 (CYP) 3A4; **AND**
- Patient has been evaluated for active liver disease

Proposed Criteria:

Initial Criteria *(6-month duration)*

- Diagnosis of Homozygous Familial Hypercholesterolemia(HoFH); **AND**
- *Diagnosis has been confirmed by ONE of the following:*
  - *Presence of a mutation in LDL receptor, ApoB, PCSK9 gene*
  - *Clinical criteria using either the Simon Broome or WHO/Dutch Lipid Network criteria; **AND***
- *Documented current LDL-C (within 3 months); **AND***
- *Patient specific target LDL-C is provided; **AND***
- *Failure to reach patient specific LDL target despite a ≥ 3-month trial (supported by claims history or clinical documentation) of concurrent therapy with both of the following, unless contraindicated or intolerance:*
  - *High-intensity statin atorvastatin/rosuvastatin*
  - *Ezetimibe;*
- Trial and failure, contraindication, or intolerance to Repatha; **AND**
- Member will be concurrently taking other lipid-lowering medications *unless documented intolerance*; **AND**
- If female, documentation patient is not currently pregnant; **AND**
- Patient is not concomitantly taking strong or moderate inhibitors of cytochrome P450 (CYP) 3A4; ~~**AND**~~
- ~~Patient has been evaluated for active liver disease~~

Renewal Criteria:

- *Documentation of a positive clinical response to therapy (e.g. LDL reduction from baseline, patient has meet LDL-C target)*

COMMITTEE VOTE

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

Prior Authorization criteria for NEXLETOL, NEXLIZET

Current Criteria:

Initial Criteria: (3-month duration)

- Age ≥ 18 years; **AND**
- Diagnosis of atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolemia (HeFH)) confirmed by:
  - Presence of a mutation in LDLR, ApoB, PCSK9 or ARH adaptor protein (LDLRAP1) gene; **OR**
  - Clinical criteria using either the Simon Broome or WHO/Dutch Lipid Network criteria; **AND**
- Secondary causes of hyperlipidemia have been addressed including diet, other diseases, and concomitant drugs; **AND**
- Prior treatment history with:

- Highest available dose or maximally tolerated dose of a high intensity statin (atorvastatin or rosuvastatin); **AND**
- [Only applicable for Nexletol] Ezetimibe (or a clinically valid reason why the patient cannot take ezetimibe); **AND**

- Failure to reach target LDL- C after at least 3 continuous months of use (at least 50% reduction from baseline OR if no baseline is available: 70 mg/dL for patients with clinical ASCVD and <100 mg/dl for patient with primary hyperlipidemia including HeFH, and no history of clinical ASCVD); **OR**
- If the patient is unable to tolerate a statin, ONE of the following must apply:
  - If the patient is not able to use a maximum dose of atorvastatin or rosuvastatin due to muscle symptoms, documentation of a causal relationship must be established between statin use and muscle symptoms. Documentation must demonstrate that the patient experienced pain, tenderness, stiffness, cramping, weakness, and/or fatigue and ALL the following:
    - Muscle symptoms resolve after discontinuation of statin
    - Muscle symptoms occurred when re-challenged at a lower dose of the same statin
    - Muscle symptoms occurred after switching to an alternative statin
    - Documentation ruling out non-statin causes of muscle symptoms (e.g., hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders, such as polymyalgia rheumatica, steroid myopathy, vitamin D deficiency, or primary muscle disease); **OR**
  - The patient has been diagnosed with statin-induced rhabdomyolysis
  - The diagnosis should be supported by acute neuromuscular illness or dark urine AND an acute elevation in creatine kinase (usually >5,000 IU/L or five times the upper limit of normal); **OR**
  - The patient has active liver disease, or unexplained persistent elevation of hepatic transaminases; **OR**
  - Patient is pregnant; **AND**
- Maximally tolerated statin will continue to be used in conjunction with bempedoic acid (unless unable to tolerate)

Renewal criteria:

- Patient must continue adherence to maximally tolerated statin dose (unless unable to tolerate) established prior to the initial bempedoic acid approval; **AND**
- Lipid panel shows an ongoing reduction in LDL-C compared to the labs prior to initiating bempedoic acid

Proposed Criteria:

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

- Age ≥ 18 years; **AND**
- Diagnosis of atherosclerotic cardiovascular disease (ASCVD); **OR**
- *Diagnosis of* Heterozygous familial hypercholesterolemia (HeFH)) confirmed by *one of the following*:
  - Presence of a mutation in LDLR, ApoB, PCSK9 or ARH adaptor protein (LDLRAP1) gene;
  - Clinical criteria using either the Simon Broome or WHO/Dutch Lipid Network criteria; **AND**
- ~~Secondary causes of hyperlipidemia have been addressed including diet, other diseases, and concomitant drugs; **AND**~~
- *Documented current LDL-C (within 3 months); **AND***
- *Patient specific target LDL-C is provided; **AND***
- *Failure to reach patient specific LDL target despite a > 3-month trial (supported by claims history or clinical documentation) of concurrent therapy with both the following, unless contraindicated or intolerance:*
  - *High-intensity statin atorvastatin/rosuvastatin*
  - *Ezetimibe (Only applicable for Nexletol requests); **AND***
- *Patient has tried and failed or have contraindication or intolerance to Repatha; **AND***
- *Agent will be used in combination with other lipid lowering therapies, unless documented intolerance*
- ~~Prior treatment history with:~~
  - ~~Highest available dose or maximally tolerated dose of a high intensity statin (atorvastatin or rosuvastatin); **AND**~~
  - ~~[Only applicable for Nexletol] Ezetimibe (or a clinically valid reason why the patient cannot take ezetimibe); **AND**~~

- ~~Failure to reach target LDL- C after at least 3 continuous months of use (at least 50% reduction from baseline OR if no baseline is available: 70 mg/dL for patients with clinical ASCVD and <100 mg/dl for patient with primary hyperlipidemia including HeFH, and no history of clinical ASCVD); **OR**~~
- ~~If the patient is unable to tolerate a statin, ONE of the following must apply:~~
  - ~~If the patient is not able to use a maximum dose of atorvastatin or rosuvastatin due to muscle symptoms, documentation of a causal relationship must be established between statin use and muscle symptoms. Documentation must demonstrate that the patient experienced pain, tenderness, stiffness, cramping, weakness, and/or fatigue and ALL the following:~~
    - ~~Muscle symptoms resolve after discontinuation of statin~~
    - ~~Muscle symptoms occurred when re-challenged at a lower dose of the same statin~~
    - ~~Muscle symptoms occurred after switching to an alternative statin~~
    - ~~Documentation ruling out non-statin causes of muscle symptoms (e.g., hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders, such as polymyalgia rheumatica, steroid myopathy, vitamin D deficiency, or primary muscle disease); **OR**~~
  - ~~The patient has been diagnosed with statin-induced rhabdomyolysis~~
  - ~~The diagnosis should be supported by acute neuromuscular illness or dark urine AND an acute elevation in creatine kinase (usually >5,000 IU/L or five times the upper limit of normal); **OR**~~
  - ~~The patient has active liver disease, or unexplained persistent elevation of hepatic transaminases; **OR**~~
  - ~~Patient is pregnant; **AND**~~
- ~~Maximally tolerated statin will continue to be used in conjunction with bempedoic acid (unless unable to tolerate)~~

Renewal criteria:

- *Documentation of a positive clinical response to therapy (e.g., LDL reduction from baseline, patient has meet LDL-C target)*
- ~~Patient must continue adherence to maximally tolerated statin dose (unless unable to tolerate) established prior to the initial bempedoic acid approval; **AND**~~
- ~~Lipid panel shows an ongoing reduction in LDL-C compared to the labs prior to initiating bempedoic acid~~

COMMITTEE VOTE

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

Quantity Limits

• PRALUENT	2 pens/28 days
• REPATHA	*2 ~~3~~*/28 days
• *REPATHA PUSHTRONEX*	*1 system/28 days*
• JUXTAPID 5 mg, 10 mg	1 cap/day
• JUXTAPID 20 mg	3 caps/day
• NEXLETOL	1/day
• NEXLIZET	1/day

COMMITTEE VOTE

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

Discussion and Approval:

A motion to approve the class recommendation, all prior authorization criteria, and quantity limits with modification was made by Dr. Phares, seconded by Dr. Alston, and unanimously carried.

Dr. Phares suggested removing step through ezetimibe for all agents in this class. Dr. Phares stated ezetimibe may provide an additional 5% LDL reduction and has no benefit in outcomes. PCSK9 inhibitors, Nexletol and Nexlizet have beneficial effects and outcomes. Dr. Phares also stated he only uses ezetimibe if required by insurance company as step therapy.

LIPOTROPICS: MISCELLANEOUS

Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred	
Lipotropics: Misc.	N/A	BYLVAY PA (odevixibat)	LIVMARLI PA (maralixibat)

Recommendation

~~Lomitapide carries a black box warning for the risk of hepatotoxicity and precautions exist when taken with other drugs; therefore, it is recommended that lomitapide is subject to prior authorization with reserve use for patients with Homozygous Familial Hypercholesterolemia (HoFH)~~. *It is recommended agents in this class be subject to PA criteria to ensure appropriate use.*

COMMITTEE VOTE

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

Prior Authorization criteria for BYLVAY

Current Criteria:

- Diagnosis of progressive familial intrahepatic cholestasis (PFIC); **AND**
- Prescribed by, or in consultation with, hepatologist or gastroenterologist; **AND**
- Patient does not have the following:
  - PFIC type 2 ABCB11 gene variant that predict non-function or complete absence of the bile salt export pump (BSEP) protein
  - Prior hepatic decompensation events
  - Concomitant liver disease
  - INR greater than 1.4
  - ALT or total bilirubin greater than 10-times the upper limit of normal (ULN)
  - Liver transplant; **AND**
- Provider attests to monitor the following:
  - Liver-function tests at baseline and during treatment; **AND**
  - Fat- soluble vitamin (FSV) levels at baseline and during treatment

Proposed Criteria:

Initial Criteria:

- ~~Diagnosis of progressive familial intrahepatic cholestasis (PFIC); **AND**~~
- *One of the following:*
  - Diagnosis of progressive familial intrahepatic cholestasis (PFIC) *confirmed by genetic test*; **AND**
    - *Patient does not have a ABCB11 variant resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3); **OR***
  - *Diagnosis of Alagille syndrome (ALGS) confirmed by presence of the JAG1 or Notch2 gene; **AND***
- Prescribed by, or in consultation with, hepatologist or gastroenterologist; **AND**
- *Patient is experiencing moderate to severe pruritus confirmed by ONE of the following:*
  - *Total serum bile acid > 3x the upper limit of normal*
  - *Conjugated bilirubin > 1 mg/dL.*
  - *Fat soluble vitamin deficiency otherwise unexplainable.*
  - *GGT > 3x the upper limit of normal*
  - *Intractable pruritus explainable only by liver disease; **AND***
- *Trial and failure to at two other conventional treatments for the symptomatic relief of pruritus (e.g., bile acid-binding agents, naltrexone, phenobarbital, rifampin, ursodeoxycholic acid); **AND***
- ~~Patient does not have the following:~~
  - ~~PFIC type 2 ABCB11 gene variant that predict non-function or complete absence of the bile salt export pump (BSEP) protein~~

- ~~Prior hepatic decompensation events~~
- ~~Concomitant liver disease~~
- ~~INR greater than 1.4~~
- ~~ALT or total bilirubin greater than 10-times the upper limit of normal (ULN)~~
- ~~Liver transplant; **AND**~~

- Provider attests to monitor the following:
  - Liver-function tests at baseline and during treatment; **AND**
  - Fat- soluble vitamin (FSV) levels at baseline and during treatment

Renewal Criteria

- *Documented positive clinical response (e.g., reduced serum bile acids, improved pruritis, less sleep disturbance)*

COMMITTEE VOTE

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

Prior Authorization criteria for LIVMARLI

Current Criteria:

- Patient is 3 months of age or older; **AND**
- Diagnosis of Alagille syndrome (ALGS) with cholestatic pruritus; **AND**
- Prescribed by, or in consultation with, hepatologist or gastroenterologist; **AND**
- Patient has a pruritus score greater than 2.0 on 0-4 scale; **AND**
- Trial and failure, contraindication, or intolerance to TWO agents used for symptomatic relief of pruritis (e.g., cholestyramine, ondansetron, rifampin); **AND**
- Provider attests to monitor the following:
  - Liver-function tests at baseline and during treatment
  - Fat- soluble vitamin (FSV) levels at baseline and during treatment

Proposed Criteria:

Initial Criteria:

- ~~Patient is 3 months of age or older; **AND**~~
- Diagnosis of Alagille syndrome (ALGS) ~~with cholestatic pruritus~~ *confirmed by presence of the JAG1 or Notch2 gene; **AND***
- Prescribed by, or in consultation with, hepatologist or gastroenterologist; **AND**
- *Patient is experiencing moderate to severe pruritus* ~~Patient has a pruritus score greater than 2.0 on 0-4 scale~~ *confirmed by ONE of the following:*
  - *Total serum bile acid > 3x the upper limit of normal*
  - *Conjugated bilirubin > 1 mg/dL.*
  - *Fat soluble vitamin deficiency otherwise unexplainable.*
  - *GGT > 3x the upper limit of normal*
  - *Intractable pruritus explainable only by liver disease; **AND***
- Trial and failure to at two other conventional treatments for the symptomatic relief of pruritus (e.g., bile *acid-binding agents* ~~cholestyramine~~, *naltrexone, phenobarbital*, rifampin, *ursodeoxycholic acid*); **AND**
- Provider attests to monitor the following:
  - Liver-function tests at baseline and during treatment
  - Fat- soluble vitamin (FSV) levels at baseline and during treatment

COMMITTEE VOTE

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

Discussion and Approval:

A motion to approve the class recommendation, all prior authorization criteria, and quantity limits with modification was made by Dr. Johns, seconded by Dr. Phares, and unanimously carried.

Dr. Johns suggested moving this class to the gastrointestinal drug category and updating the PDL class name to Ileal Bile Acid Transporter Inhibitors. Dr. John's also noted the word "mutation" is missing from the prior authorization criteria after JAG1 or Notch2 gene.

CARDIAC AGENTS, MISCELLANEOUS

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred	
Cardiac Agents, Miscellaneous	ranolazine ER PA, QL	ASPRUZYO SPRINKLE PA, QL (ranolazine packet) CAMZYOS PA, QL (mavacamten) CORLANOR PA, QL (ivabradine)	RANEXA PA, QL (ranolazine) VERQUVO PA, QL (vericiguat)

Recommendation

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

COMMITTEE VOTE

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

Prior Authorization criteria for ranolazine ER

Current Criteria:

- Diagnosis of chronic angina; **AND**
- Trial and failure, contraindication, or intolerance to at least ONE agent from TWO of the following classes:
  - Beta-blocker (e.g., atenolol, bisoprolol, metoprolol, propranolol)
  - Long-acting nitrate (e.g., nitroglycerin, isosorbide dinitrate, isosorbide mononitrate)
  - Non-DHP calcium channel blocker (e.g., diltiazem, verapamil); **AND**
- Should NOT be approved for patients with any of the following:
  - Severe Hepatic Impairment
  - Concomitant use of potent CYP3A inhibitors or inducers (e.g., ketoconazole, itraconazole, clarithromycin, nefazodone, ritonavir, nelfinavir, rifampin, barbiturates, carbamazepine, phenytoin, and St. John's Wort)

Proposed Criteria:

Remove PA

COMMITTEE VOTE

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

Prior Authorization criteria for VERQUVO

Current Criteria:

- Diagnosis of symptomatic chronic heart failure (NYHA class II-IV) with reduced ejection fraction (≤45%); **AND**
- Prescribed by, or in consultation with, a cardiologist (initial approval only); **AND**
- Patient has had a heart failure hospitalization in the last 6 months OR has received outpatient IV diuretics for heart failure in the last 3 months; **AND**
- Patient is 18 years of age or older; **AND**
- Patient is currently being treated with an ACEI, ARB, or Entresto; **AND**
- Patient is currently being treated with a beta blocker; **AND**
- Patient does not have severe renal impairment (eGFR < 15 mL/min/1.73m2); **AND**
- Patient does not have severe hepatic impairment (Child-Pugh C); **AND**
- Patient is not pregnant or breastfeeding; **AND**
- Female patients of reproductive potential will be counseled to use effective contraception during treatment with therapy and for at least one month after the last dose; **AND**
- Patient does not meet any of the following:
  - Concomitant use with another soluble guanylate cyclase (sGC) stimulator (e.g., Adempas)
  - Concomitant use with a PDE-5 inhibitor (e.g., tadalafil, sildenafil)

Proposed Criteria:

Initial Criteria:

- Diagnosis of symptomatic chronic heart failure (NYHA class II-IV) with reduced ejection fraction (≤45%); **AND**

- Prescribed by, or in consultation with, a cardiologist (initial approval only); **AND**
- Patient has had a heart failure hospitalization in the last 6 months OR has received outpatient IV diuretics for heart failure in the last 3 months; **AND**
- Patient is 18 years of age or older; **AND**
- Patient is currently being treated with an ACEI, ARB, or Entresto; **AND**
- Patient is currently being treated with a beta blocker; **AND**
- ~~Patient does not have severe renal impairment (eGFR < 15 mL/min/1.73m2);~~ **~~AND~~**
- ~~Patient does not have severe hepatic impairment (Child-Pugh C);~~ **~~AND~~**
- Patient is not pregnant or breastfeeding; **AND**
- Female patients of reproductive potential will be counseled to use effective contraception during treatment with therapy and for at least one month after the last dose; **AND**
- Patient does not meet any of the following:
  - Concomitant use with another soluble guanylate cyclase (sGC) stimulator (e.g., Adempas)
  - Concomitant use with a PDE-5 inhibitor (e.g., tadalafil, sildenafil)

COMMITTEE VOTE

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

Prior Authorization criteria for Aspruzyo Sprinkle

Current Criteria:

See ranolazine ER prior authorization criteria; **AND**

- Patient is unable to swallow solid dosage form

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for Ranexa

Current Criteria:

See ranolazine ER prior authorization criteria; **AND**

- Clinically valid reason as to why the patient cannot take generic ranolazine ER

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for Camzyos

Current Criteria:

Initial Criteria:

- Diagnosis of obstructive hypertrophic cardiomyopathy (HCM); **AND**
- Left ventricular hypertrophy (LVH) confirmed by cardiac imaging (i.e., echocardiography, cardiac MRI); **AND**
- Heart failure is classified New York Heart Association (NYHA) class II or III Patient has New York Heart Association (NYHA) Class II or III symptoms (e.g., shortness of breath, chest pain); **AND**
- Patient has left ventricular outflow tract (LVOT) peak gradient > 50 mmHg at rest or with provocation; **AND**
- Patient has a left ventricular ejection fraction > 55% (for initiation of therapy); **AND**
- Prescribed by or in consultation with a cardiologist; **AND**
- Trial and failure, contraindication, or intolerance to TWO of the following at a maximally tolerated dose:
  - Non-vasodilating beta blocker (e.g., bisoprolol, propranolol)
  - Calcium channel blocker (e.g., verapamil, diltiazem)
  - Disopyramide

Renewal Criteria:

- Documentation of positive clinical response to therapy (e.g., NHYA class remains stable or improves improved symptom relief, improvement of LVOT gradient); **AND**
- Patient has a left ventricular ejection fraction > 50%; **AND**
- Prescribed by, or in consultation with, a cardiologist

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for CORLANOR

Current Criteria:

- Diagnosis of Congestive Heart Failure (NYHA class II to IV) and documentation of the following:
  - Left ventricular ejection fraction ≤ 35%; **AND**
  - In sinus rhythm with resting heart rate ≥ 70 beats per minute; **AND**
  - One of the following:
    - Currently taking a max tolerated dose of a beta-blocker and still experiencing HF symptoms; **OR**
    - Patient has a contraindication, adverse reaction, or drug-drug interaction to a beta-blocker; **OR**
- Diagnosis of Congestive Heart Failure (NYHA class II to IV) due to dilated cardiomyopathy (DCM); **AND**
  - Left ventricular ejection fraction ≤ 45%; **AND**
  - Patient is in sinus rhythm with elevated heart rate; **AND**
- Will **NOT** be approved for patients with any of the following:
  - Concomitant use of potent CYP3A inhibitors or inducers
  - Acute decompensated heart failure
  - Clinically significant hypotension or bradycardia
  - Sick sinus syndrome, sinoatrial block, or 3rd degree AV block, unless a functioning demand pacemaker is present
  - Severe hepatic impairment
  - Pacemaker dependence (heart rate maintained exclusively by the pacemaker)

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Quantity Limits

• ranolazine ER	2/day	• CORLANOR	2/day
• ASPRUZYO SPRINKLE	2/day	• RANEXA	2/day
• CAMZYOS	1/day	• VERQUVO	1/day

COMMITTEE VOTE

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

Discussion and Approval:

A motion to approve the class recommendation, all prior authorization criteria, and quantity limits with modification was made by Dr. Phares, seconded by Dr. Johns, and unanimously carried.

Dr. Phares stated Corlanor is used off label for inappropriate sinus tachycardia very commonly and has some benefit. Dr. Phares asked how to obtain coverage for an off-label indication. Dr. Lovett responded the prescriber would have to file an appeal to obtain a medication for an off-label indication. Dr. Phares asked how long can an appeal take. Dr. Lovett responded an expedited appeal has a 14 day turnaround. Dr. Williams-Clark stated a more emergency appeal can be done within 72 hours.

OPHTHALMIC ANTI-ALLERGICS

Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred	
Ophthalmic Antiallergics	azelastine QL cromolyn sodium QL BEPREVE QL (bepotastine) ketotifen QL olopatadine drops QL (Rx and OTC)	ALOCRIL QL (nedocromil) ALOMIDE QL (lodoxamide) bepotastine QL epinastine QL LASTACAFT QL (alcaftadine)	PATADAY QL (olopatadine) *VERKAZIA PA,QL (cyclosporine 0.1%)* ZADITOR QL (ketotifen) ZERVIATE PA, QL (cetirizine)

Recommendation

It is recommended that at least 2 ophthalmic antihistamines and at least 2 ophthalmic mast stabilizers be available, one of which should be ~~either cromolyn or lodoxamide~~ *indicated* for treatment of vernal conjunctivitis.

COMMITTEE VOTE

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

Prior Authorization criteria for VERKAZIA

Interim Criteria:

Initial Criteria: (6-month duration)

- Diagnosis of moderate to severe vernal keratoconjunctivitis; **AND**
- Trial and failure, contraindication, or intolerance of one agent in ALL the following categories:
  - Ophthalmic antihistamines (e.g., azelastine, olopatadine)
  - Ophthalmic mast cell stabilizers (e.g., cromolyn sodium)
  - Ophthalmic corticosteroids (e.g., dexamethasone, prednisolone, fluorometholone)

Renewal Criteria:

- Patient demonstrates positive clinical response to therapy as evidenced by an improvement in clinical signs and symptoms (e.g., itching, photophobia, papillary hypertrophy, mucus discharge, conjunctival hyperaemia)

Proposed Criteria:

Same as interim criteria

COMMITTEE VOTE

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

Prior Authorization criteria for ZERVIATE

Current Criteria:

- Diagnosis of ocular itching associated with allergic conjunctivitis; **AND**
- Must be 2 years of age or older; **AND**
- Trial and failure of 2 preferred ophthalmic antihistamine; **AND**
- Clinically valid reason as to why patient cannot use a preferred ophthalmic antihistamine product

Proposed Criteria:

- ~~Diagnosis of ocular itching associated with allergic conjunctivitis; **AND**~~
- ~~Must be 2 years of age or older; **AND**~~
- ~~Trial and failure of 2 preferred ophthalmic antihistamine; **AND**~~
- Clinically valid reason as to why patient cannot use a preferred ophthalmic antihistamine product

COMMITTEE VOTE

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

Quantity Limits

• ALOCRIL	1 package/Rx	• olopatadine	5 mL/Rx
• ALOMIDE	1 package/Rx	• PATADAY	5 mL/Rx
• azelastine	6 mL/Rx	• epinastine	5 mL/Rx
• cromolyn sodium	1 package/Rx	• LASTACAFT	3 mL/Rx
• bepotastine	10mL/Rx	• *VERKAZIA*	*120/30 days*
• BEPREVE	10mL/Rx	• ZADITOR	10 mL/Rx
• ketotifen	10mL/Rx	• ZERVIATE	30 vials/Rx

COMMITTEE VOTE

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

Discussion and Approval:

A motion to approve the class recommendation, all prior authorization criteria, and quantity limits was made by Dr. Rhea, seconded by Dr. Alston, and unanimously carried.

Dr. Rhea asked if cromolyn is still available over the counter. Dr. Kiriakopoulos stated cromolyn eye drop is only available as prescription drug.

OPHTHALMIC NSAIDS

Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred	
Ophthalmic NSAIDS	diclofenac ~~PA~~, QL flurbiprofen ~~PA~~, QL ketorolac ~~PA~~, QL	ACULAR (ketorolac) ACULAR LS QL (ketorolac) ACUVAIL QL (ketorolac) bromfenac QL	BROMSITE QL (bromfenac) ILEVRO QL (nepafenac) NEVANAC QL (nepafenac) PROLENSA QL (bromfenac)

Recommendation

~~It is recommended that ophthalmic NSAIDs be reserved for patients for whom corticosteroid monotherapy is not appropriate~~. *It is recommended that at least 2 ophthalmic NSAIDs are available for use.*

COMMITTEE VOTE

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

Prior Authorization criteria for diclofenac, flurbiprofen, ketorolac

Current Criteria:

One of the following:

- Recipient has a contraindication, intolerance, or adverse reaction to an ophthalmic steroid (i.e., prednisolone). Acceptable reasons for not using an ophthalmic steroid (not inclusive):
  - Potential increase in intraocular pressure (IOP) with ophthalmic steroids that would place the patient at risk (i.e., glaucoma, pre/post-cataract surgery)
  - Concerns that the steroid would impair wound healing
  - Concerns that the steroid may cause/induce infection due to immunosuppression.
- Use of the agent is for pain pre/post-ocular surgery
- Concomitant use of an ophthalmic steroid and an ophthalmic NSAID is needed to control inflammation

Proposed Criteria:

Remove PA

COMMITTEE VOTE

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

Quantity Limits

• diclofenac	1 package/Rx
• flurbiprofen	1 package/Rx
• ketorolac	1 package/Rx
• ACUVAIL	1 package/Rx
• bromfenac	1 package/Rx
• BROMSITE	1 package/Rx
• ILEVRO	1 package/Rx
• NEVANAC	1 package/Rx
• PROLENSA	1 package/Rx

COMMITTEE VOTE

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

Discussion and Approval:

A motion to approve the class recommendation, all prior authorization criteria, and quantity limits was made by Dr. Rhea, seconded by Dr. Close, and unanimously carried.

~~Ophthalmic Immunomodulators~~ Dry Eye Disease Agents

Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred
Ophthalmic Immunomodulators	Lacrisert ~~PA~~ (hydroxypropyl cellulose) Restasis PA, QL (cyclosporine emulsion 0.05%) Xiidra PA, QL (lifitegrast soln 5%)	Cequa PA, QL (cyclosporine solution 0.09%) cyclosporine emulsion 0.05% PA,QL *Miebo PA, QL (perfluorohexyloctane)* Restasis multidose PA (cyclosporine emulsion 0.05%) Tyrvaya (varenicline nasal spray) PA, QL

Recommendation

Ophthalmic Dry Eye Disease

It is recommended that ophthalmic cyclosporine and at least one other agent be available for use.

~~**Ophthalmic Immunomodulators**~~

~~It is recommended that cyclosporine ophthalmic emulsion at least one ophthalmic immunomodulator is available subject to clinical criteria to ensure appropriate use.~~

~~**Ophthalmic Lubricants and Artificial Tears**~~

~~It is recommended that at least one prescription ophthalmic lubricant be available.~~

COMMITTEE VOTE

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

Prior Authorization criteria for Lacrisert

Current Criteria:

- Patient has diagnosis of Dry Eye Syndrome, Keratoconjunctivitis Sicca, or acute Keratoconjunctivitis; **AND**
- Patient has experienced therapeutic failure with Restasis in the previous 60 days

Proposed Criteria:

Remove PA

COMMITTEE VOTE

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

Prior Authorization criteria for Restasis

Current Criteria:

- One of the following:
  - Treatment of severe atopic keratoconjunctivitis; **AND**
    - Trial and failure, contraindication, or intolerance of TWO ophthalmic steroids
  - Treatment of moderate to severe keratoconjunctivitis sicca (KCS); **AND**
    - Trial and failure of ONE of the following:
      - Artificial tear drops or ointments administered at least 4x/day
      - Punctal plugs
  - Treatment of dry eyes in recipients with Sjögren's disease
  - Recipients is using the agent post corneal transplant

Proposed Criteria:

- ~~One of the following:~~
  - Treatment of *vernal keratoconjunctivitis (VKC)* (i.e. severe atopic keratoconjunctivitis); ~~**AND**~~ ***OR***
    - ~~Trial and failure, contraindication, or intolerance of TWO ophthalmic steroids~~
  - *Diagnosis of dry eye disease (i.e. dry eye syndrome, keratoconjunctivitis sicca)* ~~Treatment of moderate to severe keratoconjunctivitis sicca (KCS); **AND**~~

- ~~Trial and failure of ONE of the following:~~
  - ~~Artificial tear drops or ointments administered at least 4x/day~~
  - ~~Punctal plugs~~
- ~~Treatment of dry eyes in recipients with Sjögren's disease~~
- ~~Recipients is using the agent post corneal transplant~~

COMMITTEE VOTE

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

Prior Authorization criteria for Xiidra

Current Criteria:

- Diagnosis of severe keratoconjunctivitis sicca (KCS); **AND**
- Trial and failure of ONE of the following:
  - Artificial tear drops or ointments administered at least 4x/day
  - Punctal plugs; **AND**
- Trial and failure or contraindication to Restasis (trial duration ≥12 weeks confirmed by paid claims)

Proposed Criteria:

- Diagnosis of *dry eye disease (i.e., dry eye syndrome, keratoconjunctivitis sicca)* ~~severe keratoconjunctivitis sicca (KCS)~~; **AND**:
  - ~~Artificial tear drops or ointments administered at least 4x/day~~
  - ~~Punctal plugs; **AND**~~
- Trial and failure or contraindication to Restasis (trial duration ≥12 weeks confirmed by paid claims)

COMMITTEE VOTE

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

Prior Authorization criteria for cyclosporine emulsion 0.05%, Restasis Multidose

Current Criteria:

- One of the following:
  - Treatment of severe atopic keratoconjunctivitis; **AND**
    - Trial and failure, contraindication, or intolerance of TWO ophthalmic steroids
  - Treatment of moderate to severe keratoconjunctivitis sicca (KCS); **AND**
    - Trial and failure of ONE of the following:
      - Artificial tear drops or ointments administered at least 4x/day
      - Punctal plugs
  - Treatment of dry eyes in recipients with Sjögren's disease
  - Recipients is using the agent post corneal transplant; **AND**
- Clinically valid reason for why patient cannot use Restasis

Proposed Criteria:

- One of the following:
  - Treatment of *vernal keratoconjunctivitis (VKC)* (i.e., severe atopic keratoconjunctivitis); ~~**AND**~~ ***OR***
    - ~~Trial and failure, contraindication, or intolerance of TWO ophthalmic steroids~~
  - *Diagnosis of dry eye disease (i.e., dry eye syndrome, keratoconjunctivitis sicca)* ~~Treatment of moderate to severe keratoconjunctivitis sicca (KCS)~~; **AND**
    - *Trial and failure or contraindication to Xiidra (trial duration >12 weeks confirmed by paid claims);* ***AND***
    - ~~Trial and failure of ONE of the following:~~
      - ~~Artificial tear drops or ointments administered at least 4x/day~~
      - ~~Punctal plugs~~
  - ~~Treatment of dry eyes in recipients with Sjögren's disease~~
  - ~~Recipients is using the agent post corneal transplant; **AND**~~
- Clinically valid reason for why patient cannot use *the preferred* Restasis

COMMITTEE VOTE

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

Prior Authorization criteria for CEQUA

Current Criteria:

- Diagnosis of severe keratoconjunctivitis sicca (KCS); **AND**
- Trial and failure of ONE of the following:
  - Artificial tear drops or ointments administered at least 4x/day
  - Punctal plugs; **AND**
- Trial and failure or contraindication to Restasis® (trial duration ≥12 weeks confirmed by paid claims)

Proposed Criteria:

- Diagnosis of dr*y eye disease (i.e., dry eye syndrome, keratoconjunctivitis sicca)* ~~severe keratoconjunctivitis sicca (KCS)~~; **AND**
- ~~Trial and failure of ONE of the following:~~
  - ~~Artificial tear drops or ointments administered at least 4x/day~~
  - ~~Punctal plugs; **AND**~~
- Trial and failure, or contraindication, to *both* Restasis *and* Xiidra (trial duration *of each agen*t ≥ 12 weeks confirmed by paid claims)

COMMITTEE VOTE

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

Prior Authorization criteria for MIEBO

Interim Criteria:

- Diagnosis of dry eye disease (i.e., dry eye syndrome, keratoconjunctivitis sicca); **AND**
- Trial and failure, or contraindication, to both Restasis and Xiidra (trial duration of each agent > 12 weeks confirmed by paid claims)

Proposed Criteria:

Same as interim

COMMITTEE VOTE

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

Prior Authorization criteria for TYRVAYA

Current Criteria:

- Diagnosis of dry eye disease; **AND**
- Patient is ≥ 18 years of age or older; **AND**
- Prescribed by or in consultation with an ophthalmologist or optometrist; **AND**
- Patient has at least one positive diagnostic test (e.g., tear breakup time, tear film osmolarity, ocular surface staining, Schirmer test, etc.); **AND**
- Patient has a trial and failure, contraindication, or intolerance to Restasis

Proposed Criteria:

- Diagnosis of dry eye disease *(i.e., dry eye syndrome, keratoconjunctivitis sicca)*; **AND**
- ~~Patient is ≥ 18 years of age or older; **AND**~~
- ~~Prescribed by or in consultation with an ophthalmologist or optometrist; **AND**~~
- ~~Patient has at least one positive diagnostic test (e.g., tear breakup time, tear film osmolarity, ocular surface staining, Schirmer test, etc.); **AND**~~
- Trial and failure, or contraindication, to *both* Restasis *and Xiidra (trial duration of each agent > 12 weeks confirmed by paid claims)*

COMMITTEE VOTE

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

Quantity Limits

• CEQUA	2 vials/day
• cyclosporine emulsion	60 vials/30 days
• *MIEBO*	*3 bottles/30 days*
• LACRISERT	*60 inserts/30 days*
• RESTASIS	60 vials/30 days
• RESTASIS MULTIDOSE	*1 bottle/30 days*
• XIIDRA	2 vials/day

COMMITTEE VOTE

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

Discussion and Approval:

A motion to approve the class recommendation, all prior authorization criteria, and quantity limits was made by Dr. Capparelli, seconded by Dr. Johns, and unanimously carried.

OPHTHALMIC PROSTAGLANDIN AGENTS

Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred	
Ophthalmic Prostaglandin Agents	latanoprost QL LUMIGAN QL (bimatoprost) TRAVATAN Z QL (travoprost) ZIOPTAN QL (tafluprost)	bimatoprost QL IYUZEH (latanoprost PF) tafluprost QL travoprost PA, QL	VYZULTA ~~PA~~, QL (latanoprostene bunod) XALATAN QL (latanoprost) XELPROS ~~PA~~, QL (latanoprost)

Recommendation

It is recommended that at least 2 distinct ophthalmic prostaglandin analogues are available for use.

COMMITTEE VOTE

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

Prior Authorization criteria for VYZULTA

Current Criteria:

Initial Criteria:

- Patient has a diagnosis of open-angle glaucoma or ocular hypertension; **AND**
- Patient does not have any hypersensitivity to latanoprostene bunod or its derivatives (e.g., latanoprost); **AND**
- Patient has had an adequate trial and failure of at least 2 preferred ophthalmic prostaglandin agents

Renewal Criteria:

- Continue to meet the initial criteria; **AND**
- Documented efficacy as defined by decrease in, or sustained lowering of, intraocular pressure; **AND**
- Patient has not experienced any treatment-restricting adverse effects (e.g., significant conjunctival hyperemia, eye irritation, eye pain, and instillation site pain).

Proposed Criteria:

Remove PA

COMMITTEE VOTE

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

Prior Authorization criteria for XELPROS

Current Criteria:

Initial Criteria:

- Patient has a diagnosis of open-angle glaucoma or ocular hypertension; **AND**
- Patient does not have any hypersensitivity to latanoprost; **AND**
- Patient has an allergy or contraindication to benzalkonium chloride (BAK)

Renewal Criteria:

- Continue to meet the initial criteria; **AND**
- Documented efficacy as defined by decrease in, or sustained lowering of, intraocular pressure; **AND**
- Patient has not experienced any treatment-restricting adverse effects (e.g., significant conjunctival hyperemia, eye irritation, eye pain, and instillation site pain)

Proposed Criteria:

Remove PA

COMMITTEE VOTE

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

Prior Authorization criteria for IYUZEH

Current Criteria:

- Clinically valid reason why preferred TRAVATAN Z cannot be used

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for travoprost

Current Criteria:

- Clinically valid reason why preferred TRAVATAN Z cannot be used

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Quantity Limits

• latanoprost	5mL/Rx
• LUMIGAN 0.01%	5mL/Rx
• *IYUZEH*	*1 containers/day*
• ZIOPTAN	1 container/day
• bimatoprost 0.03%	5mL/Rx
• tafluprost	1 container/day
• TRAVATAN Z	5mL/Rx
• *travoprost*	*5ml/Rx*
• VYZULTA	5mL/Rx
• XALATAN	5mL/Rx
• XELPROS	5mL/Rx

COMMITTEE VOTE

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

Discussion and Approval:

A motion to approve the class recommendation, all prior authorization criteria, and quantity limits was made by Dr. Williams-Clark, seconded by Dr. Close, and unanimously carried.

LONG-ACTING NARCOTICS

Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred	
Long-Acting Narcotics	fentanyl patch 12, 25, 50, 75, & 100 mcg/hr PA, QL morphine ER tabs PA, QL NUCYNTA ER PA, QL (tapentadol)	BELBUCA PA, QL (buprenorphine buccal film) buprenorphine patch PA, QL BUTRANS PA, QL (buprenorphine patch) CONZIP PA, QL (tramadol ER capsule) fentanyl patch 37.5, 62.5, & 87.5mcg/hr PA, QL hydrocodone ER caps and tabs PA, QL hydromorphone ER PA, QL HYSINGLA ER PA, QL (hydrocodone ER tabs) methadone PA, QL METHADOSE PA, QL (methadone tabs and conc)	morphine ER capsules PA, QL morphine ER tabs PA, QL MS CONTIN PA, QL (morphine ER tabs) oxycodone ER PA, QL OXYCONTIN PA, QL (oxycodone ER tabs) oxymorphone ER PA, QL tramadol ER PA, QL XTAMPZA ER PA, QL (oxycodone ER caps) ZOHYDRO ER PA, QL (hydrocodone ER caps)

Recommendation

Therefore, it is recommended that at least long-acting morphine and one transdermal formulation should be available. Additionally due to the risk of abuse and misuse, it is recommended that a combination of the CDC Guidelines for prescribing opioids for chronic pain and the Tennessee Chronic Pain Guidelines be implemented as a guideline for managing utilization in this class, including implementation of a daily MME limit.

COMMITTEE VOTE

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

Prior Authorization criteria for morphine ER tabs, fentanyl patch, morphine ER capsules, MS CONTIN, hydromorphone ER, Hysingla ER, Zohydro ER, oxycodone ER, OXYCONTIN, XTAMPZA ER

Current Criteria:

- Prescriber must have checked the Tennessee Controlled Substance Database for this patient within the last 7 days; **AND**
- Pain agreement required for all PA required agents. Please refer to the Opioid and Controlled Substance Agreement document located at: Patient Medication Management Agreement; **AND**
- Concomitant use of benzodiazepines and opioids will only be approved under the care of, or referral to, a mental health provider; **AND**
- Requests for ≥ 90 MME per day [Please refer to TennCare MME Conversion Chart]:
  - Recipient must be opioid tolerant (as demonstrated by at least a week or longer history of morphine 60 mg/day or more, oral oxycodone 30 mg/day or more, oral hydromorphone 8 mg/day or more, or an equianalgesic dose of another opioid); **AND**
- Female of child-bearing age (14-44 years):
  - Is not pregnant; **AND**
  - Using contraception (e.g., barrier, oral contraceptive, rhythm method); **OR**
  - Has an intrauterine device (IUD) or implant; **OR**
  - Has history of hysterectomy, tubal ligation, or endometrial ablation
- The following should be investigated before a PA is granted:
  - History of substance abuse
  - Frequent requests for early refills
  - Reported frequent instances of lost tablets
  - Requests for odd quantities which requires fractional dosing
  - Requests for short-term or prn usage
  - Medication history indicates concurrent use of other extended-release opioids; **AND**

- Additionally, approval of non-preferred agents in the Long-Acting Narcotics class requires contraindication, drug to drug interaction, or history of toxic side effects that cause immediate or long-term damage (**Note**: This does not include GI intolerance) with ALL preferred agents, unless otherwise indicated.

Note: Use of opioid analgesics during pregnancy has been associated with Neonatal Opioid Withdrawal Syndrome. Providers MUST counsel women of childbearing age regarding the risks of becoming pregnant while receiving opioids, including the risk of Neonatal Opioid Withdrawal Syndrome. Providers should offer access to contraceptive services when necessary.

Proposed Criteria:

- *Management of severe pain with need for around-the-clock analgesia for an extended period;* ***AND***
- Prescriber must have checked the Tennessee Controlled Substance Database for this patient within the last 7 days; **AND**
- Pain agreement required for all PA required agents. Please refer to the Opioid and Controlled Substance Agreement document located at: Patient Medication Management Agreement
- Concomitant use of benzodiazepines and opioids will only be approved under the care of, or referral to, a mental health provider; **AND**
- Requests for ≥ 90 MME per day [Please refer to TennCare MME Conversion Chart]:
  - Recipient must be opioid tolerant (as demonstrated by at least a week or longer history of morphine 60 mg/day or more, oral oxycodone 30 mg/day or more, oral hydromorphone 8 mg/day or more, or an equianalgesic dose of another opioid); **AND**
- Female of child-bearing age (14-44 years):
  - Is not pregnant; **AND**
  - Using contraception (e.g., barrier, oral contraceptive, rhythm method); **OR**
  - Has an intrauterine device (IUD) or implant; **OR**
  - Has history of hysterectomy, tubal ligation, or endometrial ablation
- The *prescriber attests to investigating ALL of the following before submitting a PA:* ~~following should be investigated before a PA is granted:~~
  - History of substance abuse
  - Frequent requests for early refills
  - Reported frequent instances of lost tablets
  - Requests for odd quantities which requires fractional dosing
  - Requests for short-term or prn usage
  - Medication history indicates concurrent use of other extended-release opioids; **AND**
- Additionally, approval of non-preferred agents in the Long-Acting Narcotics class requires contraindication, drug to drug interaction, or history of toxic side effects that cause immediate or long-term damage (**Note**: This does not include GI intolerance) with ALL preferred agents, unless otherwise indicated.

Note: Use of opioid analgesics during pregnancy has been associated with Neonatal Opioid Withdrawal Syndrome. Providers MUST counsel women of childbearing age regarding the risks of becoming pregnant while receiving opioids, including the risk of Neonatal Opioid Withdrawal Syndrome. Providers should offer access to contraceptive services when necessary.

COMMITTEE VOTE

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

Prior Authorization criteria for NUCYNTA ER

Current Criteria:

- Management of severe pain with need for around-the-clock analgesia for an extended period; **AND**
- Prescriber must have checked the Tennessee Controlled Substance Database for this patient within the last 7 days; **AND**
- Pain agreement required for all PA required agents. Please refer to the Opioid and Controlled Substance Agreement document located at: Patient Medication Management Agreement; **AND**
- Concomitant use of benzodiazepines and opioids will only be approved under the care of, or referral to, a mental health provider; **AND**

- Requests for ≥ 90 MME per day [Please refer to TennCare MME Conversion Chart]:
  - Recipient must be opioid tolerant (as demonstrated by at least a week or longer history of morphine 60 mg/day or more, oral oxycodone 30 mg/day or more, oral hydromorphone 8 mg/day or more, or an equianalgesic dose of another opioid); **AND**
- Female of child-bearing age (14-44 years):
  - Is not pregnant; **AND**
  - Using contraception (e.g., barrier, oral contraceptive, rhythm method); **OR**
  - Has an intrauterine device (IUD) or implant; **OR**
  - Has history of hysterectomy, tubal ligation, or endometrial ablation
- The following should be investigated before a PA is granted:
  - History of substance abuse
  - Frequent requests for early refills
  - Reported frequent instances of lost tablets
  - Requests for odd quantities which requires fractional dosing
  - Requests for short-term or prn usage
  - Medication history indicates concurrent use of other extended-release opioids
  - Approval for patients with a known addiction to the drug should be granted only if the prescriber has a documented plan to reduce the dosage and eventually wean the patient off the drug entirely.

Note: Use of opioid analgesics during pregnancy has been associated with Neonatal Opioid Withdrawal Syndrome. Providers **MUST** counsel women of childbearing age regarding the risks of becoming pregnant while receiving opioids, including the risk of Neonatal Opioid Withdrawal Syndrome. Providers should offer access to contraceptive services when necessary.

Proposed Criteria:

- Management of severe pain with need for around-the-clock analgesia for an extended period; **AND**
- Prescriber must have checked the Tennessee Controlled Substance Database for this patient within the last 7 days; **AND**
- Pain agreement required for all PA required agents. Please refer to the Opioid and Controlled Substance Agreement document located at: Patient Medication Management Agreement; **AND**
- Concomitant use of benzodiazepines and opioids will only be approved under the care of, or referral to, a mental health provider; **AND**
- Requests for ≥ 90 MME per day [Please refer to TennCare MME Conversion Chart]:
  - Recipient must be opioid tolerant (as demonstrated by at least a week or longer history of morphine 60 mg/day or more, oral oxycodone 30 mg/day or more, oral hydromorphone 8 mg/day or more, or an equianalgesic dose of another opioid); **AND**
- Female of child-bearing age (14-44 years):
  - Is not pregnant; **AND**
  - Using contraception (e.g., barrier, oral contraceptive, rhythm method); **OR**
  - Has an intrauterine device (IUD) or implant; **OR**
  - Has history of hysterectomy, tubal ligation, or endometrial ablation
- The *prescriber attests to investigating ALL of the following before submitting a PA:* ~~The following should be investigated before a PA is granted:~~
  - History of substance abuse
  - Frequent requests for early refills
  - Reported frequent instances of lost tablets
  - Requests for odd quantities which requires fractional dosing
  - Requests for short-term or prn usage
  - Medication history indicates concurrent use of other extended-release opioids
  - ~~Approval for patients with a known addiction to the drug should be granted only if the prescriber has a documented plan to reduce the dosage and eventually wean the patient off the drug entirely.~~

Note: Use of opioid analgesics during pregnancy has been associated with Neonatal Opioid Withdrawal Syndrome. Providers **MUST** counsel women of childbearing age regarding the risks of becoming pregnant while

receiving opioids, including the risk of Neonatal Opioid Withdrawal Syndrome. Providers should offer access to contraceptive services when necessary.

COMMITTEE VOTE

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

Prior Authorization criteria for BELBUCA

Current Criteria:

- Diagnosis of moderate to severe pain with need for around-the-clock analgesia for an extended period; **AND**
- Prescriber has checked the Tennessee Controlled Substance Database for this patient within the last 7 days; **AND**
- Patients who have not been titrated down to no more than 30 mg morphine (or morphine equivalents) per day will NOT be approved; **AND**
- Pain agreement required for all PA required agents. Please refer to the Opioid and Controlled Substance Agreement document located at: Patient Medication Management Agreement; ***AND***
- Concomitant use of benzodiazepines and opioids will only be approved under the care of, or referral to, a mental health provider; **AND**
- Female of child-bearing age (14-44 years):
  - Is not pregnant; **AND**
  - Using contraception (e.g., barrier, oral contraceptive, rhythm method); **OR**
  - Has an intrauterine device (IUD) or implant; **OR**
  - Has history of hysterectomy, tubal ligation, or endometrial ablation
- Additionally, approval of non-preferred agents in the Long-Acting Narcotics class requires contraindication, drug to drug interaction, or history of toxic side effects that cause immediate or long-term damage (**Note**: This does not include GI intolerance) with ALL preferred agents, unless otherwise indicated.
- The following should be investigated before a PA is granted:
  - History of substance abuse
  - Frequent requests for early refills
  - Reported frequent instances of lost tablets
  - Requests for odd quantities which requires fractional dosing
  - Requests for short-term or prn usage
  - Medication history indicates concurrent use of other extended-release opioids

Note: Use of opioid analgesics during pregnancy has been associated with Neonatal Opioid Withdrawal Syndrome. Providers **MUST** counsel women of childbearing age regarding the risks of becoming pregnant while receiving opioids, including the risk of Neonatal Opioid Withdrawal Syndrome. Providers should offer access to contraceptive services when necessary

Proposed Criteria:

- ~~Diagnosis of~~ *Management of* ~~moderate to~~ severe pain with need for around-the-clock analgesia for an extended period; **AND**
- Prescriber has checked the Tennessee Controlled Substance Database for this patient within the last 7 days; **AND**
- Patients who have not been titrated down to no more than 30 mg morphine (or morphine equivalents) per day will NOT be approved; **AND**
- Pain agreement required for all PA required agents. Please refer to the Opioid and Controlled Substance Agreement document located at: Patient Medication Management Agreement; ***AND***
- Concomitant use of benzodiazepines and opioids will only be approved under the care of, or referral to, a mental health provider; ***AND***
- Female of child-bearing age (14-44 years):
  - Is not pregnant; **AND**
  - Using contraception (e.g., barrier, oral contraceptive, rhythm method); **OR**
  - Has an intrauterine device (IUD) or implant; **OR**

- Has history of hysterectomy, tubal ligation, or endometrial ablation
- Additionally, approval of non-preferred agents in the Long-Acting Narcotics class requires contraindication, drug to drug interaction, or history of toxic side effects that cause immediate or long-term damage (**Note**: This does not include GI intolerance) with ALL preferred agents, unless otherwise indicated; **AND**
- *The prescriber attests to investigating all of following before submitting a PA:* ~~should be investigated is granted~~:
  - History of substance abuse
  - Frequent requests for early refills
  - Reported frequent instances of lost tablets
  - Requests for odd quantities which requires fractional dosing
  - Requests for short-term or prn usage
  - Medication history indicates concurrent use of other extended-release opioids

Note: Use of opioid analgesics during pregnancy has been associated with Neonatal Opioid Withdrawal Syndrome. Providers **MUST** counsel women of childbearing age regarding the risks of becoming pregnant while receiving opioids, including the risk of Neonatal Opioid Withdrawal Syndrome. Providers should offer access to contraceptive services when necessary.

COMMITTEE VOTE

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

Prior Authorization criteria for ConZip, tramadol ER

Current Criteria:

- Management of severe pain with need for around-the-clock analgesia for an extended period; **AND**
- Prescriber must have checked the Tennessee Controlled Substance Database for this patient within the last 7 days; **AND**
- Pain agreement required for all PA required agents. Please refer to the Opioid and Controlled Substance Agreement document located at: Patient Medication Management Agreement; **AND**
- Concomitant use of benzodiazepines and opioids will only be approved under the care of, or referral to, a mental health provider.; **AND**
- Female of child-bearing age (14-44 years):
  - Is not pregnant or breastfeeding; **AND**
  - Using contraception (e.g., barrier, oral contraceptive, rhythm method); **OR**
  - Has an intrauterine device (IUD) or implant; **OR**
  - Has history of hysterectomy, tubal ligation, or endometrial ablation; **AND**
- Additionally, approval of non-preferred agents in the Long-Acting Narcotics class requires contraindication, drug to drug interaction, or history of toxic side effects that cause immediate or long-term damage (Note: This does not include GI intolerance) with ALL preferred agents, unless otherwise indicated; **AND**
- The following should be investigated before a PA is granted:
  - History of substance abuse
  - Frequent requests for early refills
  - Reported frequent instances of lost tablets
  - Requests for odd quantities which requires fractional dosing
  - Requests for short-term or prn usage
  - Medication history indicates concurrent use of other extended-release opioids; **AND**
- If patient is 12 to 18 years of age: [For patients less than 12 years of age, approval will not be granted.]
  - Patient does not have any of the following:
    - Obesity (BMI ≥ 30)
    - Obstructive Sleep Apnea
    - Severe Lung Disease (acute or severe asthma, COPD, Cystic Fibrosis, hypoxemia, hypercapnia, pneumonia, pulmonary hypertension, etc.)
    - Recent adenectomy/tonsillectomy; **AND**
  - Trial and failure or contraindication to acetaminophen; **AND**

- Trial and failure or contraindication to ALL NSAIDs

Note: Use of opioid analgesics during pregnancy has been associated with Neonatal Opioid Withdrawal Syndrome. Providers MUST counsel women of childbearing age regarding the risks of becoming pregnant while receiving opioids, including the risk of Neonatal Opioid Withdrawal Syndrome. Providers should offer access to contraceptive services when necessary.

Proposed Criteria:

- Management of severe pain with need for around-the-clock analgesia for an extended period; **AND**
- Prescriber must have checked the Tennessee Controlled Substance Database for this patient within the last 7 days; **AND**
- Pain agreement required for all PA required agents. Please refer to the Opioid and Controlled Substance Agreement document located at: Patient Medication Management Agreement; **AND**
- Concomitant use of benzodiazepines and opioids will only be approved under the care of, or referral to, a mental health provider; **AND**
- Female of child-bearing age (14-44 years):
  - Is not pregnant or breastfeeding; **AND**
  - Using contraception (e.g., barrier, oral contraceptive, rhythm method); **OR**
  - Has an intrauterine device (IUD) or implant; **OR**
  - Has history of hysterectomy, tubal ligation, or endometrial ablation; **AND**
- Additionally, approval of non-preferred agents in the Long-Acting Narcotics class requires contraindication, drug to drug interaction, or history of toxic side effects that cause immediate or long-term damage (Note: This does not include GI intolerance) with ALL preferred agents, unless otherwise indicated; **AND**
- The *prescriber attests to investigating ALL of the following before submitting a PA:* ~~should be investigated is granted~~:
  - History of substance abuse
  - Frequent requests for early refills
  - Reported frequent instances of lost tablets
  - Requests for odd quantities which requires fractional dosing
  - Requests for short-term or prn usage
  - Medication history indicates concurrent use of other extended-release opioids; **AND**
- If patient is 12 to 18 years of age: [For patients less than 12 years of age, approval will not be granted.]
  - Patient does not have any of the following:
    - Obesity (BMI ≥ 30)
    - Obstructive Sleep Apnea
    - Severe Lung Disease (acute or severe asthma, COPD, Cystic Fibrosis, hypoxemia, hypercapnia, pneumonia, pulmonary hypertension, etc.)
    - Recent adenectomy/tonsillectomy; **AND**
  - Trial and failure or contraindication to acetaminophen; **AND**
  - Trial and failure or contraindication to ALL NSAIDs

Note: Use of opioid analgesics during pregnancy has been associated with Neonatal Opioid Withdrawal Syndrome. Providers MUST counsel women of childbearing age regarding the risks of becoming pregnant while receiving opioids, including the risk of Neonatal Opioid Withdrawal Syndrome. Providers should offer access to contraceptive services when necessary.

COMMITTEE VOTE

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

Prior Authorization criteria for methadone, METHADOSE

Current Criteria:

- Diagnosis of Metastatic Neoplasia; **OR**
- Infants up to 1 year of age who are discharged from the hospital on a methadone taper will be approved for up to 30 days; **OR**
- Diagnosis of chronic severe pain **AND** patient has contraindication to all other long-acting opioids; **AND**

- Patient is not presently taking any other single entity immediate release or extend release opioids, barbiturates, carisoprodol or meprobamate; **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 7 days; **AND**
- Pain agreement required for all PA required agents. Please refer to the Opioid and Controlled Substance Agreement document located at: Patient Medication Management Agreement
- Concomitant use of benzodiazepines & opioids will only be approved under the care of, or referral to, a mental health provider
- Female of child-bearing age (14-44 years):
  - Is not pregnant; AND
  - Using contraception (e.g., barrier, oral contraceptive, rhythm method); OR
  - Has an intrauterine device (IUD) or implant; OR
  - Has history of hysterectomy, tubal ligation, or endometrial ablation
- Requests for ≥ 90 MME per day [Please refer to TennCare MME Conversion Chart]:
  - Recipient must be opioid tolerant (as demonstrated by at least a week or longer history of morphine 60 mg/day or more, oral oxycodone 30 mg/day or more, oral hydromorphone 8 mg/day or more, or an equianalgesic dose of another opioid); **AND**
- The following should be investigated before a PA is granted:
  - History of substance abuse
  - Frequent requests for early refills
  - Reported frequent instances of lost tablets
  - Requests for odd quantities which requires fractional dosing
  - Requests for short-term or prn usage
  - Medication history indicates concurrent use of other extended-release opioids

Note: TennCare does not cover any form of methadone for the treatment of opioid addiction. Use of opioid analgesics during pregnancy has been associated with Neonatal Opioid Withdrawal Syndrome. Providers MUST counsel women of childbearing age regarding the risks of becoming pregnant while receiving opioids, including the risk of Neonatal Opioid Withdrawal Syndrome. Providers should offer access to contraceptive services when necessary

Proposed Criteria:

- Diagnosis of Metastatic Neoplasia; **OR**
- Infants up to 1 year of age who are discharged from the hospital on a methadone taper will be approved for up to 30 days; **OR**
- ~~Diagnosis of~~ *Management of* ~~chronic~~ severe pain *with need for around-the-clock analgesia for an extended period* **AND** patient has contraindication to all other long-acting opioids; **AND**
- ~~Patient is not presently taking any other single entity immediate release or extend release opioids, barbiturates, carisoprodol or meprobamate; **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 7 days; **AND**
- Pain agreement required for all PA required agents. Please refer to the Opioid and Controlled Substance Agreement document located at: Patient Medication Management Agreement; **AND**
- Concomitant use of benzodiazepines & opioids will only be approved under the care of, or referral to, a mental health provider; **AND**
- Requests for ≥ 90 MME per day [Please refer to TennCare MME Conversion Chart]:
  - Recipient must be opioid tolerant (as demonstrated by at least a week or longer history of morphine 60 mg/day or more, oral oxycodone 30 mg/day or more, oral hydromorphone 8 mg/day or more, or an equianalgesic dose of another opioid); **AND**
- Female of child-bearing age (14-44 years):
  - Is not pregnant; AND
  - Using contraception (e.g., barrier, oral contraceptive, rhythm method); OR

- Has an intrauterine device (IUD) or implant; OR
- Has history of hysterectomy, tubal ligation, or endometrial ablation

- *The prescriber attests to investigating ALL of following before submitting a PA:* ~~should be investigated is granted:~~
  - History of substance abuse
  - Frequent requests for early refills
  - Reported frequent instances of lost tablets
  - Requests for odd quantities which requires fractional dosing
  - Requests for short-term or prn usage
  - Medication history indicates concurrent use of other extended-release opioids; **AND**
- Additionally, approval of non-preferred agents in the Long-Acting Narcotics class requires contraindication, drug to drug interaction, or history of toxic side effects that cause immediate or long-term damage (Note: This does not include GI intolerance) with ALL preferred agents, unless otherwise indicated.

Note: TennCare does not cover any form of methadone for the treatment of opioid addiction. Use of opioid analgesics during pregnancy has been associated with Neonatal Opioid Withdrawal Syndrome. Providers MUST counsel women of childbearing age regarding the risks of becoming pregnant while receiving opioids, including the risk of Neonatal Opioid Withdrawal Syndrome. Providers should offer access to contraceptive services when necessary

COMMITTEE VOTE

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

Prior Authorization criteria for oxymorphone ER

Current Criteria:

- Trial and failure, contraindication, intolerance, or drug-drug interaction with extended-release morphine; **AND**
- The prescriber has checked the Tennessee Controlled Substance Database for this patient within the last 7 days; **AND**
- Pain agreement required for all PA required agents. Please refer to the Opioid and Controlled Substance Agreement document located at: Patient Medication Management Agreement
- Concomitant use of benzodiazepines and opioids will only be approved under the care of, or referral to, a mental health provider; **AND**
- Requests for ≥ 90 MME per day [Please refer to TennCare MME Conversion Chart]:
  - Recipient must be opioid tolerant (as demonstrated by at least a week or longer history of morphine 60 mg/day or more, oral oxycodone 30 mg/day or more, oral hydromorphone 8 mg/day or more, or an equianalgesic dose of another opioid); **AND**
- Female of child-bearing age (14-44 years):
  - Is not pregnant; **AND**
  - Using contraception (e.g., barrier, oral contraceptive, rhythm method); **OR**
  - Has an intrauterine device (IUD) or implant; **OR**
  - Has history of hysterectomy, tubal ligation, or endometrial ablation
- Additionally, approval of non-preferred agents in the Long-Acting Narcotics class requires contraindication, drug to drug interaction, or history of toxic side effects that cause immediate or long-term damage (**NOTE**: This does not include GI intolerance) with ALL preferred agents, unless otherwise indicated.
- The following should be investigated before a PA is granted:
  - History of substance abuse
  - Frequent requests for early refills
  - Reported frequent instances of lost tablets
  - Requests for odd quantities which requires fractional dosing
  - Requests for short-term or PRN usage
  - Medication history indicates concurrent use of other extended-release opioids

Note:

1. Due to cross-reactivity with morphine, oxymorphone SR will not be approved for patients with immune-mediated morphine allergy.

2. Use of opioid analgesics during pregnancy has been associated with Neonatal Opioid Withdrawal Syndrome. Providers **MUST** counsel women of childbearing age regarding the risks of becoming pregnant while receiving opioids, including the risk of Neonatal Opioid Withdrawal Syndrome. Providers should offer access to contraceptive services when necessary

Proposed Criteria:

- ~~Trial and failure, contraindication, intolerance, or drug-drug interaction with extended-release morphine;~~ ~~**AND**~~
- *Management of severe pain with need for around-the-clock analgesia for an extended period;* ***AND***
- The prescriber has checked the Tennessee Controlled Substance Database for this patient within the last 7 days; **AND**
- Pain agreement required for all PA required agents. Please refer to the Opioid and Controlled Substance Agreement document located at: Patient Medication Management Agreement; **AND**
- Concomitant use of benzodiazepines and opioids will only be approved under the care of, or referral to, a mental health provider; **AND**
- Requests for ≥ 90 MME per day [Please refer to TennCare_MME_Conversion_Chart (optumrx.com)]:
  - Recipient must be opioid tolerant (as demonstrated by at least a week or longer history of morphine 60 mg/day or more, oral oxycodone 30 mg/day or more, oral hydromorphone 8 mg/day or more, or an equianalgesic dose of another opioid); **AND**
- Female of child-bearing age (14-44 years):
  - Is not pregnant; **AND**
  - Using contraception (e.g., barrier, oral contraceptive, rhythm method); **OR**
  - Has an intrauterine device (IUD) or implant; **OR**
  - Has history of hysterectomy, tubal ligation, or endometrial ablation
- *The prescriber attests to investigating ALL of following before submitting a PA:* ~~should be investigated is granted~~:
  - History of substance abuse
  - Frequent requests for early refills
  - Reported frequent instances of lost tablets
  - Requests for odd quantities which requires fractional dosing
  - Requests for short-term or PRN usage
  - Medication history indicates concurrent use of other extended-release opioids; **AND**
- Additionally, approval of non-preferred agents in the Long-Acting Narcotics class requires contraindication, drug to drug interaction, or history of toxic side effects that cause immediate or long-term damage (**NOTE**: This does not include GI intolerance) with ALL preferred agents, unless otherwise indicated.

Note:
1. Due to cross-reactivity with morphine, oxymorphone SR will not be approved for patients with immune-mediated morphine allergy.
2. Use of opioid analgesics during pregnancy has been associated with Neonatal Opioid Withdrawal Syndrome. Providers **MUST** counsel women of childbearing age regarding the risks of becoming pregnant while receiving opioids, including the risk of Neonatal Opioid Withdrawal Syndrome. Providers should offer access to contraceptive services when necessary

COMMITTEE VOTE

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

Prior Authorization criteria for buprenorphine patch, Butrans

Current Criteria:

See Belbuca® prior authorization criteria

- Additionally, Butrans® 7.5, 10, 15, and 20 mcg/hr will be approved for opioid-experienced patients only

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Quantity Limits

• BELBUCA	2/day*
• BUTRANS (buprenorphine patch)	4 patches/28 days*
• CONZIP (tramadol ER)	1/day*
• fentanyl patches	10 patches/30 days*
• hydromorphone ER capsules	2/day*
• HYSINGLA ER (hydromorphone ER tablets)	1/day*
• methadone 5mg tablet	8/day*
• methadone 10mg tablet	4/day*
• methadone solution 10mg/5mL	20mL/day*
• methadone solution 5mg/5mL	40mL/day*
• METHADOSE (methadone concentrate)10mg/mL	4mL/day*
• METHADOSE (methadone dispersible tab) 40 mg	1/day*
• morphine ER beads capsules	1/day*
• morphine ER capsules	2/day*
• MS CONTIN (morphine ER tabs) 15, 30, 60mg	3/day*
• MS CONTIN (morphine ER tabs) 100mg	2/day*
• MS CONTIN (morphine ER tabs) 200mg	1/day*
• NUCYNTA ER	2/day*
• OXYCONTIN (oxycodone ER)	2/day*
• oxymorphone ER	2/day*
• XTAMPZA ER	2/day*
• ZOHYDRO ER (hydrocodone ER caps)	2/day*

*Max total: Non-Chronic – 60 MME/day, Chronic – 200 MME/day

COMMITTEE VOTE

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

Discussion and Approval:

A motion to approve the class recommendation, all prior authorization criteria, and quantity limits was made by Dr. Alston, seconded by Dr. Rhea, and unanimously carried.

Dr. Capparelli stated Oxycontin was taken off the market and is no longer available; therefore, it should be removed from the PDL. **Dr. Watlington stated as a follow up item she will check the availability of Oxycontin.**

SHORT-ACTING NARCOTICS

Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred	
Short-Acting Narcotics	codeine/APAP PA (<19 years old), QL ENDOCET QL (oxycodone/acetaminophen) hydrocodone/APAP 325mg QL hydrocodone/ibuprofen QL hydromorphone tabs QL morphine IR tabs QL morphine soln 20mg/ml PA oxycodone tabs QL oxycodone/APAP QL oxycodone oral concentrate PA oxycodone oral solution tramadol PA ≤ 17 YEARS, QL tramadol/APAP PA ≤ 17 YEARS, QL	APADAZ QL (benzhydrocodone/APAP) benzhydrocodone/APAP PA, QL butalbital/APAP/caff/codeine PA, QL butalbital/ASA/caff/codeine PA, QL codeine PA, QL DEMEROL PA, QL (meperidine) dihydrocodeine/APAP/caffeine PA, QL DILAUDID PA, QL (hydromorphone) FIORICET with Codeine PA, QL (butalbital/APAP, caffeine) hydrocodone/APAP 300mg PA, QL hydromorphone liquid PA, QL hydromorphone suppositories PA levorphanol PA, QL LORTAB PA, QL (hydrocodone/APAP) meperidine PA, QL morphine suppositories PA, QL	NALOCET PA, QL (oxycodone/APAP) NUCYNTA PA, QL (tapentadol) OXAYDO PA, QL (oxycodone oxycodone caps PA, QL oxymorphone PA, QL PERCOCET PA, QL (oxycodone/APAP) PROLATE PA, QL (oxycodone/APAP) ROXICODONE PA, QL (oxycodone) ROXYBOND PA, QL (oxycodone) SEGLENTIS PA, QL (Celebrex/tramadol) ULTRACET PA, QL (APAP/tramadol) ULTRAM PA, QL (tramadol)

Recommendation

~~Opioid agents are a primary class of drugs used in pain management with short acting opioid agents playing an important role in the treatment of acute pain and breakthrough pain in patients with chronic pain. Clinical trials have consistently demonstrated the efficacy of short acting opioid agents, and studies comparing the various short acting opioids have demonstrated that no one single agent is definitively superior over the other agents in the class. The short acting opioids are similar in their adverse effects and many of the adverse effects subside with continued dosing as tolerance builds. Current clinical guidelines recommend opioid analgesics as the mainstay of therapy for the treatment of moderate to severe pain and do not distinguish between the available products. Therefore,~~ It is recommended that at least 2 unique single agent short acting opioids and at least 2 unique combinations of short acting opioids be available for use.

COMMITTEE VOTE

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

Prior Authorization criteria for codeine/APAP

Current Criteria:

- Patient is less than 18 years of age:
  - Trial and failure of acetaminophen; **AND**
  - Contraindication to ALL NSAIDs; **AND**
  - Patient does not have any of the following:
    - Obesity
    - Obstructive Sleep Apnea
    - Severe Lung Disease (acute or severe asthma, COPD, Cystic Fibrosis, hypoxemia, hypercapnia, pneumonia, pulmonary hypertension, etc.)
    - Recent adenectomy/tonsillectomy; **AND**
  - Prescriber is aware of contraindication in patients younger than 12 years of age due to serious risks, including slowed or difficult breathing and death, and agrees to accept risks

Proposed Criteria:

- *For patients less than 12 years of age, approval will not be granted*
- Patient is less than 18 years of age:

- Trial and failure of acetaminophen; **AND**
- Contraindication to ALL NSAIDs; **AND**
- Patient does not have any of the following:
  - Obesity
  - Obstructive Sleep Apnea
  - Severe Lung Disease (acute or severe asthma, COPD, Cystic Fibrosis, hypoxemia, hypercapnia, pneumonia, pulmonary hypertension, etc.)
  - Recent adenectomy/tonsillectomy; **AND**
- ~~Prescriber is aware of contraindication in patients younger than 12 years of age due to serious risks, including slowed or difficult breathing and death, and agrees to accept risks~~

COMMITTEE VOTE

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

Prior Authorization criteria for butalbital/APAP/caffeine/codeine, butalbital/ASA/caffeine/codeine, codeine, dihydrocodeine/APAP/caffeine, FIORICET with codeine

Current Criteria:

- Patient < 18 years of age:
  - Trial and failure of acetaminophen; **AND**
  - Contraindication to ALL NSAIDs; **AND**
  - Contraindication, drug to drug interaction, or history of toxic side effects that cause immediate or long-term damage (NOTE: this does not include GI intolerance) with ALL other preferred short-acting narcotic agents (excluding tramadol); **AND**
  - Patient does not have any of the following:
    - Obesity
    - Obstructive Sleep Apnea
    - Severe Lung Disease (acute or severe asthma, COPD, Cystic Fibrosis, hypoxemia, hypercapnia, pneumonia, pulmonary hypertension, etc.)
    - Recent adenectomy/tonsillectomy; **AND**
  - Prescriber is aware of contraindication in patients younger than 12 years of age due to serious risks, including slowed or difficult breathing and death, and agrees to accept risks
- Patients ≥ 18 years of age: Contraindication, drug to drug interaction, or history of toxic side effects that cause immediate or long- term damage (NOTE: this does not include GI intolerance) with ALL preferred short-acting narcotic agents.

Proposed Criteria:

- *For patients less than 12 years of age, approval will not be granted*
- Patient < 18 years of age:
  - Trial and failure of acetaminophen; **AND**
  - Contraindication to ALL NSAIDs; **AND**
  - Contraindication, drug to drug interaction, or history of toxic side effects that cause immediate or long-term damage (NOTE: this does not include GI intolerance) with ALL other preferred short-acting narcotic agents (excluding tramadol); **AND**
  - Patient does not have any of the following:
    - Obesity
    - Obstructive Sleep Apnea
    - Severe Lung Disease (acute or severe asthma, COPD, Cystic Fibrosis, hypoxemia, hypercapnia, pneumonia, pulmonary hypertension, etc.)
    - Recent adenectomy/tonsillectomy; **AND**
  - ~~Prescriber is aware of contraindication in patients younger than 12 years of age due to serious risks, including slowed or difficult breathing and death, and agrees to accept risks~~

- Patients ≥ 18 years of age: Contraindication, drug to drug interaction, or history of toxic side effects that cause immediate or long- term damage (NOTE: this does not include GI intolerance) with ALL preferred short-acting narcotic agents.

COMMITTEE VOTE

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

Prior Authorization criteria for SEGLENTIS, ULTRACET, ULTRAM

Current Criteria:

- Approval of non-preferred agents in the Short-Acting Narcotics class requires contraindication, drug to drug interaction, or history of toxic side effects that cause immediate or long-term damage (NOTE: this does not include GI intolerance) with ALL preferred agents; **AND**
- The prescriber must have checked the Tennessee Controlled Substance Database for this patient within the last 7 days; **AND**
- Pain agreement required for all PA required agents. Please refer to the Opioid and Controlled Substance Agreement document located at: Patient Medication Management Agreement; **AND**
- Concomitant use of benzodiazepines and opioids will only be approved under the care of, or referral to, a mental health provider; **AND**
- Female of child-bearing age (14-44 years):
  - Is not pregnant or breastfeeding; **AND**
  - Using contraception; **OR**
  - Has an intrauterine device (IUD) or implant; **OR**
  - Has history of hysterectomy, tubal ligation, or endometrial ablation; **AND**
- If patient is 12 to 18 years of age: [For patients less than 12 years of age, approval will not be granted.]
  - Patient does not have any of the following:
    - Obesity (BMI ≥ 30)
    - Obstructive Sleep Apnea
    - Severe Lung Disease (acute or severe asthma, COPD, Cystic Fibrosis, hypoxemia, hypercapnia, pneumonia, pulmonary hypertension, etc.)
    - Recent adenectomy/tonsillectomy; **AND**
  - Trial and failure or contraindication to acetaminophen; **AND**
  - Trial and failure or contraindication to ALL NSAIDs

Note: Use of opioid analgesics during pregnancy has been associated with Neonatal Opioid Withdrawal Syndrome. Providers MUST counsel women of childbearing age regarding the risks of becoming pregnant while receiving opioids, including the risk of Neonatal Opioid Withdrawal Syndrome. Providers should offer access to contraceptive services when necessary.

Proposed Criteria:

- *For patients less than 12 years of age, approval will not be granted*
- Approval of non-preferred agents in the Short-Acting Narcotics class requires contraindication, drug to drug interaction, or history of toxic side effects that cause immediate or long-term damage (NOTE: this does not include GI intolerance) with ALL preferred agents; **AND**
- ~~The prescriber must have checked the Tennessee Controlled Substance Database for this patient within the last 7 days; **AND**~~
- ~~Pain agreement required for all PA required agents. Please refer to the Opioid and Controlled Substance Agreement document located at: Patient Medication Management Agreement; **AND**~~
- ~~Concomitant use of benzodiazepines and opioids will only be approved under the care of, or referral to, a mental health provider; **AND**~~
- Female of child-bearing age (14-44 years):
  - Is not pregnant or breastfeeding; **AND**
  - Using contraception; **OR**
  - Has an intrauterine device (IUD) or implant; **OR**
  - Has history of hysterectomy, tubal ligation, or endometrial ablation; **AND**

- If patient is 12 to 18 years of age: ~~[For patients less than 12 years of age, approval will not be granted.]~~
  - Patient does not have any of the following:
    - Obesity (BMI ≥ 30)
    - Obstructive Sleep Apnea
    - Severe Lung Disease (acute or severe asthma, COPD, Cystic Fibrosis, hypoxemia, hypercapnia, pneumonia, pulmonary hypertension, etc.)
    - Recent adenectomy/tonsillectomy; **AND**
  - Trial and failure or contraindication to acetaminophen; **AND**
  - Trial and failure or contraindication to ALL NSAIDs

Note: Use of opioid analgesics during pregnancy has been associated with Neonatal Opioid Withdrawal Syndrome. Providers MUST counsel women of childbearing age regarding the risks of becoming pregnant while receiving opioids, including the risk of Neonatal Opioid Withdrawal Syndrome. Providers should offer access to contraceptive services when necessary.

COMMITTEE VOTE

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

Prior Authorization criteria for morphine sulfate solution 20 mg/mL

Current Criteria:

- Prescriber has checked the Tennessee Controlled Substance Database for this patient within the last 7 days (document date); OR request is for a hospice patient, HIV/AIDS patient, active cancer patient, OR long-term care facility resident (document name of facility); **AND**
- Concomitant use of benzodiazepines and opioids will only be approved under the care of, or referral to, a mental health provider; **AND**
- Pain agreement required for ALL PA required agents. Please refer to the Opioid and Controlled Substance Agreement located at https://www.optumrx.com/content/dam/openenrollment/pdfs/Tenncare/presciber/prior-authorizationforms/Patient%20Medication%20Management%20Agreement.pdf; **AND**
- Female of child-bearing age (14-44 years):
  - Is not pregnant; **AND**
  - Using contraception; **OR**
  - Has an intrauterine device (IUD) or implant; **OR**
  - Has history of hysterectomy, tubal ligation, or endometrial ablation
- Patient is opioid tolerant as indicated by 1 of the following:
  - At least 60 mg oral morphine per day for 1 week; **OR**
  - At least 25 mcg/hr transdermal fentanyl for 1 week; **OR**
  - At least 30 mg oral oxycodone per day for 1 week; **OR**
  - At least 8 mg oral hydromorphone per day for 1 week; **OR**
  - At least 25 mg oral oxymorphone per day for at least 1 week; **OR**
  - An equianalgesic dose of another opioid for at least 1 week.

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for oxycodone oral concentrate

Current Criteria:

- Prescriber has checked the Tennessee Controlled Substance Database for this patient within the last 7 days (document date); **OR** request is for a hospice patient, HIV/AIDS patient, active cancer patient, OR long-term care facility resident (document name of facility); AND

- Concomitant use of benzodiazepines and opioids will only be approved under the care of, or referral to, a mental health provider; **AND**
- Pain agreement required for ALL PA required agents. Please refer to the Opioid and Controlled Substance Agreement located at Patient Medication Management Agreement**; AND**
- Female of child-bearing age (14-44 years):
  - Is not pregnant; **AND**
  - Using contraception; **OR**
  - Has an intrauterine device (IUD) or implant; **OR**
  - Has history of hysterectomy, tubal ligation, or endometrial ablation
- Patient is opioid tolerant as indicated by 1 of the following:
  - At least 60 mg oral morphine per day for 1 week; **OR**
  - At least 25 mcg/hr transdermal fentanyl for 1 week; **OR**
  - At least 30 mg oral oxycodone per day for 1 week; **OR**
  - At least 8 mg oral hydromorphone per day for 1 week; **OR**
  - At least 25 mg oral oxymorphone per day for at least 1 week; **OR**
  - An equianalgesic dose of another opioid for at least 1 week

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for tramadol, tramadol/APAP

Current Criteria:

- For patients less than 12 years of age, approval will not be granted
- If patient is 12 to 18 years of age:
  - Patient does not have any of the following:
    - Obesity (BMI ≥ 30)
    - Obstructive Sleep Apnea
    - Severe Lung Disease (acute or severe asthma, COPD, Cystic Fibrosis, hypoxemia, hypercapnia, pneumonia, pulmonary hypertension, etc.)
    - Recent adenectomy/tonsillectomy; **AND**
- Trial and failure or contraindication to acetaminophen; **AND**
- Trial and failure or contraindication to ALL NSAIDs
- Note: Patients 18 years and older will only be subject to the quantity limit and opioid criteria

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for DEMEROL, DILAUDID, hydrocodone/APAP 5/300, hydrocodone/APAP 10/300, hydromorphone liquid, hydromorphone suppositories, levorphanol, LORTAB, meperidine, morphine suppositories, NALOCET, NUCYNTA, OXAYDO, oxycodone caps, oxymorphone, PERCOCET, *PROLATE,* ROXICODONE, ROXYBOND

Current Criteria:

- Approval of non-preferred agents in the Short-Acting Narcotics class requires contraindication, drug to drug interaction, or history of toxic side effects that cause immediate or long-term damage (NOTE: this does not include GI intolerance) with ALL preferred agents.
- The prescriber must have checked the Tennessee Controlled Substance Database for this patient within the last 7 days; **AND**

- Pain agreement required for all PA required agents. Please refer to the Opioid and Controlled Substance Agreement document located at: Patient Medication Management Agreement
- Concomitant use of benzodiazepines and opioids will only be approved under the care of, or referral to, a mental health provider.
- Female of child-bearing age (14-44 years):
  - Is not pregnant; **AND**
  - Using contraception; **OR**
  - Has an intrauterine device (IUD) or implant; **OR**
  - Has history of hysterectomy, tubal ligation, or endometrial ablation

Note: Use of opioid analgesics during pregnancy has been associated with Neonatal Opioid Withdrawal Syndrome. Providers **MUST** counsel women of childbearing age regarding the risks of becoming pregnant while receiving opioids, including the risk of Neonatal Opioid Withdrawal Syndrome. Providers should offer access to contraceptive services when necessary

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Quantity Limits

• codeine/APAP	12/day*
• ENDOCET (2.5/325mg)	12/day*
• ENDOCET (all other strengths)	8/day*
• hydrocodone/APAP (2.5/325mg, 5/325mg, 5/300mg)	12/day*
• hydrocodone/APAP^ (all other strengths)	8/day*
• hydrocodone/APAP^ solution (2.5-108mg/5mL, 5-217mg/10mL, 7.5 325mg/15mL)	120mL/day*
• hydrocodone/APAP^ solution (all other strengths)	89mL/day*
• hydrocodone/ibuprofen (2.5/200mg, 5/200mg)	12/day*
• hydrocodone/ibuprofen (10/200mg)	6/day*
• hydromorphone§ (2mg)	7/day*
• hydromorphone§ (4mg)	3/day*
• hydromorphone§ (8mg)	1/day*
• morphine IR (excluding suppositories)	6/day*
• morphine sulfate solution (20mg/mL)	*
• oxycodone tablets (5mg, 7.5mg, 10mg)	8/day*
• oxycodone tablets (15mg, 20mg, 30mg)	4/day*
• oxycodone/APAP solution	40mL/day*
• oxycodone/APAP (2.5/325mg)	12/day*
• oxycodone/APAP (all other strengths)	8/day*
• tramadol	8/day*
• tramadol/APAP	12/day*
• *tramadol solution (5mg/1 mL)*	*80 mL/day*
• APADAZ (6.12/325mg)	8/day
• APADAZ (8.16/325mg)	6/day
• APADAZ (4.08/325mg)	12/day
• benzhydrocodone/APAP	same as APADAZ above
• butalbital/APAP/caffeine/codeine	20 tabs/caps of butalbital-containing products/30 days£
• butalbital/ASA/caffeine/codeine	20 tabs/caps of butalbital-containing products/30 days
• codeine (15mg, 30mg)	12/day*
• codeine (60mg)	6/day*
• DEMEROL (50mg)	12/day*
• DEMEROL (100mg)	6/day*
• DEMEROL solution	60mL/day*
• dihydrocodeine/APAP/caffeine (16/356/30mg)	8/day£
• DILAUDID (2mg)	7/day*

• DILAUDID (4mg)	3/day*
• DILAUDID (8mg)	1/day*
• DILAUDID liquid	15mL/day*
• FIORICET with codeine	20 tabs/caps of butalbital-containing products/30 days[£]
• hydrocodone/APAP (5/300)	12/day*
• hydrocodone/APAP (10/300)	6/day*
• hydrocodone/APAP solution	89mL/day*
• hydromorphone liquid	15mL/day*
• hydromorphone suppositories	5/day*
• levorphanol	6/day*
• LORTAB (5/325mg)	8/day*
• LORTAB (all other strengths)	8/day*
• LORTAB solution	89mL/day*
• meperidine (50mg)	8/day*
• meperidine (all other strengths)	6/day*
• meperidine solution	89mL/day*
• morphine suppositories (5mg)	12/day*
• morphine suppositories (all other strengths)	6/day*
• NALOCET	12/day*
• NUCYNTA	6/day*
• OXAYDO	8/day*
• oxycodone capsules	8/day*
• oxycodone oral concentrate	*
• oxymorphone	4/day*
• PERCOCET (2.5/325mg)	12/day*
• PERCOCET (all other strengths)	8/day*
• *PROLATE tablets*	*8/day**
• *PROLATE solution*	*40mL/day**
• ROXICODONE	4/day*
• *ROXYBOND*	*4/day**
• *SEGLENTIS*	*4/day**
• ULTRACET	12/day*
• ULTRAM	8/day*

*Max Total: Non-Chronic 60 MME/day; Chronic 200 MME/day; ^Excluding generic for Xodol; [§]Excluding suppositories and liquid; [£]APAP Max = 4g/day

COMMITTEE VOTE

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

Discussion and Approval:

A motion to approve the class recommendation, all prior authorization criteria, and quantity limits was made by Dr. Capparelli, seconded by Dr. Johns, and unanimously carried.

Dr. Capparelli stated there have been multiple drug shortages across the state and at different pharmacies. Dr. Capparelli asked if more agents could be moved to the preferred side due to drug shortages. Dr. Williams-Clark stated OptumRx has a robust drug shortage and allocation program to closely monitor drug shortages. OptumRx provides recommendations to the clinical team at TennCare to act quickly when drug shortages occur and allow the call center to make appropriate overrides. Dr. Williams-Clark noted in the coming months we will see more shortages due to industry shift and federal policy changes. Dr. Williams-Clark also stated TennCare's flexibility with PDL class recommendations allows the program to shift products from non-preferred to preferred status as needed. Dr. Rhea asked if pharmacies are allowed to hold controlled substances for their regular patients and refuse prescriptions from new patients. Dr. Williams-Clark stated she has heard of pharmacies implementing that practice. TennCare has limited ability to force a pharmacy to dispense medications, but she has alerted the Tennessee Pharmacy Association and the Board of Pharmacy of these concerns.

Abbreviated Drug Class Reviews

ACE INHIBITORS (ACEI)

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred	
ACE Inhibitors (ACEI)	benazepril enalapril lisinopril ramipril QL	ACCUPRIL (quinapril) ALTACE QL (ramipril) captopril PA EPANED PA (enalapril, oral solution) enalapril suspension PA fosinopril LOTENSIN (benazepril)	moexipril QL perindopril QL quinapril trandolapril QL QBRELIS solution PA (lisinopril) VASOTEC (enalapril) ZESTRIL (lisinopril)

Recommendation

It is recommended at least 4 ACE inhibitors should be available for use. ~~Given the additional FDA-approved indications as well as evidence showing decreased mortality with ramipril and perindopril post-myocardial infarction, either~~ Ramipril ~~or perindopril~~ should be available for use in patients determined to be at high-risk for cardiovascular complications.

COMMITTEE VOTE

APPROVED **APPROVED with MODIFICATION**

Prior Authorization criteria for captopril

Current Criteria:

- Trial and failure, contraindication, or intolerance of TWO preferred agents
  Note: PA is not required for members < 18 years of age

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for EPANED, enalapril suspension

Current Criteria:

- Patient is unable to swallow solid dosage forms
  Note: PA is not required for members < 8 years of age

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for QBRELIS SOLUTION

Current Criteria:

- Patient is unable to swallow solid dosage forms
  Note: PA is not required for members < 8 years of age

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Quantity Limits

• ramipril 1.25mg, 2.5mg, 5mg	2 ~~1~~/day
• ramipril 10mg	2/day
• ALTACE 1.25mg, 2.5mg, 5mg	2 ~~1~~/day
• ALTACE 10mg	2/day
• moexipril 7.5mg	1/day
• moexipril 15mg	2/day
• perindopril 2mg, 4mg	1/day
• perindopril 8mg	2/day
• trandolapril	1/day

COMMITTEE VOTE

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

ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS)

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred	
Angiotensin II Receptor Blockers (ARBs)	irbesartan QL losartan QL olmesartan QL valsartan QL	ATACAND QL (candesartan) AVAPRO QL (irbesartan) BENICAR QL (olmesartan) candesartan QL COZAAR QL (losartan)	DIOVAN QL (valsartan) EDARBI QL (azilsartan) MICARDIS QL (telmisartan) telmisartan QL valsartan solution PA, QL

Recommendation

It is recommended at least three ARBs should be available.

COMMITTEE VOTE

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

Prior Authorization criteria for valsartan solution

Current Criteria:

- Patient unable to swallow solid dosage forms

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Quantity Limits

• irbesartan	1/day	• candesartan 8mg, 16mg	2/day
• losartan 25mg, 100mg	1/day	• COZAAR 25mg, 100mg	1/day
• losartan 50mg	2/day	• COZAAR 50mg	2/day
• olmesartan	1/day	• DIOVAN	1/day
• valsartan	1/day	• EDARBI	1/day
• ATACAND	1/DAY	• MICARDIS	1/day
• AVAPRO	1/day	• telmisartan	1/day
• BENICAR	1/day	• valsartan solution	80 mL/day
• candesartan 4mg, 32mg	1/day		

COMMITTEE VOTE

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

ARB + NEPRILYSIN INHIBITOR

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred
ARB + Neprilysin Inhibitor	ENTRESTO [PA, QL] (sacubitril/valsartan)	N/A

Recommendation

It is recommended that agents within the angiotensin II receptor blockers – neprilysin inhibitor class be available to patients in whom they are clinically appropriate.

COMMITTEE VOTE

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

Prior Authorization criteria for ENTRESTO

Current Criteria:

- Diagnosis of chronic heart failure (NYHA Class II-IV)

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Quantity Limits

- ENTRESTO 2/day

COMMITTEE VOTE

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

ANTIANGINALS: NITRATES

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred
Antianginals: Nitrates	isosorbide dinitrate tablets (excluding 10mg) isosorbide mononitrate nitroglycerin (excluding spray) NITROLINGUAL (nitroglycerin, spray) NITROSTAT (nitroglycerin, sublingual tablet) RECTIV [PA] (nitroglycerin, rectal ointment)	GONITRO Powder [PA] (nitroglycerin, sublingual packet) ISORDIL (isosorbide dinitrate) isosorbide dinitrate 10mg tab NITRO-BID (nitroglycerin, transdermal ointment) NITRO-DUR (nitroglycerin, patch) nitroglycerin spray [PA] Nitro-Time (nitroglycerin)

Recommendation

To ensure adequate patient and prescriber choice, it is recommended that a *sublingual spray*, short-acting agent, and a long-acting agent be available. ~~Additionally, due to concerns with stability of the sublingual tablets as well as ease of use of the sublingual spray, it is recommended sublingual spray should be available.~~

COMMITTEE VOTE

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

Prior Authorization criteria for RECTIV

Current Criteria:

- Diagnosis of history of anal fissure; **AND**
- Patient is a candidate for surgery

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for GONITRO POWDER

Current Criteria:

- Diagnosis of an FDA approved indication; **AND**
- Clinically valid reason why the preferred agents cannot be used; **AND**
- Patient is unable to swallow solid dosage forms or sublingual formulations (e.g., spray, tablet)

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for nitroglycerin spray

Current Criteria:

- Diagnosis of an FDA approved indication; **AND**

- Trial and failure, contraindication, or intolerance of TWO preferred agents; **AND**
- Clinically valid reason why the preferred agents cannot be used

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

ANTIARRHYTHMICS, ORAL

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred	
Antiarrhythmics, Oral	amiodarone	BETAPACE (sotalol)	RYTHMOL SR (propafenone)
	disopyramide	BETAPACE AF (sotalol)	SORINE (sotalol)
	dofetilide QL	MULTAQ PA (dronedarone)	SOTYLIZE (sotalol, oral solution) PA
	flecainide	NORPACE (disopyramide)	TIKOSYN QL (dofetilide)
	mexiletine	NORPACE CR (disopyramide)	
	propafenone	PACERONE (amiodarone)	
	sotalol	propafenone ER	
	sotalol AF	quinidine gluconate & sulfate	

Recommendation

It is recommended that the various unique chemical entities included in the anti-arrhythmic class all be made available. However, given the increased risk of mortality with dronedarone in specified populations, it is recommended dronedarone should be subject to clinical criteria.

COMMITTEE VOTE

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

Prior Authorization criteria for MULTAQ

Current Criteria:

- Not on concurrent Class I or III anti-arrhythmic agent; **AND**
- Not hospitalized for exacerbation of heart failure in past 30 days; **AND**
- Patient does not have NYHA class IIIb or IV heart failure; **AND**
- Trial and failure, contraindication, or intolerance of TWO of the following preferred antiarrhythmic agents: (Note: Requirement is waived if patient has structural heart disease)
  - Amiodarone, flecainide, propafenone, OR sotalol

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for SOTYLIZE

Current Criteria:

- Patient is unable to swallow tablets and capsules
  Note: PA is not required for patients < 8 years of age

Proposed Criteria:

Same as current

Quantity Limits

- dofetilide 2/day
- Tikosyn 2/day

COMMITTEE VOTE

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

ANTIHYPERTENSIVES, MISCELLANEOUS

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred		Non-Preferred	
Antihypertensives, Miscellaneous	clonidine IR clonidine weekly TD patch QL guanfacine	hydralazine methyldopa methyldopa/HCTZ	CATAPRES-TTS (clonidine, weekly TD patch) clonidine 24hr ER QL	minoxidil tablet PA reserpine VECAMYL PA, QL (mecamylamine)

Recommendation

It is recommended at least two agents in the miscellaneous antihypertensives class should be available for use, one of which should be clonidine and one of which is recommended for use in pregnancy. Additionally, ~~due to its potential for serious adverse events and specific FDA approved indication,~~ minoxidil *and* ~~is considered an inferior agent in this class and should be subject to clinical criteria. Lastly,~~ Vecamyl should be subject to clinical criteria to ensure its use in the appropriate patient population.

COMMITTEE VOTE

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

Prior Authorization criteria for minoxidil tablet

Current Criteria:

- Diagnosis of severe hypertension (symptomatic or associated with target organ damage only); **AND**
- Trial and failure, contraindication, or intolerance to TWO of the following:
  - ACEI or ARBs
  - Beta-blocker
  - Calcium channel blockers
  - Methyldopa
  - Clonidine; **AND**
- Patient is concomitantly taking a diuretic (e.g., hydrochlorothiazide, chlorthalidone, furosemide, etc.); **AND**
- Patient does not have diagnosis of pheochromocytoma (minoxidil may stimulate secretions of catecholamines from the tumor)

Note: Minoxidil will not be approved for alopecia

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for VECAMYL

Current Criteria:

- Diagnosis of Essential Hypertension or Malignant Hypertension, **AND**
- Trial and failure, contraindication, or intolerance to **ALL** the following:
  - ACE inhibitor or ARB
  - Beta blocker
  - Calcium Channel Blocker
  - Clonidine
  - Hydralazine; **AND**
- Patient is concomitantly taking a diuretic (e.g., hydrochlorothiazide, chlorthalidone, furosemide)

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Quantity Limits

• clonidine patch 0.1mg, 0.2mg	4/28 days
• clonidine patch 0.3mg (patient ≤ ≤ 21)	4/28 days
• clonidine patch 0.3mg (patient >21)	8/28 days
• clonidine 24hr ER	1/day
• VECAMYL	10/day

COMMITTEE VOTE

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

BETA BLOCKERS

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred	
Beta Blockers	atenolol bisoprolol fumarate metoprolol succinate QL metoprolol tartrate nadolol nebivolol propranolol sotalol	acebutolol BETAPACE (sotalol) betaxolol CORGARD (nadolol) HEMANGEOL PA (propranolol) INDERAL LA (propranolol) INDERAL XL (propranolol) INNOPRAN XL QL (propranolol)	KAPSPARGO SPRINKLE PA, QL (metoprolol) LOPRESSOR (metoprolol) pindolol SORINE (sotalol) SOTYLIZE PA (sotalol) TENORMIN (atenolol) timolol maleate TOPROL XL PA, QL (metoprolol)

Recommendation

It is recommended that at least 5 beta-blockers which includes a cardioselective, non-cardioselective, an agent with and without intrinsic sympathomimetic activity (ISA) be available. In addition, due to its unique indication for heart failure and recommendation by the current guidelines for the treatment of CHF, metoprolol succinate should be available for patients with heart failure.

COMMITTEE VOTE

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

Prior Authorization criteria for HEMANGEOL

Current Criteria:

- Diagnosis of Infantile Hemangioma; **AND**
- Clinically valid reason why the preferred propranolol solution cannot be used

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for KAPSPARGO SPRINKLE

Current Criteria:

- Diagnosis of ONE of the following:
  - Heart Failure or LVEF ≤ 40%
  - Hypertension
  - Angina Pectoris; **AND**
- Patient is unable to swallow tablets and capsules

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for SOTYLIZE

Current Criteria:

- Patient is unable to swallow tablets and capsules
  Note: PA is not required for patients < 8 years of age

Proposed Criteria:
Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for TOPROL XL

Current Criteria:
- Diagnosis of one of the following:
  - Heart Failure or LVEF ≤ 40%
  - Paroxysmal Atrial Fibrillation

Proposed Criteria:
Remove PA Criteria

COMMITTEE VOTE

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

Quantity Limits

• metoprolol succinate ER	1/day
• INNOPRAN XL 80mg	2/day
• INNOPRAN XL 120mg	1/day
• KAPSPARGO SPRINKLE	1/day
• TOPROL XL	1/day

COMMITTEE VOTE

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

CALCIUM CHANNEL BLOCKERS (DHP)

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred	
Calcium Channel Blockers (DHP)	amlodipine QL felodipine ER nicardipine nifedipine tabs QL NORLIQVA PA, QL (amlodipine besylate soln)	isradipine QL KATERZIA PA, QL (amlodipine benzoate, suspension) nifedipine caps nimodipine PA	nisoldipine QL NORVASC QL (amlodipine) NYMALIZE PA, QL (nimodipine soln) PROCARDIA XL QL (nifedipine) SULAR QL (nisoldipine)

Recommendation

It is recommended that at least 4 dihydropyridine calcium channel blockers are available for use. Due to its unique indication, nimodipine should be available for patients with subarachnoid hemorrhage.

COMMITTEE VOTE

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

Prior Authorization criteria for NORLIQVA

Current Criteria:

- Diagnosis of one of the following:
  - Hypertension
  - Chronic stable angina or treatment
  - Vasospastic Angina (Prinzmetal's or Variant Angina)
  - Confirmed or suspected vasospastic angina
  - Angiographically documented Coronary Artery Disease in patients without heart failure and an ejection fraction ≥40%; **AND**
- One of the following:
  - Patient is unable to swallow solid dosage forms; **OR**
  - Clinically valid reason why nimodipine capsules cannot be used

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for KATERZIA

Current Criteria:

See NORLIQVA prior authorization criteria; AND

- Trial and failure, contraindication, or intolerance to NORLIQVA

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for nimodipine

Current Criteria:

- Diagnosis of subarachnoid hemorrhage (SAH)

Proposed Criteria:
Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for NYMALIZE

Current Criteria:
- Diagnosis of subarachnoid hemorrhage; **AND**
- One of the following:
  - Patient is unable to swallow solid dosage forms
  - Clinically valid reason why nimodipine capsules cannot be used

Proposed Criteria:
Same as current

COMMITTEE VOTE

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

Quantity Limits

• amlodipine 2.5mg, 5mg	1.5/day	• nisoldipine	1/day
• amlodipine 10mg	1/day	• NORVASC 2.5mg, 5mg	1.5/day
• nifedipine ER/SA/XL	1/day	• NORVASC 10mg	1/day
• NORLIQVA	10mL/day	• NYMALIZE	120mL/day
• isradipine 2.5mg	2/day	• PROCARDIA XL	1/day
• isradipine 5mg	4/day	• SULAR	1/day
• KATERZIA	10mL/day		

COMMITTEE VOTE

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

CALCIUM CHANNEL BLOCKERS (NON-DHP)

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred		Non-Preferred	
Calcium Channel Blockers (non-DHP)	CARTIA XT (diltiazem ER) diltiazem caps diltiazem IR tabs DILT XR (diltiazem ER)	TIADYLT (diltiazem ER) TAZTIA XT (diltiazem ER) verapamil verapamil ER/SR QL	CARDIZEM (diltiazem) CARDIZEM CD (diltiazem) CARDIZEM LA QL (diltiazem diltiazem ER tabs QL MATZIM LA QL (diltiazem ER)	TIAZAC (diltiazem ER) verapamil ER PM VERELAN (verapamil SR) VERELAN PM (verapamil ER)

Recommendation

It is recommended that both immediate and extended-release formulations of verapamil and diltiazem are available for use.

COMMITTEE VOTE

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

Quantity Limits

- verapamil ER/SR 1/day
- CARDIZEM LA 1/day
- diltiazem ER caps 1/day
- MATZIM LA 1/day

COMMITTEE VOTE

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

DIURETICS: LOOP

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred		Non-Preferred	
Diuretics: Loop	bumetanide ethacrynic acid	furosemide torsemide	EDECRIN PA (ethacrynic acid) FUROSCIX PA, QL (furosemide, SC kit)	LASIX (furosemide tabs)

Recommendation

It is recommended that at least 2 loop diuretics should be available as well as ethacrynic acid for patients with a sulfonamide allergy.

COMMITTEE VOTE

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

Prior Authorization criteria for EDECRIN

Current Criteria:

- Clinically valid reason why ethacrynic acid cannot be used

Proposed Criteria:

Remove PA criteria

COMMITTEE VOTE

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

Prior Authorization criteria for FUROSCIX

Current Criteria:

- Diagnosis of New York Heart Association (NYHA) Class II or Class III chronic heart failure; **AND**
- Patient has signs and symptoms of congestive heart failure due to fluid overload; **AND**
- The patient is currently receiving maximal oral diuretic therapy; **AND**
- Prescriber attest that additional oral diuretic therapy would be ineffective; **AND**
- Prescribed by, or in verbal consultation with, a cardiologist; **AND**
- Prescriber has demonstrated appropriate administration use of the On-Body Infusor®

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Quantity Limits

- FUROSCIX 4 devices/month

COMMITTEE VOTE

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

DIURETICS: THIAZIDE AND RELATED

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred		Non-Preferred
Diuretics: Thiazide and Related	chlorothiazide chlorthalidone hydrochlorothiazide	indapamide metolazone	DIURIL suspension [PA] (chlorothiazide) THALITONE (chlorthalidone)

Recommendation

It is recommended that at least 3 agents be available for use, one of which should be hydrochlorothiazide as this is the most commonly used agent. Additionally, either chlorothiazide or metolazone should be available.

COMMITTEE VOTE

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

Prior Authorization criteria for DIURIL SUSPENSION

Current Criteria:

- Patient is unable to swallow solid dosage forms

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

HEMOSTATICS, ORAL

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred		Non-Preferred
Hemostatics, Oral	aminocaproic acid LYSTEDA [PA, QL] (tranexamic acid)	tranexamic acid [PA, QL]	AMICAR (aminocaproic acid)

Recommendation

It is recommended that aminocaproic acid and tranexamic acid be available for use.

COMMITTEE VOTE

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

Prior Authorization criteria for tranexamic acid, LYSTEDA

Current Criteria:

- Diagnosis of acute uterine or cyclic heavy menstrual bleeding; **AND**
  - Trial and failure, contraindication, or intolerance to ALL the following:
    - Two other forms of hormone therapy (oral, vaginal, topical, or injectable estrogen and/or progesterone)
  - Levonorgestrel-releasing IUD; **OR**
- All other diagnoses require trial and failure, intolerance, or contraindication to aminocaproic acid

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Quantity Limits

- LYSTEDA 30/28 days

COMMITTEE VOTE

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

LIPOTROPICS: BILE ACID SEQUESTRANTS

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred		Non-Preferred	
Lipotropics: Bile Acid Sequestrants	cholestyramine cholestyramine light	PREVALITE (cholestyramine resin) WELCHOL tablets (colesevelam)	COLESTID (colestipol) colesevelam packets PA colesevelam tablets colestipol	QUESTRAN (cholestyramine resin) QUESTRAN LIGHT (cholestyramine resin) WELCHOL PACKETS PA (colesevelam)

Recommendation

~~Colesevelam has been associated with a lower incidence of GI related symptoms compared to colestipol and cholestyramine. Due to its potential benefits compared to others,~~ It is recommended that colesevelam be available for use. Because of cholestyramine's additional FDA-approved indication, it is also recommended that it be available for use.

COMMITTEE VOTE

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

Prior Authorization criteria for colesevelam packets, WELCHOL PACKETS

Current Criteria:

- Patient is unable to swallow solid dosage forms

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

LIPOTROPICS: FIBRIC ACID DERIVATIVES

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred	
Fibric Acid Derivatives	fenofibrate tabs 48, 145, & 160mg gemfibrozil	ANTARA PA (fenofibrate caps) fenofibrate caps PA fenofibrate tabs 40, 54, & 120mg PA fenofibric acid PA FENOGLIDE PA (fenofibrate tabs)	FIBRICOR PA (fenofibric acid tabs) LIPOFEN PA (fenofibrate caps) LOPID (gemfibrozil) TRICOR PA (fenofibrate tabs) TRILIPIX PA (fenofibrate DR caps)

Recommendation

Gemfibrozil is the only fibric acid derivative approved for reducing the risk of developing coronary heart disease; therefore, it is recommended that at least gemfibrozil should be available for use. Additionally, due to fewer potential drug-drug interactions with fenofibrate compared to gemfibrozil, a fenofibrate product be available to individuals requiring dual therapy with a statin or currently receiving repaglinide, a TZD, or a sulfonylurea.

COMMITTEE VOTE

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

Prior Authorization criteria for ANTARA, fenofibrate caps, fenofibrate tabs (40/54/120mg), fenofibric acid, FENOGLIDE, FIBRICOR, LIPOFEN, LOFIBRA, TRICOR, TRILIPIX

Current Criteria:

- Patient will take fenofibrate concomitantly with a sulfonylurea, thiazolidinedione, repaglinide, or a statin; **OR**
- Clinically valid reason why a preferred agents cannot be used (e.g., gemfibrozil, fenofibrate tabs 48, 145, & 160 mg)

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

PLATELET INHIBITORS

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred		Non-Preferred	
Platelet Inhibitors	aspirin/dipyridamole anagrelide BRILINTA PA (ticagrelor) cilostazol	clopidogrel 75 mg dipyridamole *prasugrel PA*	AGRYLIN (anagrelide) CABLIVI PA (caplacizumab) clopidogrel 300 mg DURLAZA PA, QL (aspirin)	EFFIENT PA (prasugrel) PLAVIX (clopidogrel) YOSPRALA PA, QL (aspirin/omeprazole) ZONTIVITY PA, QL (vorapaxar)

Recommendation

It is recommended at least clopidogrel, *anagrelide,* and *dipyridamole/aspirin* should be available for use. *It is recommended that* ticagrelor and prasugrel should be subject*ed* to prior authorization ~~restriction use~~ to *ensure appropriate use for* FDA-approved indications. ~~Based on current clinical guidelines recommending dual antiplatelet therapy with ticagrelor and aspirin for the first year after ACS, it is recommended ticagrelor should be available for this population. Based on the available evidence demonstrating a clinical benefit, the recommendations from current clinical guidelines and the recognition that the combination product cannot be interchanged with the individual drug components, it is recommended that the dipyridamole/aspirin combination product should be available for use. Additionally, due to its unique indication, anagrelide should be available for the treatment of thrombocythemia associated with myeloproliferative disorders.~~

COMMITTEE VOTE

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

Prior Authorization criteria for BRILINTA

Current Criteria:

- History of Myocardial Infarction (MI); **OR**
- ACS initial event (USA, NSTEMI or STEMI) or recurrence within previous 12 months; **OR**
- Patient has diagnosis of coronary artery disease (CAD) and is at high risk for myocardial infarction (MI) or stroke, **OR**
- Acute ischemic stroke or transient ischemic attack (TIA) risk reduction

Note: Will NOT be approved if patient is receiving aspirin doses > 100mg/day (includes Rx & OTC aspirin containing products)

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for prasugrel, EFFIENT

Current Criteria:

- Patients has unstable angina, NSTEMI, or STEMI; **AND**
- PCI has been performed or PCI is planned; **AND**
- Age < 75 years; **AND**
- Weight ≥ 60 kg; **AND**
- No history of stroke or TIA; **AND**
- Contraindication, drug-drug interaction, or intolerance to Brilinta®.

Proposed Criteria:

- Patients has unstable angina, NSTEMI, or STEMI; **AND**
- PCI has been performed or PCI is planned; **AND**
- Age < 75 years; **AND**
- Weight ≥ 60 kg; **AND**
- No history of stroke or TIA; **AND**
- ~~Contraindication, drug-drug interaction, or intolerance to Brilinta®.~~
- *If request if for brand EFFIENT, clinically valid reason as to why the preferred generic prasugrel cannot be used*

COMMITTEE VOTE

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

Prior Authorization criteria for CABLIVI

Current Criteria:

Criteria: (2-month duration)

- Diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP); **AND**
- Used in combination with both of the following:
  - Plasma exchange until at least 2 days after normalization of the platelet count
  - Immunosuppressive therapy (e.g., corticosteroids); **AND**
- Date Cablivi IV was initiated/administered by a healthcare provider; **AND**
- Total treatment duration will be limited to 58 days beyond the last therapeutic plasma exchange; **AND**
- The patient has not experienced more than two recurrences of aTTP while on Cablivi

Note: If started as an inpatient hospital regimen and this is continuation of therapy, Cablivi® will be approved

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for DURLAZA

Current Criteria:

- Trial and failure, contraindication, or intolerance to 2 preferred platelet inhibitors with the same indication; **AND**
- Clinically valid reason why OTC aspirin cannot be used

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for YOSPRALA

Current Criteria:

- Diagnosis of one of the following:
  - Ischemic stroke,
  - Transient ischemia of the brain,
  - Previous myocardial infarction,
  - Unstable angina pectoris,
  - Chronic stable angina pectoris; **OR**
- Patient has had ONE of the following:
  - Coronary Artery Bypass Graft (CABG)

- Percutaneous Transluminal Coronary Angioplasty (PTCA); **AND**

- Patient meets ALL of the following:
  - Patient is considered a high-risk candidate for aspirin-associated gastric ulcers due to ONE of the following:
    - Age ≥ 55, **OR**
    - Documented history of gastric ulcers; **AND**
  - Patient had an inadequate treatment response, or intolerance to use of aspirin and omeprazole separately

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for ZONTIVITY

Current Criteria:

- Patient has a history of myocardial infarction (MI) or established peripheral arterial disease (PAD); **AND**
- Patients must not have a history of stroke, transient ischemic attack (TIA), intracranial hemorrhage (ICH), active pathological bleeding, or peptic ulcer due to the risk of bleeding; **AND**
- Concomitant therapy with clopidogrel, unless patient has a contraindication to clopidogrel, in which case patient must have concomitant therapy with aspirin

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Quantity Limits

• DURLAZA	1/day
• YOSPRALA	1/day
• ZONTIVITY	1/day

COMMITTEE VOTE

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

PULMONARY FIBROSIS AGENTS

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred		Non-Preferred	
Pulmonary Fibrosis Agents	OFEV PA, QL (nintedanib)	pirfenidone tablets PA, QL	ESBRIET PA, QL (pirfenidone)	pirfenidone capsules PA, QL

Recommendation

It is recommended that Ofev and Esbriet be available with prior authorization criteria.

COMMITTEE VOTE

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

Prior Authorization criteria for OFEV

Current Criteria:

- Diagnosis of one of the following:
  - Idiopathic pulmonary fibrosis
  - Interstitial Lung Disease Associated with Systemic Sclerosis- associated interstitial lung disease (SSc-ILD)
  - Chronic Fibrosing Interstitial Lunch Diseases (ILDs) with a progressive phenotype (at least 10% of the lungs show presence of fibrotic ILD); **AND**
- Prescribed by, or in consultation with, a Pulmonologist (initial approval only)

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for pirfenidone tablets

Current Criteria:

- Patient has a diagnosis of idiopathic pulmonary fibrosis; **AND**
- Prescribed by, or in consultation with, a Pulmonologist (initial approval only)

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for ESBRIET TABLETS AND CAPSULES, pirfenidone capsules

Current Criteria:

- Patient has a diagnosis of idiopathic pulmonary fibrosis; **AND**
- Prescribed by, or in consultation with, a Pulmonologist (initial approval only); **AND**
- Clinically valid reason why the preferred pirfenidone cannot be used

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Quantity Limits

• OFEV	2/day
• pirfenidone tablets 534mg, 801mg	3/day
• pirfenidone tablets 267mg	9/day
• ESBRIET 801mg	3/day
• ESBRIET 267mg	9/day
• pirfenidone capsules 267mg	9/day

COMMITTEE VOTE

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

OPHTHALMIC ANTIBIOTIC/STEROID COMBINATIONS

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred
Antibiotic/ Steroid Combos	neomycin/BAC/poly B/HC QL neomycin/poly B/dexamethasone sulfacetamide/prednisolone QL PRED-G QL (prednisolone/gentamicin) tobramycin/dexamethasone suspension QL	BLEPHAMIDE QL (sulfacetamide/prednisolone) MAXITROL QL (neomycin/poly B/dexamethasone) neomycin/poly B/HC QL TOBRADEX ointment QL (tobramycin/dexamethasone) TOBRADEX suspension QL (tobramycin/dexamethasone) TOBRADEX ST suspension QL (tobramycin/dexamethasone) ZYLET PA, QL (loteprednol/tobramycin)

Recommendation

It is recommended that at least three ophthalmic antibiotic steroid combination products be available for use, with at least one of these being an ointment formulation and one approved for use in patients down to 2 years of age. Additionally, given that loteprednol is associated with a lower increase in IOP than other ophthalmic steroids, tobramycin/loteprednol should be available for those patients in whom increased IOP is a concern.

COMMITTEE VOTE

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

Prior Authorization criteria for ZYLET

Current Criteria:

- Trial and failure, contraindication, or intolerance of TWO preferred agents; **OR**
- There is concern over a potential increase in intra-ocular pressure (IOP) with other steroids (i.e., glaucoma, recipient is pre- or post-cataract surgery and a known steroid-responder)

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Quantity Limits

• neomycin/BAC/poly B/HC	1 package/Rx
• sulfacetamide/prednisolone	1 package/Rx
• PRED-G	1 package/Rx
• tobramycin/dexamethasone suspension	1 package/Rx
• BLEPHAMIDE	1 package/Rx
• MAXITROL	1 package/Rx
• neomycin/poly B/HC	1 package/Rx
• TOBRADEX ointment and suspension	1 package/Rx
• TOBRADEX ST suspension	1 package/Rx
• ZYLET	1 package/Rx

COMMITTEE VOTE

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

OPHTHALMIC ANTIFUNGALS

PDL Placement:

	Preferred	Non-Preferred
Ophthalmic Antifungals	NATACYN [PA, QL] (natamycin)	N/A

Recommendation

It is recommended that natamycin be available for use in ocular fungal infections.

COMMITTEE VOTE

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

Prior Authorization criteria for NATACYN

Current Criteria:

- Diagnosis of ophthalmic fungal infection

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Quantity Limits

- NATACYN 1 package/Rx

COMMITTEE VOTE

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

OPHTHALMIC ANTIVIRALS

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred		Non-Preferred
Ophthalmic Antivirals	trifluridine QL	ZIRGAN ~~PA >5yr old~~, QL (ganciclovir)	N/A

Recommendation

It is recommended that at least one ophthalmic antiviral agent be available for use. Additionally, ophthalmic ganciclovir should be available for patients less than 6 years of age.

COMMITTEE VOTE

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

Prior Authorization criteria for ZIRGAN

Current Criteria:

Prior authorization required for beneficiaries ages 5 years and older

Proposed Criteria:

Remove PA

COMMITTEE VOTE

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

Quantity Limits

- trifluridine 1 package/Rx
- ZIRGAN 1 package/Rx

COMMITTEE VOTE

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

OPHTHALMIC STEROIDS

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred	
Ophthalmic Steroids	ALREX QL (loteprednol) difluprednate emulsion QL fluorometholone QL LOTEMAX drops QL (loteprednol) PRED MILD QL (prednisolone) prednisolone acetate QL	dexamethasone QL DUREZOL QL (difluprednate) EYSUVIS PA, QL (loteprednol) FLAREX QL (fluorometholone) FML FORTE QL (fluorometholone) FML LIQUIFILM QL (fluorometholone)	INVELTYS (loteprednol) LOTEMAX gel & ointment QL (loteprednol) loteprednol suspension and gel QL MAXIDEX QL (dexamethasone) prednisolone sodium phosphate QL PRED FORTE QL (prednisolone)

Recommendation

It is recommended that at least three ophthalmic steroids should be available for use, one of which should be prednisolone acetate. Additionally, due to the decreased relative risk of elevated intraocular pressure, loteprednol should be available for patients where a potential increase in intraocular pressure would place the patient at risk.

COMMITTEE VOTE

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

Prior Authorization criteria for EYSUVIS

Current Criteria:

- Patient is being treated for symptoms of Dry Eye disease; **AND**
- Patient has had a trial and failure of Restasis; **AND**
- Patient has had a trial and failure of a preferred loteprednol product (e.g., Alrex, Lotemax suspension)

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Quantity Limits

• ALREX	1 package/Rx	• FLAREX	1 package/Rx
• DUREZOL	1 package/Rx	• FML FORTE	1 package/Rx
• fluorometholone	1 package/Rx	• FML LIQUIFILM and ointment	1 package/Rx
• LOTEMAX suspension	1 package/Rx	• LOTEMAX gel and ointment	1 package/Rx
• PRED MILD	1 package/Rx	• loteprednol gel	1 package/Rx
• prednisolone acetate	1 package/Rx	• loteprednol drops	15mL/Rx
• dexamethasone	1 package/Rx	• MAXIDEX	1 package/Rx
• difluprednate emulsion	1 package/Rx	• prednisolone phosphate	1 package/Rx
• EYSUVIS	1 package/Rx	• PRED FORTE	1 package/Rx

COMMITTEE VOTE

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

BUPRENORPHINE AND BUPRENORPHINE/NALOXONE

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred
Buprenorphine and Buprenorphine /Naloxone	**Buprenorphine Enhanced Supportive Medication-Assisted Recovery and Treatment (BESMART) Network Provider only:**	
	buprenorphine/naloxone tabs PA, QL buprenorphine/naloxone film PA, QL	buprenorphine PA, QL SUBOXONE film PA, QL (buprenorphine/naloxone SL film) ZUBSOLV PA, QL (buprenorphine/naloxone SL tablet)
	All other TennCare Providers:	
	buprenorphine/naloxone tabs PA, QL	buprenorphine PA, QL buprenorphine/naloxone film PA, QL SUBOXONE film PA, QL (buprenorphine/naloxone SL film) ZUBSOLV PA, QL (buprenorphine/naloxone SL tablet)

Recommendation

Given the need for intensive monitoring of therapy, extensive training of prescribers, and potential side effects of these products, it is recommended that buprenorphine and buprenorphine/naloxone be available for the treatment of opioid dependence subject to prior authorization but with clinical criteria and time limits to ensure their appropriate use, while minimizing barriers to timely access and appropriate duration of therapy.

COMMITTEE VOTE

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

**** For children, larger quantities may be approved as medically necessary.***
^ Requests for 4/day will only be approved if dose is being titrated or patient's condition is too unstable to attempt to change to a higher strength

Buprenorphine Enhanced Supportive Medication-Assisted Recovery and Treatment (BESMART) Network Provider only:

Prior Authorization criteria for buprenorphine/naloxone tablets, buprenorphine/naloxone film, BUNAVAIL

Current Criteria:

No PA required for up to max daily dose (MDD) of 16 mg of preferred products buprenorphine/naloxone tabs and films.

Criteria for requests for patients 21 years of age and older for >16mg to ≤24mg **

- Diagnosis of opiate addiction; **AND**
- Prescriber is NOT a nurse practitioner or physician assistant; **AND**
- Prescriber is enrolled and in good standing in the BESMART program; **AND**
- Prescriber provides clinical rationale for the requested dosage with one of the following reasons:
  - Pregnant patients confirmed by provider attestation.
  - Postpartum patients for a period of 12 months from delivery date as shown by medical records or insurance claim.
  - Recent IV drug users confirmed by prescriber attestation and a positive urine drug screen
  - Current users receiving greater than 50 mg of methadone for OUD treatment transitioning to buprenorphine agonist therapy demonstrated by paid claims data from the enrollee's health insurer, provider attestation, or medical records.
  - Newly eligible TennCare enrollees who are current users of 16 mg to 24 mg per day of buprenorphine demonstrated by paid claims data from the enrollee's previous health insurer

PA duration: Initial Authorization – 6 months; Total duration up to 12 months; Pregnancy: through the duration of pregnancy; Post-partum: 12 months post-delivery date
**Applies to adult enrollees only. Children have access to 24 mg of buprenorphine daily across both networks; criterion applies.

Proposed Criteria:
Same as current

COMMITTEE VOTE
APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for buprenorphine

Current Criteria:
See buprenorphine/naloxone tab prior authorization criteria
- Additionally, must be unable to take buprenorphine/naloxone as indicated by ONE of the following:
  - Patients who are actively pregnant or breastfeeding
  - Patient is unable to take naloxone containing products due to a contraindication, drug to drug interaction, or history of toxic side effects that caused immediate or long-term damage (Note: This does not include GI intolerance – FAX DOCUMENTATION REQUIRED)

PA duration: Pregnant Patients – Duration of Pregnancy; Breastfeeding Patients – 6 months; Contraindication to Naloxone – Initial Authorization 6 months, Reauthorization 12 months

Proposed Criteria:
Same as current

COMMITTEE VOTE
APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

Prior Authorization criteria for SUBOXONE FILM, ZUBSOLV

Current Criteria:
See buprenorphine/naloxone tab prior authorization criteria
- Additionally, a documented allergy to inactive ingredient in preferred product that is not in requested product

Proposed Criteria:
Same as current

COMMITTEE VOTE
APPROVED **DISAPPROVED** **APPROVED with MODIFICATION**

All other TennCare Providers:

Prior Authorization criteria for buprenorphine/naloxone tablets

Current Criteria:
Preferred buprenorphine/naloxone products will be approved for recipients who meet **ALL** of the following criteria:
- Diagnosis of opiate addiction
- Physician attests they have reviewed the Tennessee Controlled Substances Database for this patient on the date of prior authorization request to ensure concomitant narcotic or benzodiazepine use is not occurring.

Additional Information:
- Buprenorphine will not be approved for treatment of depression or pain.

- Buprenorphine will not be approved for recipients whose medication history indicates use of concomitant narcotics or benzodiazepines without a clinically valid reason and drug tapering plan
- Quantity limit is as a single daily dose. Twice daily dosing may be approved as clinically necessary.
- Physicians will be asked to provide an anticipated treatment plan for the patient (including anticipated dosing for induction & maintenance phases, anticipated frequency of office visits, & anticipated plan for psychosocial counseling).
- The "Here to Help" program as an exclusive provider of counseling will not be accepted.
- Prior Authorizations will be assigned to the prescribing physician.
- Requests for buprenorphine from a different physician will require a new prior authorization request and documentation that the previous prescribing physician has communicated transfer of care

Proposed Criteria:
Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for buprenorphine

Current Criteria:
See buprenorphine/naloxone tab prior authorization criteria
- Additionally, must be unable to take buprenorphine/naloxone as indicated by ONE of the following:
  - Patients who are actively pregnant (Note: Buprenorphine without naloxone will not be approved for patients who are breastfeeding)
  - Patient is unable to take naloxone containing products due to a contraindication, drug to drug interaction, or history of toxic side effects that caused immediate or long-term damage (Note: This does not include GI intolerance, nausea, vomiting, headaches – FAX DOCUMENTATION REQUIRED)

Proposed Criteria:
Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for buprenorphine/naloxone film, SUBOXONE FILM, ZUBSOLV

Current Criteria:
See buprenorphine/naloxone tab prior authorization criteria
- Additionally, a documented allergy to inactive ingredient in preferred product that is not in requested product

Proposed Criteria:
Same as current

COMMITTEE VOTE

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

Quantity Limits

Buprenorphine Enhanced Supportive Medication-Assisted Recovery and Treatment (BESMART) Network Provider only:
- buprenorphine/naloxone tablets 8/2mg 2/day
- buprenorphine/naloxone tablets 2/0.5mg 3/day^
- buprenorphine/naloxone film 12/3mg 1/day
- buprenorphine/naloxone film 8/2mg 2/day
- buprenorphine/naloxone film 4/1mg 1/day

- buprenorphine/naloxone film 2/0.5mg 3/day^
- buprenorphine 8mg 2/day
- buprenorphine 2mg 3/day^
- SUBOXONE film 12/3mg 1/day
- SUBOXONE film 8/2mg 2/day
- SUBOXONE film 4/1mg 2/day
- SUBOXONE film 2/0.5mg 3/day^
- ZUBSOLV 11.4/2.9MG 1/DAY
- ZUBSOLV 8.6/2.1MG 1/DAY
- ZUBSOLV 5.7/1.4MG 2/DAY
- ZUBSOLV 2.9/0.71MG 2/DAY
- ZUBSOLV 1.4/0.36MG 3/DAY
- ZUBSOLV 0.7/0.18MG 3/DAY

All other TennCare Providers:

- buprenorphine/naloxone tablets 8/2mg 2/day x 6 months, then 1/day*
- buprenorphine/naloxone tablets 2/0.5mg 3/day*^
- buprenorphine 8mg 2/day x 6 months, then 1/day*
- buprenorphine 2mg 3/day*^
- buprenorphine/naloxone film 8/2mg 2/day x 6 months, then 1/day*
- buprenorphine/naloxone film 2/0.5mg 3/day*^
- SUBOXONE film 12/3mg 1/day x 6 months*
- SUBOXONE film 8/2mg 2/day x 6 months, then 1/day*
- SUBOXONE film 4/1mg 2/day
- SUBOXONE film 2/0.5mg 3/day*^
- ZUBSOLV 11.4/2.9MG 1/day x 6 months
- ZUBSOLV 8.6/2.1MG 1/day x 6 months
- ZUBSOLV 5.7/1.4MG 2/day x 6 months, then 1/day*
- ZUBSOLV 2.9/0.71MG 2/day
- ZUBSOLV 1.4/0.36MG 3/day
- ZUBSOLV 0.7/0.18MG 3/day*

^Requests for 4/day will only be approved if dose is being titrated or patient's condition is too unstable to attempt to change to a higher strength
*For children, larger quantities may be approved as medically necessary

COMMITTEE VOTE

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

NALOXONE PRODUCTS

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred
Naloxone Products	*naloxone injection* QL naloxone nasal spray QL NARCAN nasal spray QL (naloxone) KLOXXADO nasal spray QL (naloxone) *OPVEE QL (nalmefene)*	N/A

Recommendation

~~Naloxone hydrochloride injection and naloxone hydrochloride nasal spray offer methods for emergency treatment for opioid overdose until medical treatment is obtained. Both naloxone formulations in this class are FDA-approved for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.~~ Current clinical guidelines recommend clinicians should incorporate offering naloxone into the opioid management plan strategy when factors that increase risk for opioid overdose are present. Therefore, it is recommended at least one naloxone formulation indicated for emergency treatment of known or suspected opioid overdose be available for use for patients considered to be high-risk for opioid overdose.

COMMITTEE VOTE

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

Quantity Limits

- *Naloxone injection* — *2 injections/30 days*
- Naloxone nasal spray — 2 sprayers/30 days
- Narcan nasal spray — 2 sprayers/30 days
- Kloxxado nasal spray — 2 sprayers/30 days
- *Opvee* — *2 sprayers/30 days*

COMMITTEE VOTE

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

NARCOTICS AGONIST/ANTAGONISTS

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred
Narcotic Agonist/Antagonists	nalbuphine injection PA, QL	butorphanol NS PA, QL pentazocine/naloxone PA, QL

Recommendation

The narcotic agonist/antagonist class includes butorphanol nasal solution, nalbuphine and the combination tablets pentazocine/naloxone. All of the agents in this class are FDA approved for the treatment of pain. Limited clinical information regarding the safety and effectiveness of these agents is available within the literature and current clinical guidelines do not specifically discuss the role these agents play in the treatment of pain. Due to limited clinical data as well as the potential for abuse, physical dependence, and/or psychological dependence, it is recommended all agents in this class are subject to clinical criteria.

COMMITTEE VOTE

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

Prior Authorization criteria for nalbuphine

Current Criteria:

- Trial and failure of at least 2 short acting narcotics; **OR**
- Documented contraindication, or intolerance to short acting narcotics; **AND**
- Unable to swallow, OR Unable to absorb medications through the GI tract.

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for butorphanol nasal spray

Current Criteria:

- Documented inability to swallow or absorb PO narcotics, **OR**
- For the treatment of migraines; **AND**
  - Recipient MUST be receiving prophylactic therapy for migraines, **AND**
  - Trial and failure, intolerance, or contraindication to at least **ONE** agent in EACH of the following categories:
    - 5HT1 receptor antagonist (triptans)
    - Anti-migraine combinations
    - NSAIDs

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Prior Authorization criteria for pentazocine/naloxone

Current Criteria:

- Contraindication, or intolerance to ALL short acting narcotics
- Prescriber has checked the Tennessee Controlled Substance Database for this patient within the last 30 days

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Quantity Limits

• nalbuphine (10mg/mL)	4mL/day
• nalbuphine (20mg/mL)	8mL/day
• butorphanol nasal spray	2.5mL/30 days
• pentazocine/naloxone	12/day

COMMITTEE VOTE

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

TRANSMUCOSAL FENTANYL PRODUCTS

Abbreviated Re-Review: Pharmacy Initiatives

PDL Placement:

	Preferred	Non-Preferred
Transmucosal Fentanyl Products	N/A	fentanyl lozenge [PA, QL] Fentora [PA, QL] (fentanyl buccal tablet) Subsys [PA, QL] (fentanyl SL liquid)

Recommendation

Fentanyl transmucosal products are short-acting opioids that are FDA approved for the management of breakthrough cancer pain in patients who are already receiving and who are tolerant to around-the-clock therapy for their underlying persistent pain. ~~The effectiveness of fentanyl is well documented by clinical trials. Currently no head-to-head trials comparing the available formulations have been conducted and all agents in this category can be considered therapeutic alternatives. Therefore, it is recommended at least one transmucosal fentanyl product should be available for use. Additionally,~~ Due to the significant safety concerns in opioid non-tolerant patients as well as the potential for abuse, it is recommended all agents in this class should be subject to clinical criteria.

COMMITTEE VOTE

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

Prior Authorization criteria for fentanyl lozenge, FENTORA, SUBSYS

Current Criteria:

- Medication is ordered for the treatment of breakthrough cancer pain
- Recipient must be receiving around-the-clock scheduled long-acting opioids
- Recipient must be tolerant to opioids, defined as one of the following:
  - ≥ 60 mg oral morphine per day for at least one week without adequate pain relief
  - ≥ 25 mcg/hr transdermal fentanyl for at least one week without adequate pain relief
  - ≥ 30 mg oral oxycodone/day for at least one week without adequate pain relief
  - ≥ 8 mg oral hydromorphone/day for at least one week without adequate pain relief
  - ≥ 25 mg oral oxymorphone/day for at least one week without adequate pain relief
  - Equianalgesic dose of another opioid for at least one week without adequate pain relief
- Trial and failure, contraindication, intolerance, or drug-to-drug interaction with at least two immediate release opioid products

Note: Prescription should be written by or in consultation with an oncologist or pain management specialist unless patient is enrolled in or eligible for hospice care.

Proposed Criteria:

Same as current

COMMITTEE VOTE

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

Quantity Limits

• fentanyl lozenge	4/day
• FENTORA	4/day
• SUBSYS	4/day

COMMITTEE VOTE

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

Discussion and Approval:

A motion to approve all class recommendations, all prior authorization criteria, and quantity limits for all abbreviated drug class reviews was made by Dr. Johns, seconded by Dr. Alston, and unanimously carried.

Dr. Phares asked if carvedilol is preferred or non-preferred medication. Dr. Lovett stated carvedilol is listed under the alpha-beta blocker category on the PDL and it is preferred without PA with quantity limits. Dr. Capparelli stated according to state law, nurse practitioners and physician assistants cannot prescribe buprenorphine.

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.

- **Cardiovascular**
  - Alpha-Blockers
  - Alpha-Beta Blockers
  - ACEI + Calcium Channel Blocker
  - ACEI + Diuretic
  - ARB + Calcium Channel Blocker
  - ARB + Diuretic
  - Anticoagulants, Injectable
  - Beta Blockers + Diuretic
  - Cardiac Glycosides
  - Direct Renin Inhibitors
  - Diuretics: Carbonic Anhydrase
  - Diuretics: Combinations
  - Intermittent Claudication
  - Lipotropics: Cholesterol Absorption Inhibitors
  - Lipotropics: Combination Agents
  - Lipotropics: Niacin Derivatives
  - Lipotropics: Statins, Low Intensity
  - Lipotropics: Statins, Moderate Intensity
  - Lipotropics: Statins, High Intensity
  - Lipotropics: Statin + Calcium Channel Blocker
  - Pheochromocytoma Agents
  - Thrombopoietin Agonists, Oral
  - Transthyretin Amyloidosis Agents
  - Vasodilator + Nitrate
  - Vasopressor Receptor Antagonists
  - Vasopressors
- **Ophthalmics**
  - Alpha Agonists
  - Antibiotics
  - Beta Blockers
  - Carbonic Anhydrase Inhibitors
  - Glaucoma Combinations
  - Kinase Inhibitors
  - Lubricants and Artificial Tears
  - Miotics
  - Miscellaneous Ophthalmics
  - Mydriatics and Mydriatic Combos

Discussion and Approval:

A motion to approve all class recommendations, all prior authorization criteria, and quantity limits for all low utilization drug class reviews was made by Dr. Alston, seconded by Dr. Phares, and unanimously carried.

REVIEW OF DECISIONS FROM PREVIOUS MEETING (GRAYED-OUT PACKET)

Dr. Kiriakopoulos reviewed decisions made by TennCare from the August 10, 2023, PAC meeting.
She noted that all recommendations made by the committee were accepted.

AD HOC DISCUSSION

Dr. Williams-Clark reviewed the proposed 2024 PAC meeting dates with the committee. The May 9th PAC meeting will be in person the others will be virtual via Microsoft Teams.

MEETING ADJOURNMENT