TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Targeted Immunomodulators – Biological Agents

Effective: January 15, 2021

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	Oral or SC: RX IV or SC: MED	Department to Review	RXUM/ MM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

Intravenous medications and Ilumya
MM: 888.415.9055

Self-administered formulations (oral, subcutaneous injection)
RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Brand Name	MOA	Benefit	AS	CD	PsO	PsA	pJIA	RA	sJIA	UC
Actemra IV	IL antagonist (6)	MB	-	-	-	-	x	x	x	-
Actemra SC	IL antagonist (6)	RX	-	-	-	-	-	x	x	-
Cimzia	TNF inhibitor	RX	x	x	x	x	-	x	-	-
Cosentyx	IL antagonist (17A)	RX	x		x	x	-	-	-	-
Enbrel[PD]	TNF inhibitor	RX	x	-	x	x	x	x	-	-
Entyvio	IRA	MB	-	x		-	-	-	-	x
Humira[PD]	TNF inhibitor	RX	x	x	x	x	x	x	-	x
Ilumya	IL antagonist (23)	MB	-	-	x	-	-	-	-	-
Inflectra	TNF inhibitor	MB	x	x	x	x	-	x	-	x
Kevzara	IL antagonist (6)	RX	-	-	-	-	-	x	-	-
Kineret	IL antagonist (1)	RX	-	-	-	-	-	x	-	-
Olumiant	JAKI	RX	-	-	-	-	-	x	-	-
Orencia IV	T cell	MB	-	-	-	x	x	x	-	-
Orencia SC	T cell	RX	-	-	-	x	x	x	-	-
Otezla	PDE4I	RX	-	-	x	x	-		-	-
Remicade	TNF inhibitor	MB	x	x	x	x	-	x	-	x
Renflexis	TNF inhibitor	MB	x	x	x	x	-	x	-	x
Rinvoq	JAKI	RX	-	-	-	-	-	x	-	-
Siliq	IL antagonist (17A)	RX	-	-	x	-	-	-	-	-
Simponi SC	TNF inhibitor	RX	x	-	-	x	-	x	-	x
Simponi Aria IV	TNF inhibitor	MB	x	-	-	x	x	x	-	-
Skyrizi	IL antagonist (23)	Rx	-	-	x	-	-	-	-	-
Stelara IV[PD]	IL antagonist (12/23)	MB	-	x	-	-	-	-	-	x

Brand Name	MOA	Benefit	AS	CD	PsO	PsA	pJIA	RA	sJIA	UC
Stelara SC[PD]	IL antagonist (12/23)	RX	-	x	x	x	-	-	-	x
Taltz[PD]	IL antagonist (17A)	RX	x	-	x	x	-	-	-	-
Tremfya	IL antagonist (23)	RX	-	-	x	x	-	-	-	-
Xeljanz/ Xeljanz XR[PD]	JAKI	RX	-	-	-	x	x	x	-	x

AS=ankylosing spondylitis, CD=Crohn's disease, JAKI=janus kinase inhibitor, IL=interleukin, IRA=integrin receptor antagonist, IV=intravenous, MB=medical benefit, MOA=mechanism of action, PD=Preferred Drug, PDE4I=phosphodiesterase, pJIA=polyarticular juvenile idiopathic arthritis, PsA=psoriatic arthritis, PsO=plaque psoriasis, RA=rheumatoid arthritis, RX=pharmacy benefit, SC=subcutaneous, sJIA=systemic juvenile idiopathic arthritis, TNF=tumor necrosis factor, UC=ulcerative colitis

Actemra (tocilizumab)
In addition to the conditions in the table above, Actemra (tocilizumab) is also indicated for the treatment of:

- **Cytokine release syndrome**
  Chimeric antigen receptor T cell-induced severe or life-threatening cytokine release syndrome in adults and pediatric patients 2 years of age and older
- **Giant cell arteritis**
  Giant cell arteritis in adult patients

Cimzia (certolizumab pegol)
In addition to the conditions in the table above, Cimzia (certolizumab pegol) is also indicated for the treatment of:

- **Non-radiographic Axial Spondyloarthritis**
  Active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation in adults

Cosentyx (secukinumab)
In addition to the conditions in the table above, Cosentyx (secukinumab) is also indicated for the treatment of:

- **Non-radiographic Axial Spondyloarthritis**
  Active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation in adults

Humira (adalimumab)
In addition to the conditions in the table above, Humira (adalimumab) is also indicated for the treatment of:

- **Hidradenitis Suppurativa**
  Moderate to severe hidradenitis suppurativa in patients 12 years of age and older
- **Uveitis:**
  Non-infectious intermediate, posterior and panuveitis in adults and pediatric patients 2 years of age and older

Kineret (anakinra)
In addition to the conditions in the table above, Kineret (anakinra) is also indicated for the treatment of **Neonatal-Onset Multisystem Inflammatory Disease** (NOMID)

Otezla (apremilast)
In addition to the conditions in the table above, Otezla (apremilast) is also indicated for the treatment of adults with **oral ulcers associated with Behcet's disease**

Taltz (ixekizumab)
In addition to the conditions in the table above, Taltz (ixekizumab) is also indicated for the treatment of:

- **Non-radiographic Axial Spondyloarthritis**
  Active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation in adults

COVERAGE GUIDELINES

1. Actemra (tocilizumab)

Cytokine release syndrome

The plan may authorize coverage of **Actemra intravenous injection** for Members when all of the following criteria are met:

1. Documented diagnosis of cytokine release syndrome

AND

2. Documentation of concurrent therapy with CAR T-cell therapies with date of anticipated administration included

Giant cell arteritis

The plan may authorize coverage of **Actemra subcutaneous injection** for Members when all of the following criteria are met:

1. Documented diagnosis of giant cell arteritis

AND

2. Documentation of **one (1) of the following:**
    a. Inadequate response or adverse reaction to **one (1)** systemic glucocorticoid
    b. Contraindication to **all** systemic glucocorticoids

AND

3. Documentation of **one (1) of the following:**
    a. Inadequate response or adverse reaction to **one (1)** systemic immunosuppressive therapy
    b. Contraindication to **all** systemic immunosuppressive therapies

Polyarticular juvenile idiopathic arthritis

The plan may authorize coverage of **Actemra intravenous and subcutaneous injection** for Members when all of the following criteria are met:

1. Documented diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis

AND

2. Documentation of **one (1)** of the following:
    a. Inadequate response or adverse reaction to **one (1)** or contraindication to **all** traditional disease modifying antirheumatic drugs
    b. Inadequate response, adverse reaction, or contraindication to Humira

Systemic juvenile idiopathic arthritis

The plan may authorize coverage of **Actemra intravenous and subcutaneous injection** for Members when all of the following criteria are met:

1. Documented diagnosis of systemic juvenile idiopathic arthritis

AND

2. Documentation of **one (1)** of the following:
    a. Inadequate response or adverse reaction to **one (1)** or contraindication to **all** traditional disease modifying antirheumatic drug
    b. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of rheumatoid arthritis

Rheumatoid arthritis

1. Documented diagnosis of moderate to severe rheumatoid arthritis

AND

2. Documentation of **one (1) of the following:**
    a. Inadequate response or adverse reaction to **one (1)** or contraindication to **all** traditional disease modifying antirheumatic drugs
    b. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of rheumatoid arthritis

Note: *Traditional disease modifying antirheumatic drugs for rheumatoid arthritis include hydroxychloroquine, sulfasalazine, and methotrexate.*

2. Cimzia (certolizumab)

The plan will authorize coverage of Cimzia for Members when all of the following criteria are met:

Ankylosing spondylitis

1. Documented diagnosis of ankylosing spondylitis

AND

2. Documented inadequate response or adverse reaction to **two (2)** or contraindication to **all** nonsteroidal anti-inflammatory drugs

AND

3. Clinical rationale for use of the requested agent instead of Enbrel and Humira

Crohn's disease

1. Documented diagnosis of moderate to severe Crohn's disease

AND

2. Clinical rationale for use of the requested agent instead of Humira

Note: *Moderate to severe disease may be evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease.*

Non-radiographic Axial Spondyloarthritis

1. Documented diagnosis of non-radiographic axial spondyloarthritis

AND

2. Documented inadequate response or adverse reaction to **two (2)** or contraindication to **all** nonsteroidal anti-inflammatory drugs

AND

3. Clinical rationale for use of the requested agent instead of Enbrel and Humira

Plaque psoriasis

1. Documented diagnosis of moderate to severe plaque psoriasis

AND

2. Documentation of **one (1) of the following**:
    a. Inadequate response or adverse reaction to **one (1)** conventional therapy: Topical agents, phototherapy, systemic agents
    b. Contraindication to **all** conventional therapies: Topical agents, phototherapy, systemic agents
    c. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of plaque psoriasis

AND

3. Clinical rationale for use of the requested agent instead of Enbrel and Humira

Psoriatic arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Clinical rationale for use of the requested agent instead of Enbrel and Humira

Rheumatoid arthritis

1. Documented diagnosis of moderate to severe rheumatoid arthritis

AND

2. Documentation of **one (1) of the following:**
    a. Inadequate response or adverse reaction to **one (1)** or contraindication to **all** traditional disease modifying antirheumatic drugs
    b. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of rheumatoid arthritis

AND

3. Clinical rationale for use of the requested agent instead of Enbrel and Humira

Note: *Traditional disease modifying antirheumatic drugs for rheumatoid arthritis include hydroxychloroquine, sulfasalazine, and methotrexate.*

3. Cosentyx (secukinumab)

The plan may authorize coverage of Cosentyx for Members when all of the following criteria are met:

Ankylosing spondylitis

1. Documented diagnosis of ankylosing spondylitis

AND

2. Documented inadequate response or adverse reaction to **two (2)** or contraindication to **all** nonsteroidal anti-inflammatory drugs

AND

3. Documented inadequate response or adverse reaction to **one (1)** anti-TNF agent that is indicated for the treatment of ankylosing spondylitis (Cimzia, Enbrel, Humira, infliximab, Simponi, Simponi Aria)

Non-radiographic Axial Spondyloarthritis

1. Documented diagnosis of non-radiographic axial spondyloarthritis

AND

2. Documented inadequate response or adverse reaction to **two (2)** or contraindication to **all** nonsteroidal anti-inflammatory drugs

AND

3. Documented inadequate response or adverse reaction to **one (1)** anti-TNF agent that is indicated for the treatment of non-radiographic axial spondyloarthritis (Cimzia)

Plaque psoriasis

1. Documented diagnosis of moderate to severe plaque psoriasis

AND

2. Documentation of **one (1) of the following**:
    a. Inadequate response or adverse reaction to **one (1)** conventional therapy: Topical agents, phototherapy, systemic agents
    b. Contraindication to **all** conventional therapies: Topical agents, phototherapy, systemic agents
    c. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of plaque psoriasis

Psoriatic arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Documentation of **one (1) of the following:**
    a. Inadequate response or adverse reaction to **one (1)** anti-TNF agent that is indicated for the treatment of psoriatic arthritis (Cimzia, Enbrel, Humira, infliximab, Simponi, Simponi Aria)
    b. Contraindication to **all** anti-TNF agents indicated for the treatment of psoriatic arthritis

4. Enbrel (etanercept)

The plan may authorize coverage of Enbrel for Members when all of the following criteria are met:

Ankylosing spondylitis

1. Documented diagnosis of ankylosing spondylitis

AND

2. Documented inadequate response or adverse reaction to **two (2)** or contraindication to all nonsteroidal anti-inflammatory drugs

Non-radiographic axial spondyloarthritis

1. Documented diagnosis of non-radiographic axial spondyloarthritis

AND

2. Documented inadequate response or adverse reaction to **two (2)** or contraindication to all nonsteroidal anti-inflammatory drugs

Plaque Psoriasis

1. Documented diagnosis of moderate to severe plaque psoriasis

AND

2. Documentation of **one (1) of the following**:
    a. Inadequate response or adverse reaction to **one (1)** conventional therapy: Topical agents, phototherapy, systemic agents
    b. Contraindication to **all** conventional therapies: Topical agents, phototherapy, systemic agents
    c. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of plaque psoriasis

Polyarticular juvenile idiopathic arthritis

1. Documented diagnosis moderate to severe polyarticular juvenile idiopathic arthritis

AND

2. Documentation of **one (1) of the following**:
    a. Inadequate response or adverse reaction to **one (1)** or contraindication to **all** traditional disease modifying antirheumatic drugs
    b. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of polyarticular juvenile idiopathic arthritis

Psoriatic Arthritis

1. Documented diagnosis of psoriatic arthritis

Rheumatoid Arthritis

1. Documented diagnosis of moderate to severe rheumatoid arthritis

AND

2. Documentation of **one (1) of the following:**
    a. Inadequate response or adverse reaction to **one (1)** or contraindication to **all** traditional disease modifying antirheumatic drugs
    b. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of rheumatoid arthritis

Note: *Traditional disease modifying antirheumatic drugs for rheumatoid arthritis include hydroxychloroquine, sulfasalazine, and methotrexate.*

5. Entyvio (vedolizumab)

The plan may authorize coverage of Entyvio for Members when all of the following criteria are met:

Crohn's disease

1. Documented diagnosis moderate to severe Crohn's disease

Note: *Moderate to severe disease may be evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease.*

Ulcerative colitis

1. Documented diagnosis of moderate to severe ulcerative colitis

Note: *Moderate to severe disease may be evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease.*

6. Humira (adalimumab)

The plan may authorize coverage of Humira for Members when all of the following criteria are met:

Ankylosing spondylitis

1. Documented diagnosis of ankylosing spondylitis

AND

2. Documented inadequate response or adverse reaction to **two (2)** or contraindication to all nonsteroidal anti-inflammatory drugs

Crohn's disease

1. Documented diagnosis of moderate to severe Crohn's disease

Note: *Moderate to severe disease may be evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease.*

Hidradenitis suppurativa

1. Documented diagnosis of moderate to severe hidradenitis suppurativa

OR

2. Documentation of **both** of the following:
    a. Documented diagnosis of mild hidradenitis suppurativa
    b. Inadequate response or adverse reaction to **one (1)** oral antibiotic or contraindications to all oral antibiotics

Non-radiographic axial spondyloarthritis

1. Documented diagnosis of non-radiographic axial spondyloarthritis

AND

2. Documented inadequate response or adverse reaction to **two (2)** or contraindication to **all** nonsteroidal anti-inflammatory drugs

Plaque Psoriasis

1. Documented diagnosis of moderate to severe plaque psoriasis

AND

2. Documentation of **one (1) of the following**:
    a. Inadequate response or adverse reaction to **one (1)** conventional therapy: Topical agents, phototherapy, systemic agents
    b. Contraindication to **all** conventional therapies: Topical agents, phototherapy, systemic agents
    c. Inadequate response or adverse reaction to one biologic disease modifying antirheumatic drug indicated for the treatment of plaque psoriasis

Polyarticular juvenile idiopathic arthritis

1. Documented diagnosis moderate to severe polyarticular juvenile idiopathic arthritis

AND

2. Documentation of **one (1) of the following**:
    a. Inadequate response or adverse reaction to **one (1)** or contraindication to **all** traditional disease modifying antirheumatic drugs
    b. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of polyarticular juvenile idiopathic arthritis

Psoriatic arthritis

1. Documented diagnosis of psoriatic arthritis

Rheumatoid Arthritis

1. Documented diagnosis of moderate to severe rheumatoid arthritis

AND

2. Documentation of **one (1) of the following:**
    a. Inadequate response or adverse reaction to **one (1)** or contraindication to **all** traditional disease modifying antirheumatic drugs
    b. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of rheumatoid arthritis

Note: *Traditional disease modifying antirheumatic drugs for rheumatoid arthritis include hydroxychloroquine, sulfasalazine, and methotrexate.*

Ulcerative Colitis

1. Documented diagnosis of moderate to severe ulcerative colitis

Note: *Moderate to severe disease may be evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease.*

Uveitis

1. Documented diagnosis of non-infectious uveitis

AND

2. Documentation of **one (1) of the following:**
    a. Inadequate response or adverse reaction to **one (1)** topical and systemic glucocorticoids
    b. Contraindication to **all** topical and systemic glucocorticoids

AND

3. Documentation of **one (1) of the following:**
    a. Inadequate response or adverse reaction to **one (1)** systemic immunosuppressive therapy
    b. Contraindication to **all** systemic immunosuppressive therapies

7. Ilumya (tildrakizumab-asmn)

The plan may authorize coverage of Ilumya for Members when all of the following criteria are met:

Plaque Psoriasis

1. Documented diagnosis of moderate to severe plaque psoriasis

AND

2. Documentation of **one (1) of the following**:
    a. Inadequate response or adverse reaction to **one (1)** conventional therapy: Topical agents, phototherapy, systemic agents
    b. Contraindication to **all** conventional therapies: Topical agents, phototherapy, systemic agents
    c. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of plaque psoriasis

8. Infliximab-products (Avsola [infliximab-axxq], Inflectra [infliximab-dyyb], Remicade [infliximab], and Renflexis [infliximab-adba])

Avsola (infliximab-axxq), Inflectra (infliximab-dyyb), and Renflexis (infliximab-adba)

The plan may authorize coverage of **Avsola, Inflectra, or Renflexis** for Members when all of the following criteria are met:

Ankylosing spondylitis

1. Documented diagnosis of ankylosing spondylitis

AND

2. Documented inadequate response or adverse reaction to **two (2)** or contraindication to **all** nonsteroidal anti-inflammatory drugs

Crohn's disease

1. Documented diagnosis of **one (1) of the following:**
    a. Moderate to severe Crohn's disease
    b. Fistulizing Crohn's disease

Note: *Moderate to severe disease may be evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease.*

Plaque psoriasis

1. Documented diagnosis of moderate to severe plaque psoriasis

AND

2. Documentation of **one (1) of the following**:
    a. Inadequate response or adverse reaction to **one (1)** conventional therapy: Topical agents, phototherapy, systemic agents
    b. Contraindication to **all** conventional therapies: Topical agents, phototherapy, systemic agents
    c. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of plaque psoriasis

Psoriatic arthritis

1. Documented diagnosis of psoriatic arthritis

Rheumatoid arthritis

1. Documented diagnosis of moderate to severe rheumatoid arthritis

AND

2. Documentation of **one (1) of the following:**
    a. Inadequate response or adverse reaction to **one (1)** or contraindication to **all** traditional disease modifying antirheumatic drugs
    b. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of rheumatoid arthritis

Note: *Traditional disease modifying antirheumatic drugs for rheumatoid arthritis include hydroxychloroquine, sulfasalazine, and methotrexate.*

Ulcerative colitis

1. Documented diagnosis of moderate to severe ulcerative colitis

Note: *Moderate to severe disease may be evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease.*

Remicade (infliximab)

In addition to the coverage criteria for Avsola, Inflectra, and Renflexis, the plan may authorize coverage of **Remicade** for Members when the following criteria are met:

1. Documented previous failure of or clinical inappropriateness with an infliximab biosimilar

9. Kevzara (sarilumab)

The plan may authorize coverage of Kevzara for Members when all of the following criteria are met:

Rheumatoid Arthritis

1. Documented diagnosis of moderate to severe rheumatoid arthritis

AND

2. Documentation of **one (1) of the following:**
    a. Inadequate response or adverse reaction to **one (1)** or contraindication to **all** traditional disease modifying antirheumatic drugs
    b. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of rheumatoid arthritis

Note: *Traditional disease modifying antirheumatic drugs for rheumatoid arthritis include hydroxychloroquine, sulfasalazine, and methotrexate.*

10. Kineret (anakinra)

The plan may authorize coverage of Kineret for Members when all of the following criteria are met:

Neonatal-Onset Multisystem Inflammatory Disease (NOMID)

1. Documented diagnosis of neonatal-onset multisystem inflammatory disease

Rheumatoid arthritis

1. Documented diagnosis of moderate to severe rheumatoid arthritis

AND

2. Documented inadequate response or adverse reaction to **one (1)** or contraindication to **all** traditional disease modifying antirheumatic drugs

Note: *Traditional disease modifying antirheumatic drugs for rheumatoid arthritis include hydroxychloroquine, sulfasalazine, and methotrexate.*

AND

3. Documentation of **one (1) of the following:**
    a. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of rheumatoid arthritis
    b. Contraindication to all biologic disease modifying antirheumatic drugs indicated for the treatment of rheumatoid arthritis

11. Olumiant (baricitinib)

The plan may authorize coverage of Olumiant for Members when the following criteria are met:

Rheumatoid Arthritis

1. Documented diagnosis of moderate to severe rheumatoid arthritis

AND

2. Documented inadequate response or adverse reaction to **one (1)** or contraindication to **all** traditional disease modifying antirheumatic drugs

Note: *Traditional disease modifying antirheumatic drugs for rheumatoid arthritis include hydroxychloroquine, sulfasalazine, and methotrexate.*

AND

3. Documentation of **one (1) of the following:**
    a. Inadequate response or adverse reaction to **one (1)** biologic disease-modifying antirheumatic drugs indicated for the treatment of rheumatoid arthritis
    b. Contraindication to **all** biologic disease-modifying antirheumatic drugs indicated for the treatment of rheumatoid arthritis

AND

4. Documented inadequate response, adverse reaction, or contraindication to Xeljanz/Xeljanz XR

12. Orencia (abatacept)

The plan may authorize coverage of **Orencia intravenous and subcutaneous injection** for Members when the following criteria are met:

Polyarticular juvenile idiopathic arthritis

1. Documented diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis

AND

2. Documentation of **one (1)** of the following:
    a. Inadequate response or adverse reaction to **one (1)** or contraindication to **all** traditional disease modifying antirheumatic drugs
    b. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of polyarticular juvenile idiopathic arthritis

Psoriatic arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Documentation of **one (1) of the following:**
    a. Inadequate response or adverse reaction to **one (1)** anti-TNF agent that is indicated for the treatment of psoriatic arthritis (Cimzia, Enbrel, Humira, infliximab, Simponi, Simponi Aria)
    b. Contraindication to **all** anti-TNF agents indicated for the treatment of psoriatic arthritis

Rheumatoid arthritis

1. Documented diagnosis of moderate to severe rheumatoid arthritis

AND

2. Documentation of **one (1) of the following:**
    a. Inadequate response or adverse reaction to **one (1)** or contraindication to **all** traditional disease modifying antirheumatic drugs
    b. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of rheumatoid arthritis

Note: *Traditional disease modifying antirheumatic drugs for rheumatoid arthritis include hydroxychloroquine, sulfasalazine, and methotrexate.*

13. Otezla (apremilast)

The plan may authorize coverage of Otezla for Members when all of the following criteria are met:

Behcet's disease

1. Documented diagnosis of oral ulcers associated with Behcet's disease

Plaque psoriasis

1. Documented diagnosis of moderate to severe plaque psoriasis

AND

2. Documentation of **one (1) of the following**:
    a. Inadequate response or adverse reaction to **one (1)** conventional therapy: Topical agents, phototherapy, systemic agents
    b. Contraindication to **all** conventional therapies: Topical agents, phototherapy, systemic agents
    c. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of plaque psoriasis

Psoriatic arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Documentation of **one (1) of the following:**
    a. Inadequate response or adverse reaction to **one (1)** anti-TNF agent that is indicated for the treatment of psoriatic arthritis (Cimzia, Enbrel, Humira, infliximab, Simponi, Simponi Aria)
    b. Contraindication to **all** anti-TNF agents indicated for the treatment of psoriatic arthritis

14. Rinvoq (upadacitinib)

The plan may authorize coverage of Rinvoq for Members when all of the following criteria are met:

Rheumatoid Arthritis

1. Documented diagnosis of moderate to severe rheumatoid arthritis

AND

2. Documented inadequate response or adverse reaction to **one (1)** or contraindication to **all** traditional disease modifying antirheumatic drugs

Note: *Traditional disease modifying antirheumatic drugs for rheumatoid arthritis include hydroxychloroquine, sulfasalazine, and methotrexate.*

AND

3. Documentation of **one (1) of the following:**
    a. Inadequate response or adverse reaction to **one (1)** biologic disease-modifying antirheumatic drugs indicated for the treatment of rheumatoid arthritis
    b. Contraindication to **all** biologic disease-modifying antirheumatic drugs indicated for the treatment of rheumatoid arthritis

AND

4. Documented inadequate response, adverse reaction, or contraindication to Xeljanz/Xeljanz XR

15. Siliq (brodalumab)

The plan may authorize coverage of Siliq for Members when the following criteria are met:

Plaque Psoriasis

1. Documented diagnosis of moderate to severe plaque psoriasis

AND

2. Documentation of **one (1) of the following**:
    a. Inadequate response or adverse reaction to **one (1)** conventional therapy: Topical agents, phototherapy, systemic agents
    b. Contraindication to **all** conventional therapies: Topical agents, phototherapy, systemic agents
    c. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of plaque psoriasis

16. Simponi (golimumab) and Simponi Aria (golimumab)

The plan may authorize coverage of **Simponi or Simponi Aria** for Members when all of the following criteria are met:

Ankylosing spondylitis

1. Documented diagnosis of ankylosing spondylitis

AND

2. Documented inadequate response or adverse reaction to **two (2)** or contraindication to **all** nonsteroidal anti-inflammatory drugs

AND

3. Clinical rationale for use of the requested agent instead of Enbrel and Humira

Psoriatic arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Clinical rationale for use of the requested agent instead of Enbrel and Humira

Rheumatoid arthritis

1. Documented diagnosis of moderate to severe rheumatoid arthritis

AND

2. Documentation of **one (1) of the following:**
    a. Inadequate response or adverse reaction to **one (1)** or contraindication to **all** traditional disease modifying antirheumatic drugs
    b. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of rheumatoid arthritis

Note: *Traditional disease modifying antirheumatic drugs for rheumatoid arthritis include hydroxychloroquine, sulfasalazine, and methotrexate.*

AND

3. Clinical rationale for the use of the requested agent instead of Enbrel and Humira

The plan may authorize coverage of **Simponi** for Members when all of the following criteria are met:

Ulcerative colitis

1. Documented diagnosis of moderate to severe ulcerative colitis

AND

2. Clinical rationale for the use of the requested agent instead of Humira

Note: *Moderate to severe disease may be evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease.*

The plan may authorize coverage of **Simponi Aria** for Members when all of the following criteria are met:

Polyarticular juvenile idiopathic arthritis

1. Documented diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis

AND

2. Documentation of **one (1) of the following:**
    a. Inadequate response or adverse reaction to **one (1)** or contraindication to **all** traditional disease modifying antirheumatic drugs
    b. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of polyarticular juvenile idiopathic arthritis

AND

3. Clinical rationale for use of the requested agent instead of Enbrel and Humira

17. Skyrizi (risankizumab-rzaa)

The plan may authorize coverage of Skyrizi for Members when all of the following criteria are met:

Plaque Psoriasis

1. Documented diagnosis of moderate to severe plaque psoriasis

AND

2. Documentation of **one (1) of the following**:
    a. Inadequate response or adverse reaction to **one (1)** conventional therapy: Topical agents, phototherapy, systemic agents
    b. Contraindication to **all** conventional therapies: Topical agents, phototherapy, systemic agents
    c. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of plaque psoriasis

18. Stelara (ustekinumab)

The plan may authorize coverage of **Stelara intravenous and subcutaneous injection** for Members when all of the following criteria are met:

Crohn's disease

1. Documented diagnosis of moderate to severe Crohn's disease

AND

2. Documentation of **one (1) of the following:**
    a. Inadequate response or adverse reaction to **one (1)** biologic disease modifying anti-rheumatic drugs indicated for the treatment of Crohn's disease
    b. Contraindication to **all** biologic disease modifying anti-rheumatic drugs indicated for the treatment of Crohn's disease

Note: *Moderate to severe disease may be evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease.*

Plaque psoriasis

1. Documented diagnosis of moderate to severe plaque psoriasis

AND

2. Documentation of **one (1) of the following**:
    a. Inadequate response or adverse reaction to **one (1)** conventional therapy: Topical agents, phototherapy, systemic agents
    b. Contraindication to **all** conventional therapies: Topical agents, phototherapy, systemic agents
    c. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of plaque psoriasis

Psoriatic arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Documentation of **one (1) of the following:**
    a. Inadequate response or adverse reaction to **one (1)** anti-TNF agent that is indicated for the treatment of psoriatic arthritis (Cimzia, Enbrel, Humira, infliximab, Simponi, Simponi Aria)
    b. Contraindication to **all** anti-TNF agents indicated for the treatment of psoriatic arthritis

Ulcerative Colitis

1. Documented diagnosis of moderate to severe ulcerative colitis

AND

2. Documentation of **one (1) of the following:**
    a. Inadequate response or adverse reaction to **one (1)** biologic disease modifying anti-rheumatic drugs indicated for the treatment of ulcerative colitis
    b. Contraindication to **all** biologic disease modifying anti-rheumatic drugs indicated for the treatment of ulcerative colitis

Note: *Moderate to severe disease may be evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease.*

19. Taltz (ixekizumab)

The plan may authorize coverage of Taltz for Members when all of the following criteria are met:

Ankylosing spondylitis

1. Documented diagnosis of ankylosing spondylitis

AND

2. Documented inadequate response or adverse reaction to **two (2)** or contraindication to **all** nonsteroidal anti-inflammatory drugs

AND

3. Documented inadequate response or adverse reaction to **one (1)** anti-TNF agent that is indicated for the treatment of ankylosing spondylitis (Cimzia, Enbrel, Humira, infliximab, Simponi, Simponi Aria)

Non-radiographic Axial Spondyloarthritis

1. Documented diagnosis of non-radiographic axial spondyloarthritis

AND

2. Documented inadequate response or adverse reaction to **two (2)** or contraindication to **all** nonsteroidal anti-inflammatory drugs

AND

3. Documented inadequate response or adverse reaction to **one (1)** anti-TNF agent that is indicated for the treatment of non-radiographic axial spondyloarthritis (Cimzia)

Plaque psoriasis

1. Documented diagnosis of moderate to severe plaque psoriasis

AND

2. Documentation of **one (1) of the following**:
    a. Inadequate response or adverse reaction to **one (1)** conventional therapy: Topical agents, phototherapy, systemic agents
    b. Contraindication to **all** conventional therapies: Topical agents, phototherapy, systemic agents
    c. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of plaque psoriasis

Psoriatic arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Documentation of **one (1) of the following:**
    a. Inadequate response or adverse reaction to **one (1)** anti-TNF agent that is indicated for the treatment of psoriatic arthritis (Cimzia, Enbrel, Humira, infliximab, Simponi, Simponi Aria)
    b. Contraindication to **all** anti-TNF agents indicated for the treatment of psoriatic arthritis

20. Tremfya (guselkumab)

The plan may authorize coverage of Siliq for Members when the following criteria are met:

Plaque psoriasis

1. Documented diagnosis of moderate to severe plaque psoriasis

AND

2. Documentation of **one (1) of the following**:
    a. Inadequate response or adverse reaction to **one (1)** conventional therapy: Topical agents, phototherapy, systemic agents
    b. Contraindication to **all** conventional therapies: Topical agents, phototherapy, systemic agents
    c. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of plaque psoriasis

Psoriatic arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Documentation of **one (1) of the following:**
    a. Inadequate response or adverse reaction to **one (1)** anti-TNF agent that is indicated for the treatment of psoriatic arthritis (Cimzia, Enbrel, Humira, infliximab, Simponi, Simponi Aria)
    b. Contraindication to **all** anti-TNF agents indicated for the treatment of psoriatic arthritis

21. Xeljanz/Xeljanz XR (tofacitinib)

The plan may authorize coverage of Xeljanz/Xeljanz XR for Members when all of the following criteria are met:

Psoriatic arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Documentation of **one (1)** of the following:
    a. Inadequate response or adverse reaction to **one (1)** or contraindication to **all** traditional disease modifying antirheumatic drugs
    b. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of psoriatic arthritis

Rheumatoid arthritis

1. Documented diagnosis of moderate to severe rheumatoid arthritis

AND

2. Documentation of **one (1) of the following:**
    a. Inadequate response or adverse reaction to **one (1)** or contraindication to **all** traditional disease modifying antirheumatic drugs
    b. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of rheumatoid arthritis

Note: *Traditional disease modifying antirheumatic drugs for rheumatoid arthritis include hydroxychloroquine, sulfasalazine, and methotrexate.*

Polyarticular juvenile idiopathic arthritis

1. Documented diagnosis moderate to severe polyarticular juvenile idiopathic arthritis

AND

2. Documentation of **one (1) of the following**:
    a. Inadequate response or adverse reaction to **one (1)** or contraindication to **all** traditional disease modifying antirheumatic drugs
    b. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of polyarticular juvenile idiopathic arthritis

Ulcerative colitis

1. Documented diagnosis of moderate to severe ulcerative colitis

AND

2. Documentation of **one (1) of the following:**
    a. Inadequate response or adverse reaction to **one (1)** or contraindication to **all** traditional disease modifying antirheumatic drugs
    b. Inadequate response or adverse reaction to **one (1)** biologic disease modifying antirheumatic drug indicated for the treatment of ulcerative colitis

Note: *Moderate to severe disease may be evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease.*

LIMITATIONS

- Documentation of inconvenience does not qualify as a contraindication to phototherapy.
- Documentation of a Member being a social drinker does not qualify as a medically acceptable contraindication or clinically inappropriateness to methotrexate therapy.
- Documentation of a Member having a needle phobia does not qualify as a medically acceptable contraindication or clinical inappropriateness to injectable products.
- Approval of Actemra intravenous injection for cytokine release syndrome will be limited to 1 month.
- Quantity limitations – coverage of the requested medication will be limited as follows:

Brand Name	Indication	Quantity
Actemra IV	All	80 mg:10 vials per 28 days 200 mg: 4 vials per 28 days 400 mg: 2 vials per 28 days
Actemra SC	Giant cell arteritis, RA, sJIA	4 syringes per 28 days
Cimzia	All	2 syringes per 28 days
	AS, CD, PsA, PsO, RA	Starter pack: One time fill
Cosentyx	AS*, PsA*	150 mg: 1 syringe per 28 days
	PsO*	300 mg dose pack: 1 per 28 days (total of two 150 mg syringes)
	Non-radiographical AS^	150 mg; 1 syringe per 28 days
Enbrel	AS, pJIA, PsA, PsO*, RA	25 mg: 8 syringes per 28 days 50 mg: 4 auto-injectors, cartridges, or syringes per 28 days
Humira	AS, CD, pJIA, PsA, PsO, RA, uveitis	2 per 28 days
	HS	4 per 28 days
	CD, HS, psoriasis, UC, uveitis	Stater pack: One time fill
Kevzara	All	2 pens or syringes per 28 days
Kineret	All	28 syringes per 28 days
Orencia IV	All	4 vials per 28 days
Orencia SC	All	4 auto-injectors or syringes per 28 days
Otezla	All	60 tablets per 30 days
		Starter pack: One time fill
Rinvoq	All	30 tablets per 30 days
Siliq*	All	2 syringes per 28 days
Simponi	All (UC*)	1 auto-injector or syringe per 28 days
Simponi Aria	AS	5 vials per 60 days
Skyrizi*	All	2 prefilled syringes per 84 days
Stelara IV	All	4 vials for a one time fill
Stelara SC	PsA*, PsO*	45 mg syringes or vials: 1 per 84 days
	CD	90 mg syringes: 1 per 54 days
	PsA*, PsO*	90 mg syringes: 1 per 84 days
Taltz	All*	1 auto-injector or syringe per 28 days
Tremfya*	All	1 per 54 days
Xeljanz	All	5, 10 mg: 60 tablets per 30 days 11 mg: 30 tablets per 30 days

*Loading dose required
^With or without loading dose
AS=ankylosing spondylitis, CD=Crohn's disease, HS=hidradenitis suppurativa, pJIA=polyarticular juvenile idiopathic arthritis, PsA=psoriatic arthritis, PsO=plaque psoriasis, RA=rheumatoid arthritis, SC=subcutaneous, sJIA=systemic juvenile idiopathic arthritis, UC=ulcerative colitis

CODES

The following HCPCS/CPT code(s) are:

Code	Description
J0129	Injection, abatacept, per 10 mg
J1602	Injection, golimumab, 1 mg, for intravenous use
J1745	Injection, infliximab, 10mg
J3245	Injection, tildrakizumab, 1 mg
J3262	Injection, tocilizumab, 1 mg
J3358	Ustekinumab, for intravenous injection, 1 mg
J3380	Injection, vedolizumab, 1 mg
Q5103	Injection, infliximab-dyyb, biosimilar, (Inflectra), 10 mg
Q5104	Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg
Q5121	Injection, infliximab-axxq, biosimilar, (AVSOLA), 10 mg

Note: Medical billing codes may not be used for Actemra, Orencia, Simponi, or Stelara injections for subcutaneous use. These formulations must be obtained via the Member's pharmacy benefit.

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APPROVAL HISTORY

October 2006: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1. October 7, 2014: No changes
2. November 4, 2014: Removed age limit for Crohn's disease; modified age restriction under Polyarticular Juvenile Idiopathic Arthritis.
3. December 2, 2014: Added dosing for Pediatric Crohn's Disease and Polyarticular Juvenile Idiopathic Arthritis including new dosage form.
4. September 16, 2015: Added pharmacy coverage guidelines for the treatment of hidradenitis suppurativa. Updated other biologic agents based on indication.
5. February 9, 2016: Updated quantity limitation for the indication of hidradenitis suppurativa.
6. September 13, 2016: Added pharmacy coverage guidelines and quantity limitations for the treatment of uveitis.
7. April 11, 2017: Administrative update, adding Tufts Health RITogether to the template.
8. August 8, 2017: No changes
9. September 12, 2017: Effective 1/1/18, for the treatment rheumatoid arthritis, changed the prerequisite DMARD trial to a three drug generic regimen of methotrexate, sulfasalazine, hydroxychloroquine for patients with low to moderate disease activity.
10. November 14, 2017: Administrative update adding a limitation to clarify that for plaque psoriasis, inconvenience does not qualify as a contraindication to phototherapy.
11. April 10, 2018: Removed age requirement for ankylosing spondylitis, plaque psoriasis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, rheumatoid arthritis, ulcerative colitis, and uveitis to be in line with State preferred product strategy requirements. Added the Limitation that documentation of a Member being a social drinker does not qualify as a medically acceptable contraindication or clinically inappropriateness to methotrexate therapy. For the diagnosis of rheumatoid arthritis in Members with low to moderate disease activity, removed the requirement of a documented clinical assessment scale score.
12. September 18, 2018: Effective January 1, 2019, created therapeutic class Medical Necessity Guideline and changed name of Medical Necessity Guideline from "Humira (adalimumab)" to "Anti-inflammatory Conditions." Updated stability rules for non-preferred anti-TNF inhibitors (Cimzia, infliximab products, Simponi, and Simponi Aria) to allow for continuation of the requested agent if documentation of previous hospitalization for the submitted diagnosis. Updated criteria for infliximab products to allow for continuation of Renflexis if the provider indicates that switching to Humira will result in adverse clinical outcomes. Non-biologic prerequisite requirements removed for all non-preferred products. Removed the following two limitations: "Entyvio (vedoliziumab) will not be approved if administered concomitantly with a tumor necrosis factor antagonist or Tysabri (natalizumab)" and "Orencia will not be approved if administered concomitantly with another

tumor necrosis factor antagonist or Kineret (anakinra)." Added age requirements for Actemra for giant cell arteritis. Removed age requirements for Cimzia, Entyvio, infliximab products, Orencia, Simponi, and Stelara (Crohn's disease and psoriatic arthritis only) Updated duration of approval to life of plan for Enbrel, Cimzia, Kevzara, Kineret, Orencia, Simponi (all indications except ulcerative colitis), Simponi Aria, and Xeljanz (all indications except ulcerative colitis). Updated the initial duration of approval for Humira, Simponi, and Xeljanz for the indication of ulcerative colitis to be limited to 8 weeks. Added coverage criteria for cytokine release syndrome for Actemra intravenous injection.

13. October 16, 2018: Effective January 1, 2019, added Actemra subcutaneous injection to the approval criteria for systemic juvenile idiopathic arthritis and added Olumiant to the medical necessity guideline.
14. November 13, 2018: Effective January 1, 2019, updated Humira's age restrictions for hidradenitis suppurativa based on updated package labeling.
15. December 19, 2018: Effective January 1, 2019, added Ilumya to the Medical Necessity Guideline.
16. May 7, 2019: Added criteria for Cimzia for the expanded indication of Non-radiographic Axial Spondyloarthritis and updated quantity limitation of Humira to 4 pens per month for members approved for HS.
17. August 13, 2019: Added Skyrizi to the Medical Necessity Guideline. Added criteria for Otezla for the supplemental indication of treatment of adult patients with oral ulcers associated with Behcet's disease.
18. October 15, 2019: Effective November 18, 2019, added Rinvoq to the Medical Necessity Guideline, added criteria for Taltz for the supplemental indication of treatment of ankylosing spondylitis, and for the treatment of Crohn's disease and ulcerative colitis, added documentation the Member is high-risk to criteria for preferred agents.
19. November 12, 2019: Added criteria for Stelara for the supplemental indication of treatment of ulcerative colitis.
20. January 14, 2020: Added criteria for Xeljanz XR for the supplemental indication of ulcerative colitis. Effective April 1, 2020, removed criteria allowing for documentation of previous hospitalization, removed criteria asking for documentation of clinical inappropriateness of subcutaneous formulations for all intravenous formulations. Orencia subcutaneous and intravenous have the same criteria. Added the following Limitation, "Documentation of a Member having a needle phobia does not qualify as a medically acceptable contraindication or clinical inappropriateness to injectable products." Added non-biologic perquisite criteria for all non-preferred agents back to coverage criteria.
21. February 11, 2020: Effective April 1, 2020, removed the low to moderate disease activity prerequisite criteria for rheumatoid arthritis.
22. Date of April 28, 2020: Effective May 1, 2020, Taltz and Xeljanz are preferred products. Updated coverage criteria for Taltz to require a trial and failure or clinical inappropriateness with at least one of the following: Enbrel or Humira. Updated coverage criteria for Taltz for the treatment plaque psoriasis to require member age of at least 6 years of age. Updated coverage criteria for Xeljanz for psoriatic arthritis and rheumatoid arthritis to remove step through Enbrel and Humira.
23. July 14, 2020: Added Avsola to the Medical Necessity Guideline and removed the step through Renflexis for Inflectra. Updated the Remicade criteria to require previous failure, contraindication, or clinical inappropriateness of all infliximab biosimilars. Added coverage criteria for Cosentyx's and Taltz's supplemental indication for non-radiographic axial spondyloarthritis. Removed reauthorization criteria for Entyvio, Humira, Simponi, and Xeljanz.
24. August 11, 2020: Added coverage criteria for Tremfya's supplemental indication for psoriatic arthritis. Updated coverage criteria for Xeljanz and Taltz to be first-line biological therapy for all indications.
25. November 24, 2020: Effective January 1, 2021, criteria updated to be in line with MassHealth ACPP/MCO Partial Unified Formulary coverage requirements and updated the title of the Medical Necessity Guideline from "Anti-Inflammatory Drugs" to "Targeted Immunomodulators – Biological Agents." Criteria for all indications have been adjusted. Removed all provider specialty and age requirements. Removed the following Limitations "Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response and will not be considered for prior authorization" and "Maximal doses of methotrexate are defined as 15 to 25 mg per week depending on the patient's tolerance."
26. January 12, 2021: Per MassHealth ACPP/MCO Unified Pharmacy Product List, updated Stelara to a Preferred Drug effective January 15, 2021. No coverage changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.