

## Criteria for Indiana Medicaid Targeted Immunomodulators PA Criteria

Prepared for State of Indiana by OptumRx

### EXECUTIVE SUMMARY

**Purpose:** Promote prudent prescribing of Targeted Immunomodulators

**Setting & Population:** All members

**Type of Criteria:**  Increased Risk of ADE  Non-Preferred Agent  
 Appropriate Indications  Other:

**Data Sources:**  Only administrative databases  Databases + Prescriber-supplied

TARGETED PRODUCTS	HCPCS CODE
<b>PREFERRED AGENTS</b>	
ACTEMRA (TOCILIZUMAB)	J3262
ADALIMUMAB-FKJP (unbranded HULIO)	None
ADBRY (TRALOKINUMAB-LDRM)	None
ENBREL (ETANERCEPT)	J1438
HADLIMA (ADALIMUMAB-BWWD)	None
HUMIRA (ADALIMUMAB)	J0135
INFLIXIMAB (unbranded REMICADE)	J1745
KINERET (ANAKINRA)	None
OLUMIANT (BARICITINIB)	N/A
ORENCIA (ABATACEPT)	J0129
OTEZLA (APREMILAST)	N/A
SIMLANDI (ADALIMUMAB-RYVK)	None
SIMPONI (GOLIMUMAB); SIMPONI ARIA (GOLIMUMAB)	J1602
TALTZ (IXEKIZUMAB)	None
TYENNE (TOCILIZUMAB-AAZG)	Q5135
XELJANZ (TOFACITINIB)	N/A
YUSIMRY (ADALIMUMAB-AQVH)	None
<b>PREFERRED AGENTS (ONE-STEP)</b>	
AVSOLA (INFLIXIMAB-AXXQ)	Q5121
CIMZIA (CERTOLIZUMAB)	J0717
ENTYVIO (VEDOLIZUMAB); ENTYVIO PEN (VEDOLIZUMAB)	J3380

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KEVZARA (SARILUMAB)	None
LITFULO (RITLECITINIB)	N/A
NEMLUVIO (NEMOLIZUMAB-ILTO)	None
RINVOQ (UPADACITINIB)	N/A
RINVOQ LQ (UPADACITINIB)	N/A
XELJANZ XR (TOFACITINIB)	N/A
<b>NON-PREFERRED AGENTS (ONE-STEP)</b>	
COSENTYX (SECUKINUMAB)	J3247
SILIQ (BRODALUMAB)	None
<b>NON-PREFERRED AGENTS (TWO-STEP)</b>	
ABRILADA (ADALIMUMAB-AFZB)	Q5132
ADALIMUMAB-AACF (unbranded IDACIO)	Q5131
ADALIMUMAB-AATY (unbranded YUFLYMA)	None
ADALIMUMAB-ADAZ (unbranded HYRIMOZ)	None
ADALIMUMAB-ADBM (unbranded CYLTEZO)	None
ADALIMUMAB-RYVK (unbranded SIMLANDI)	None
AMJEVITA (ADALIMUMAB-ATTO)	None
ARCALYST (RILONACEPT)	J2793
BIMZELX (BIMEKIZUMAB-BKZX)	None
CIBINQO (ABROCITINIB)	N/A
CYLTEZO (ADALIMUMAB-ADBM)	None
EBGLYSS (LEBRIKIZUMAB-LBKZ)	None
HULIO (ADALMIMUMAB-FKJP)	None
HYRIMOZ (ADALIMUMAB-ADAZ)	None
IDACIO (ADALIMUMAB-AACF)	Q5131
ILARIS (CANAKINUMAB)	J0638
ILUMYA (TILDRAKIZUMAB-ASMN)	J3245
INFLECTRA (INFLIXIMAB-DYYB)	Q5103
OMVOH (MIRIKIZUMAB-MRKZ)	J2267
OTULFI (USTEKINUMAB-AAUZ)	Q9999
PYZCHIVA (USTEKINUMAB-TTWE)	Q9996, Q9997
REMICADE (INFLIXIMAB)	J1745
RENFLEXIS (INFLIXIMAB-ABDA)	Q5104
SELARSDI (USTEKINUMAB-AEKN)	Q9998

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SKYRIZI (RISANKIZUMAB-RZAA)	J2327
SOTYKTU (DEUCRAVACITINIB)	N/A
SPEVIGO (SPESOLIMAB-SBZO)	J1747
STELARA (USTEKINUMAB)	J3357, J3358
STEQEYMA (USTEKINUMAB-STBA)	Q5099
TOFIDENCE (TOCILIZUMAB-BAVI)	Q5133
TREMFYA (GUSELKUMAB)	J1628
USTEKINUMAB	J3357, J3358
USTEKINUMAB-AEKN	Q9998
USTEKINUMAB-TTWE	Q9996, Q9997
VELSIPITY (ETRASIMOD)	N/A
YESINTEK (USTEKINUMAB-KFCE)	Q5100
YUFLYMA (ADALIMUMAB-AATY)	None
ZYMFENTRA (INFLIXIMAB-DYYB)	J1748

### APPROVAL DURATION

- Approvals will be granted for up to 1 year, unless otherwise specified below

### APPROVAL CRITERIA

*Prior authorization for the prescribed drug will be granted when the following approval criteria has been met:*

**Note:** *The member must meet one of the criteria sets and have no history of a targeted immunomodulator (except Otezla (apremilast)) other than the one on the incoming claim in the past 30 days. Point of Sale Quick Check will process based on diagnosis history within the past 2 years or prior claims history within the past 365 days, unless otherwise specified.*

### PREFERRED AGENTS

#### ACTEMRA

##### Initial Authorization

- Must meet ONE of the following:
  - Diagnosis of cytokine release syndrome, polyarticular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis, or systemic sclerosis-associated interstitial lung disease (SSc-ILD)
  - Diagnosis of giant cell arteritis and BOTH of the following:
    - ≥90 days of drug therapy with one of the following: systemic glucocorticoid, azathioprine, or methotrexate
    - Member will be using a systemic glucocorticoid concurrently with tocilizumab
  - Diagnosis of rheumatoid arthritis and ONE of the following:
    - ≥90 days of drug therapy with one of the following: azathioprine, hydroxychloroquine, leflunomide, methotrexate, or sulfasalazine

## Criteria for Indiana Medicaid Targeted Immunomodulators PA Criteria

- Previous trial and failure of another targeted immunomodulator agent

### Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

### **ADALIMUMAB-FKJP (unbranded HULIO); HADLIMA; HUMIRA; SIMLANDI; YUSIMRY**

### Initial Authorization

- Must meet ONE of the following:
  - Diagnosis of ankylosing spondylitis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, or ulcerative colitis
  - Diagnosis of Crohn's disease and ONE of the following:
    - Diagnosis of Crohn's disease classified as moderate, severe, or fistulizing
    - ≥90 days of drug therapy with one or more of the following: azathioprine, mercaptopurine, mesalamine, methotrexate, or systemic glucocorticoid
    - Previous trial and failure of another targeted immunomodulator agent
  - Diagnosis of hidradenitis suppurativa and the following:
    - ≥90 days of drug therapy with one of the following: oral or topical antibiotic therapy, oral retinoid therapy, dapsone, or acitretin
  - Diagnosis of non-infectious uveitis and the following:
    - ≥90 days of drug therapy with one of the following: oral/injectable steroid therapy, methotrexate, mycophenolate, azathioprine, cyclosporine, tacrolimus, or cyclophosphamide
  - Diagnosis of psoriasis and ONE of the following:
    - Diagnosis of psoriasis classified as severe
    - Diagnosis of psoriasis of the fingernail
    - ≥90 days of topical drug therapy with one of the following: calcipotriene, corticosteroids, or tazarotene
    - ≥90 days of systemic drug therapy with one of the following: cyclosporine, methotrexate, or acitretin
    - Previous trial and failure of another targeted immunomodulator agent
  - Diagnosis of rheumatoid arthritis and ONE of the following:
    - ≥90 days of drug therapy with one of the following: azathioprine, hydroxychloroquine, leflunomide, methotrexate, or sulfasalazine
    - Previous trial and failure of another targeted immunomodulator agent

### Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

### **ADBRY**

### Initial Authorization

- Must meet ALL of the following:
  - Diagnosis of moderate to severe atopic dermatitis
  - Member is 12 years of age or older
  - One of the following:
    - ≥ 45 days of topical drug therapy with one of the following: corticosteroids, pimecrolimus, or tacrolimus
    - Prescriber has provided valid medical justification for the use of Adbry (tralokinumab-ldrm) over topical drug therapies

### Reauthorization

## Criteria for Indiana Medicaid Targeted Immunomodulators PA Criteria

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

### ENBREL

#### Initial Authorization

- Must meet ONE of the following:
  - Diagnosis of polyarticular juvenile idiopathic arthritis, psoriatic arthritis (adult or juvenile), or ankylosing spondylitis
  - Diagnosis of psoriasis and ONE of the following:
    - Diagnosis of psoriasis classified as severe
    - $\geq 90$  days of topical drug therapy with one of the following: calcipotriene, corticosteroids, or tazarotene
    - $\geq 90$  days of systemic drug therapy with one of the following: cyclosporine, methotrexate, or acitretin
    - Previous trial and failure of another targeted immunomodulator agent
  - Diagnosis of rheumatoid arthritis and ONE of the following:
    - $\geq 90$  days of drug therapy with one of the following: azathioprine, hydroxychloroquine, leflunomide, methotrexate, or sulfasalazine
    - Previous trial and failure of another targeted immunomodulator agent

#### Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

### INFLIXIMAB (unbranded REMICADE)

#### Initial Authorization

- Must meet ONE of the following:
  - Diagnosis of ankylosing spondylitis, psoriatic arthritis, or ulcerative colitis
  - Diagnosis of Crohn's disease and ONE of the following:
    - Diagnosis of Crohn's disease classified as moderate, severe, or fistulizing
    - $\geq 90$  days of drug therapy with one or more of the following: azathioprine, mercaptopurine, mesalamine, methotrexate, or systemic glucocorticoid
    - Previous trial and failure of another targeted immunomodulator agent
  - Diagnosis of psoriasis and ONE of the following:
    - Diagnosis of psoriasis classified as severe
    - $\geq 90$  days of topical drug therapy with one of the following: calcipotriene, corticosteroids, or tazarotene
    - $\geq 90$  days of systemic drug therapy with one of the following: cyclosporine, methotrexate, or acitretin
    - Previous trial and failure of another targeted immunomodulator agent
  - Diagnosis of rheumatoid arthritis and ONE of the following:
    - $\geq 90$  days of drug therapy with one of the following: azathioprine, hydroxychloroquine, leflunomide, methotrexate, or sulfasalazine
    - Previous trial and failure of another targeted immunomodulator agent

#### Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

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### KINERET

#### Initial Authorization

- Must meet ONE of the following:
  - Diagnosis of neonatal onset multisystem inflammatory disease (NOMID) or deficiency of interleukin-1 receptor antagonist (DIRA)
  - Diagnosis of rheumatoid arthritis and ONE of the following:
    - $\geq 90$  days of drug therapy with one of the following: azathioprine, hydroxychloroquine, leflunomide, methotrexate, or sulfasalazine
    - Previous trial and failure of another targeted immunomodulator agent

#### Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

### OLUMIANT

#### Initial Authorization

- Must meet ONE of the following:
  - Diagnosis of rheumatoid arthritis and the following:
    - Previous trial and failure of at least ONE TNF blocker and ONE other targeted immunomodulator agents
  - Diagnosis of severe alopecia areata defined as  $\geq 50\%$  of hair loss (must submit chart documentation) and BOTH of the following\*:
    - Member is 18 years of age or older
    - Prescribed by, or in consultation with, a dermatologist

#### Reauthorization

- Must meet BOTH of the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation
  - For severe alopecia areata indication ONLY: provider has submitted documentation regarding status of patient and response to therapy

***\*Note: Olumiant for severe alopecia areata indication will only be granted approval for 6 months on initial authorization, and 1 year for reauthorization.***

### ORENCIA

#### Initial Authorization

- Must meet ONE of the following:
  - Diagnosis of polyarticular juvenile idiopathic arthritis or psoriatic arthritis
  - Diagnosis of rheumatoid arthritis and ONE of the following:
    - $\geq 90$  days of drug therapy with one of the following: azathioprine, hydroxychloroquine, leflunomide, methotrexate, or sulfasalazine
    - Previous trial and failure of another targeted immunomodulator agent
  - Diagnosis of acute graft-versus-host disease prophylaxis and BOTH of the following:
    - Member will be using abatacept concurrently with both methotrexate and a calcineurin inhibitor
    - Member will be concurrently undergoing hematopoietic stem cell transplantation from a matched or 1 allele-mismatched unrelated donor

#### Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

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### OTEZLA

#### Initial Authorization

- Must meet ONE of the following:
  - Diagnosis of psoriatic arthritis
  - Diagnosis of adults with oral ulcers associated with Behcet's disease and the following:
    - $\geq 90$  days of drug therapy with colchicine
  - Diagnosis of psoriasis and ONE of the following:
    - Diagnosis of psoriasis classified as severe
    - $\geq 90$  days of topical drug therapy with one of the following: calcipotriene, corticosteroids, or tazarotene
    - $\geq 90$  days of systemic drug therapy with one of the following: cyclosporine, methotrexate, or acitretin
    - Previous trial and failure of another targeted immunomodulator agent

#### Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

### SIMPONI; SIMPONI ARIA

#### Initial Authorization

- Must meet ONE of the following:
  - Diagnosis of ankylosing spondylitis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, or ulcerative colitis
  - Diagnosis of rheumatoid arthritis and ONE of the following:
    - $\geq 90$  days of drug therapy with one of the following: azathioprine, hydroxychloroquine, leflunomide, methotrexate, or sulfasalazine
    - Previous trial and failure of another targeted immunomodulator agent

#### Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

### TALTZ

#### Initial Authorization

- Must meet ONE of the following:
  - Diagnosis of ankylosing spondylitis, non-radiographic axial spondyloarthritis, or psoriatic arthritis
  - Diagnosis of psoriasis and ONE of the following:
    - Diagnosis of psoriasis classified as severe
    - $\geq 90$  days of topical drug therapy with one of the following: calcipotriene, corticosteroids, or tazarotene
    - $\geq 90$  days of systemic drug therapy with one of the following: cyclosporine, methotrexate, or acitretin
    - Previous trial and failure of another targeted immunomodulator agent

#### Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

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### TYENNE

#### Initial Authorization

- Must meet ONE of the following:
  - Diagnosis of polyarticular juvenile idiopathic arthritis or systemic juvenile idiopathic arthritis
  - Diagnosis of giant cell arteritis and BOTH of the following:
    - ≥90 days of drug therapy with one of the following: systemic glucocorticoid, azathioprine, or methotrexate
    - Member will be using a systemic glucocorticoid concurrently with tocilizumab
  - Diagnosis of rheumatoid arthritis and ONE of the following:
    - ≥90 days of drug therapy with one of the following: azathioprine, hydroxychloroquine, leflunomide, methotrexate, or sulfasalazine
    - Previous trial and failure of another targeted immunomodulator agent

#### Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

### XELJANZ

#### Initial Authorization

- Must meet ONE of the following:
  - Diagnosis of ankylosing spondylitis or psoriatic arthritis and BOTH of the following:
    - Previous trial and failure of at least ONE or more TNF blocker
    - Dose does not exceed 5mg twice daily
  - Diagnosis of polyarticular juvenile idiopathic arthritis and BOTH of the following:
    - Previous trial and failure of a TNF blocker with juvenile idiopathic arthritis indication: adalimumab agents, Enbrel (etanercept), or Simponi (golimumab)
    - Dose does not exceed 5mg twice daily
  - Diagnosis of rheumatoid arthritis and BOTH of the following:
    - One of the following:
      - Previous trial and failure of at least ONE or more TNF blocker
      - ≥90 days of drug therapy with one of the following: azathioprine, hydroxychloroquine, leflunomide, methotrexate, or sulfasalazine
    - Dose does not exceed 5mg twice daily
  - Diagnosis of ulcerative colitis and BOTH of the following:
    - Previous trial and failure of a TNF blocker with an ulcerative colitis indication: adalimumab agents, infliximab agents, or Simponi (golimumab)
    - One of the following:
      - Dose does not exceed 10mg twice daily for the induction period up to 16 weeks
      - Dose does not exceed 5mg twice daily for the maintenance period

#### Reauthorization

- Must meet BOTH of the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation
  - Dose requested does not exceed established quantity limits for the indication

**Note: Xeljanz oral solution requires member to be 2 years of age or older and weighing 10 kg or more AND less than 18 years of age and weighing less than 40kg, OR provider has submitted documentation supporting inability to swallow tablet formulation**

## Criteria for Indiana Medicaid Targeted Immunomodulators PA Criteria

### PREFERRED AGENTS (ONE-STEP)

#### AVSOLA

##### Initial Authorization

- Must meet BOTH of the following:
  - Diagnosis of ankylosing spondylitis, moderate or severe Crohn's disease, psoriasis, psoriatic arthritis, rheumatoid arthritis, or ulcerative colitis
  - Previous trial of preferred infliximab AND prescriber has provided valid medical rationale for the use of Avsola (infliximab-axxq) over the preferred infliximab product(s)

##### Reauthorization

- Must meet BOTH of the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation
  - Previous trial of preferred infliximab AND prescriber has provided valid medical rationale for the use of Avsola (infliximab-axxq) over the preferred infliximab product(s)

#### CIMZIA

##### Initial Authorization

- Must meet BOTH of the following:
  - Diagnosis of ankylosing spondylitis, moderate or severe Crohn's disease, non-radiographic axial spondyloarthritis, psoriasis, psoriatic arthritis, polyarticular juvenile idiopathic arthritis, or rheumatoid arthritis
  - Previous trial and failure of another targeted immunomodulator agent

##### Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

#### ENTYVIO; ENTYVIO PEN

##### Initial Authorization

- Must meet BOTH of the following:
  - Diagnosis of moderate or severe Crohn's disease or ulcerative colitis
  - Previous trial and failure of another targeted immunomodulator agent

##### Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

#### KEVZARA

##### Initial Authorization

- Must meet ONE of the following:
  - Diagnosis of polyarticular juvenile idiopathic arthritis AND the following:
    - Previous trial and failure of another targeted immunomodulator agent
    - Member weighs  $\geq$  63 kg

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- Diagnosis of polymyalgia rheumatica AND the following:
  - ≥90 days of drug therapy with oral corticosteroids or methotrexate
- Diagnosis of rheumatoid arthritis AND the following:
  - Previous trial and failure of another targeted immunomodulator agent

### Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

### LITFULO

#### Initial Authorization

- Must meet ALL of the following:
  - Diagnosis of severe alopecia areata defined as  $\geq 50\%$  of hair loss (must submit chart documentation)\*
  - Member is 12 years of age or older
  - Previous trial and failure of Olumiant (baricitinib)
  - Prescribed by, or in consultation with, a dermatologist

#### Reauthorization

- Must meet BOTH of the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation
  - Provider has submitted documentation regarding status of patient and response to therapy

***\*Note: Litfulo for severe alopecia areata indication will only be granted approval for 6 months on initial authorization, and 1 year for reauthorization.***

### NEMLUVIO

#### Initial Authorization

- Must meet ONE of the following:
  - Diagnosis of atopic dermatitis and ALL of the following:
    - Member is 12 years of age or older
    - One of the following:
      - Previous trial and failure of Adbry (tralokinumab) (documentation required)
      - If member is unable to utilize Adbry (tralokinumab), member has trialed  $\geq 45$  days of topical drug therapy with one of the following: corticosteroids, pimecrolimus, or tacrolimus (documentation required)
      - Prescriber has provided valid medical justification for the use of Nemludio (nemolizumab-ilt) over Adbry (tralokinumab)
  - Diagnosis of prurigo nodularis and ALL of the following:
    - Member is 18 years of age or older
    - One of the following:
      - Previous trial and failure of Dupixent (dupilumab) (documentation required)
      - If member is unable to utilize Dupixent (dupilumab), member has trialed  $\geq 30$  days of topical drug therapy with one of the following: corticosteroids, pimecrolimus, and/or tacrolimus (documentation required)
      - Prescriber has provided valid medical justification for the use of Nemludio (nemolizumab-ilt) over Dupixent (dupilumab)

#### Reauthorization

- Must meet the following:

## Criteria for Indiana Medicaid Targeted Immunomodulators PA Criteria

- History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

### RINVOQ

#### Initial Authorization

- Must meet ONE of the following:
  - Diagnosis of atopic dermatitis and ALL of the following:
    - Member is 12 years of age or older and weighing at least 40 kg
    - One of the following:
      - Previous trial and failure of at least ONE systemic agent with an atopic dermatitis indication
      - If member is unable to utilize a systemic agent, member has trialed ≥ 45 days of topical drug therapy with one of the following: pimecrolimus, tacrolimus, or corticosteroids (documentation required)
      - Prescriber has provided valid medical justification for the use of Rinvoq (upadacitinib) over topical corticosteroids and/or topical immunomodulator agents
    - For members ≥ 65 years of age, requested dose does not exceed 15 mg daily
  - Diagnosis of ankylosing spondylitis, non-radiographic axial spondyloarthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, or rheumatoid arthritis AND the following:
    - Previous trial and failure of at least ONE TNF blocker
  - Diagnosis of moderate or severe Crohn's disease AND the following:
    - Previous trial and failure of at least ONE TNF blocker with Crohn's disease indication (adalimumab agents, Cimzia (certolizumab), infliximab agents)
  - Diagnosis of ulcerative colitis AND the following:
    - Previous trial and failure of at least ONE TNF blocker with ulcerative colitis indication (adalimumab agents, infliximab agents, Simponi (golimumab))

#### Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

### RINVOQ LQ

#### Initial Authorization

- Must meet ALL of the following:
  - Diagnosis of psoriatic arthritis or polyarticular juvenile idiopathic arthritis
  - Previous trial and failure of at least ONE TNF blocker
  - Must be 2 years of age and older and weighs ≥ 10 kg
  - One of the following:
    - Member is less than 18 years of age and weighs < 30 kg
    - Provider has submitted documentation supporting inability to swallow tablet formulation

#### Reauthorization

- Must meet BOTH of the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation
  - One of the following:
    - Member is less than 18 years of age and weighs < 30 kg
    - Provider has submitted documentation supporting inability to swallow tablet formulation

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### XELJANZ XR

#### Initial Authorization

- Must meet ONE of the following:
  - Diagnosis of ankylosing spondylitis, psoriatic arthritis, or rheumatoid arthritis and BOTH of the following:
    - Previous trial and failure of a TNF blocker or Xeljanz IR
    - Dose does not exceed 11mg once daily
  - Diagnosis of ulcerative colitis and BOTH of the following:
    - Previous trial and failure of a TNF blocker with ulcerative colitis indication (adalimumab agents, infliximab agents, or Simponi (golimumab)) or Xeljanz IR
    - One of the following:
      - Dose does not exceed 22mg once daily for the induction period up to 16 weeks
      - Dose does not exceed 11mg once daily for the maintenance period

#### Reauthorization

- Must meet BOTH of the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation
  - Dose requested does not exceed established quantity limits for the indication

### **NON-PREFERRED AGENTS (ONE-STEP)**

### COSENTYX

#### Initial Authorization

- Must meet ONE of the following:
  - Diagnosis of ankylosing spondylitis, non-radiographic axial spondyloarthritis, psoriasis, psoriatic arthritis, or rheumatoid arthritis AND the following:
    - Previous trial and failure of another targeted immunomodulator agent
  - Diagnosis of hidradenitis suppurativa AND the following:
    - Previous trial and failure of a preferred adalimumab agent
  - Diagnosis of enthesitis-related arthritis (ERA)

#### Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

### SILIQ

#### Initial Authorization

- Must meet BOTH of the following:
  - Diagnosis of psoriasis
  - Previous trial and failure of another targeted immunomodulator agent

#### Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

## Criteria for Indiana Medicaid Targeted Immunomodulators PA Criteria

### NON-PREFERRED AGENTS (TWO-STEP)

ABRILADA; ADALIMUMAB-AACF (unbranded IDACIO); ADALIMUMAB-AATY (unbranded YUFLYMA); ADALIMUMAB-ADAZ (unbranded HYRIMOZ); ADALIMUMAB-ADBM (unbranded CYLTEZO); ADALIMUMAB-RYVK (unbranded SIMLANDI); AMJEVITA; CYLTEZO; HULIO; HYRIMOZ; IDACIO; YUFLYMA

#### Initial Authorization

- Must meet ALL of the following:
  - Diagnosis of ankylosing spondylitis, moderate or severe Crohn's disease, hidradenitis suppurativa, non-infectious uveitis, polyarticular juvenile idiopathic arthritis, psoriasis, psoriatic arthritis, rheumatoid arthritis, or ulcerative colitis
  - Previous trial and failure of at least ONE other targeted immunomodulator agent that is not adalimumab
  - Previous trial of ALL preferred adalimumab product(s) AND prescriber has provided valid medical rationale for the use of the requested non-preferred adalimumab product over ALL of the preferred adalimumab product(s)

#### Reauthorization

- Must meet BOTH of the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation
  - Previous trial of ALL preferred adalimumab product(s) AND prescriber has provided valid medical rationale for the use of the requested non-preferred adalimumab product over ALL of the preferred adalimumab product(s)

### ARCALYST

#### Initial Authorization

- Must meet ONE of the following:
  - Diagnosis of cryopyrin-associated periodic syndromes (CAPS) (including familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS))
  - Both of the following:
    - Diagnosis of recurrent pericarditis (RP)
    - ≥90 days of drug therapy with colchicine or systemic glucocorticoids
  - Both of the following:
    - Diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA)
    - Previous trial and failure of Kineret (anakinra)

#### Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

### BIMZELX

#### Initial Authorization

- Must meet BOTH of the following:
  - Diagnosis of ankylosing spondylitis, hidradenitis suppurativa, non-radiographic axial spondyloarthritis, psoriasis, psoriatic arthritis
  - Previous trial and failure of at least TWO other targeted immunomodulator agents

#### Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

## Criteria for Indiana Medicaid Targeted Immunomodulators PA Criteria

### CIBINQO

#### Initial Authorization

- Must meet ALL of the following:
  - Diagnosis of moderate to severe atopic dermatitis
  - Member is ≥12 years of age
  - One of the following:
    - ≥ 60 days of therapy with Dupixent (dupilumab) and ≥ 120 days Adbry (tralokinumab-ldrm)
    - ≥ 60 days of therapy with Rinvoq (upadacitinib)
    - Prescriber has provided valid medical justification for the use of Cibinqo (abrocitinib) over Dupixent (dupilumab), Adbry (tralokinumab-ldrm), and Rinvoq (upadacitinib)

#### Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

### EBGLYSS

#### Initial Authorization

- Must meet ALL of the following:
  - Diagnosis of atopic dermatitis
  - Must be 12 years of age or older and weigh ≥ 40 kg
  - Previous trial and failure of at least TWO other targeted immunomodulator agents

#### Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

### ILARIS

#### Initial Authorization

- Must meet ONE of the following:
  - Diagnosis of cryopyrin-associated periodic syndromes (CAPS) (including familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS)), systemic juvenile idiopathic arthritis, tumor necrosis factor receptor associated periodic syndrome (TRAPS), or hyperimmunoglobulin D (Hyper-IgD) syndrome (HIDS)/mevalonate kinase deficiency (MKD)
  - Diagnosis of adult-onset Still's disease AND the following:
    - ≥90 days of drug therapy with one of the following: corticosteroids, methotrexate, NSAIDs
  - Diagnosis of familial Mediterranean fever (FMF) AND the following:
    - ≥90 days of drug therapy with colchicine
  - Diagnosis of gout flares and ONE of the following:
    - Both of the following:
      - Previous trial and failure of colchicine, corticosteroids, AND NSAIDs in the past 30 days
      - Prescriber has submitted chart documentation illustrating inadequate response
    - Prescriber has submitted chart documentation supporting contraindication to colchicine, NSAIDs, AND prolonged corticosteroid use

#### Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

## Criteria for Indiana Medicaid Targeted Immunomodulators PA Criteria

### ILUMYA

#### Initial Authorization

- Must meet BOTH of the following:
  - Diagnosis of psoriasis
  - Previous trial and failure of at least TWO other targeted immunomodulator agents

#### Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

### INFLECTRA; REMICADE; RENFLEXIS

#### Initial Authorization

- Must meet ALL of the following:
  - Diagnosis of ankylosing spondylitis, moderate or severe Crohn's disease, psoriasis, psoriatic arthritis, rheumatoid arthritis, or ulcerative colitis
  - Previous trial and failure of at least ONE other targeted immunomodulator agent that is not infliximab
  - Previous trial of preferred infliximab AND prescriber has provided valid medical rationale for the use of the requested non-preferred infliximab product over the preferred infliximab product(s)

#### Reauthorization

- Must meet BOTH of the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation
  - Previous trial of preferred infliximab AND prescriber has provided valid medical rationale for the use of the requested non-preferred infliximab product over the preferred infliximab product(s)

### OMVOH

#### Initial Authorization

- Must meet BOTH of the following:
  - Diagnosis of moderate to severe Crohn's disease or ulcerative colitis
  - Previous trial and failure of at least TWO other targeted immunomodulator agents

#### Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

### OTULFI, PYZCHIVA, SELARSDI, STELARA, STEQEYMA, USTEKINUMAB, USTEKINUMAB-AEKN, USTEKINUMAB-TTWE, YESINTEK

#### Initial Authorization

- Must meet BOTH of the following:
  - Diagnosis of moderate or severe Crohn's disease, psoriasis, psoriatic arthritis, or ulcerative colitis
  - Previous trial and failure of at least TWO other targeted immunomodulator agents

#### Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

## Criteria for Indiana Medicaid Targeted Immunomodulators PA Criteria

### SKYRIZI

#### Initial Authorization

- Must meet BOTH of the following:
  - Diagnosis of moderate or severe Crohn's disease, psoriasis, psoriatic arthritis, or ulcerative colitis
  - Previous trial and failure of at least TWO other targeted immunomodulator agents

#### Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

### SOTYKTU

#### Initial Authorization

- Must meet ALL of the following:
  - Must be 18 years of age or older
  - Diagnosis of psoriasis
  - Previous trial and failure of at least TWO other targeted immunomodulator agents

#### Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

### SPEVIGO

#### Initial Authorization

- Must meet ALL of the following:
  - Must be 12 years of age or older and weighs  $\geq 40$  kg
  - Diagnosis of generalized pustular psoriasis (GPP)
  - Prescribed by, or in consultation with, a dermatologist or rheumatologist

#### Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

### TOFIDENCE

#### Initial Authorization

- Must meet ALL of the following:
  - Diagnosis of giant cell arteritis, polyarticular juvenile idiopathic arthritis, rheumatoid arthritis, or systemic juvenile idiopathic arthritis
  - Previous trial and failure of at least ONE other targeted immunomodulator agent that is not tocilizumab
  - Previous trial of preferred tocilizumab products AND prescriber has provided valid medical rationale for the use of the requested non-preferred tocilizumab product over the preferred tocilizumab product(s)

#### Reauthorization

- Must meet BOTH of the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation
  - Previous trial of preferred tocilizumab products AND prescriber has provided valid medical rationale for the use of the requested non-preferred tocilizumab product over the preferred tocilizumab product(s)

**Criteria for Indiana Medicaid  
Targeted Immunomodulators PA Criteria**

**TREMFYA**

Initial Authorization

- Must meet BOTH of the following:
  - Diagnosis of psoriasis, psoriatic arthritis, or ulcerative colitis
  - Previous trial and failure of at least TWO other targeted immunomodulator agents

Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

**VELSIPITY**

Initial Authorization

- Must meet BOTH of the following:
  - Diagnosis of ulcerative colitis
  - Previous trial and failure of Zeposia (ozanimod) AND at least ONE other targeted immunomodulator agent

Reauthorization

- Must meet the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation

**ZYMFENTRA**

Initial Authorization

- Must meet ALL of the following:
  - Diagnosis of moderate to severe Crohn's disease or ulcerative colitis
  - Previous trial and failure of at least ONE other targeted immunomodulator agent that is not infliximab
  - Previous trial of preferred infliximab products AND prescriber has provided valid medical rationale for the use of the requested non-preferred infliximab product over the preferred infliximab product(s)

Reauthorization

- Must meet BOTH of the following:
  - History of the requested agent for at least 90 of the past 120 days, as confirmed by claims history or chart documentation
  - Previous trial of preferred infliximab products AND prescriber has provided valid medical rationale for the use of the requested non-preferred infliximab product over the preferred infliximab product(s)

- Existing Criteria
- Revision of Existing Criteria
- New Criteria