

Pharmacy Medical Necessity Guidelines: Anti-Inflammatory Conditions

Effective: September 21, 2020

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: MED	Department to Review	RXUM/ MM
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p>Commercial Products</p> <ul style="list-style-type: none"> <input type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input type="checkbox"/> Tufts Health Freedom Plan products – small group plans • CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization <p>Tufts Health Public Plans Products</p> <ul style="list-style-type: none"> <input type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan 		<p>Fax Numbers:</p> <p><i>Intravenous injection</i> MM: 888.415.9055</p> <p><i>Self-administered formulations (oral, subcutaneous injection)</i> RXUM: 617.673.0988</p>	

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

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

The biologics for the treatment of anti-inflammatory conditions bolded in the table below are preferred.

Actemra (tocilizumab)

In addition to the conditions in the table below, 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 below, 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 below, 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 below, 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 below, 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 below, 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 below, 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

Brand Name	MOA	Benefit	AS	CD	PsO	PsA	pJIA	RA	sJIA	UC
Preferred										
Enbrel	TNF inhibitor	RX	x	-	x	x	x	x	-	-
Humira	TNF inhibitor	RX	x	x	x	x	x	x	-	x
Taltz	IL antagonist (17A)	RX	x	-	x	x	-	-	-	-
Xeljanz	JAKI	RX	-	-	-	x	-	x	-	x
Nonpreferred										
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	-	-	-	-
Entyvio	IRA	MB	-	x		-	-	-	-	x
Ilumya	IL antagonist (23)	MB	-	-	x	-	-	-	-	-
Inflectra	TNF inhibitor	MB	x	x	x	x	-	x	-	x
Olumiant	JAKI	RX	-	-	-	-	-	x	-	-
Kevzara	IL antagonist (6)	RX	-	-	-	-	-	x	-	-
Kineret	IL antagonist (1)	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	-	-
Skyrizi	IL antagonist (23)	Rx	-	-	x	-	-	-	-	-
Stelara IV	IL antagonist (12/23)	MB	-	x	-	-	-	-	-	x
Stelara SC	IL antagonist (12/23)	RX	-	x	x	x	-	-	-	x
Tremfya	IL antagonist (23)	RX	-	-	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, 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

COVERAGE GUIDELINES**PREFERRED PRODUCTS****1. 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. The prescribing physician is a rheumatologist
- AND**
3. Documentation of **one (1) of the following:**
 - a. The Member demonstrated an inadequate response to at least one nonsteroidal anti-inflammatory drug or the provider has indicated clinical inappropriateness with nonsteroidal anti-inflammatory drugs
 - b. The Member has tried and failed treatment with another biological agent for the treatment of ankylosing spondylitis
 - c. The Member is new to the plan and has been stable on Enbrel prior to enrollment

Plaque Psoriasis

1. Documented diagnosis of plaque psoriasis
- AND**
2. The prescribing physician is a dermatologist
- AND**
3. Documentation of **one (1) of the following:**
 - a. The Member has demonstrated an inadequate response to phototherapy and at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - i. Soriatane (acitretin)
 - ii. Cyclosporine
 - iii. Methotrexate
 - b. The Member has tried and failed treatment with another biological for the treatment of plaque psoriasis
 - c. The Member is new to the plan and has been stable on Enbrel prior to enrollment

Polyarticular juvenile idiopathic arthritis and Psoriatic arthritis

1. Documented diagnosis of one of the following:
 - a. Polyarticular juvenile idiopathic arthritis
 - b. Psoriatic arthritis
- AND**
2. The prescribing physician is a rheumatologist
- AND**
3. Documentation of **one (1) of the following:**
 - a. The Member has demonstrated an inadequate response to at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - i. Azathioprine
 - ii. Gold therapy
 - iii. Hydroxychloroquine
 - iv. Methotrexate
 - v. Penicillamine
 - vi. Sulfasalazine
 - vii. Cyclosporine
 - viii. Leflunomide
 - b. The Member has tried and failed treatment with another biological agent for the treatment of polyarticular juvenile idiopathic arthritis or psoriatic arthritis
 - c. The Member is new to the plan and has been stable on Enbrel prior to enrollment

Rheumatoid Arthritis

1. Documented diagnosis of rheumatoid arthritis
- AND**
2. The prescribing physician is a rheumatologist
- AND**
3. Documentation of **one (1) of the following:**
 - a. The Member has demonstrated an inadequate response to at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - i. Azathioprine
 - ii. Gold therapy
 - iii. Hydroxychloroquine
 - iv. Methotrexate
 - v. Penicillamine
 - vi. Sulfasalazine
 - vii. Cyclosporine
 - viii. Leflunomide
 - b. The Member has tried and failed treatment with another biological agent for the treatment of rheumatoid arthritis
 - c. The Member is new to the plan and has been stable on Enbrel prior to enrollment

2. 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. The prescribing physician is a rheumatologist
- AND**
3. Documentation of **one (1) of the following**:
 - a. The Member demonstrated an inadequate response to at least one nonsteroidal anti-inflammatory drug or the provider has indicated clinical inappropriateness with nonsteroidal anti-inflammatory drugs
 - b. The Member has tried and failed treatment with another biological agent for the treatment of ankylosing spondylitis
 - c. The Member is new to the plan and has been stable on Humira prior to enrollment

Crohn's disease and Ulcerative colitis

1. Documented diagnosis of one of the following:
 - a. Crohn's disease
 - b. Ulcerative colitis
- AND**
2. The prescribing physician is a gastroenterologist
- AND**
3. Documentation of **one (1) of the following**:
 - a. The Member has demonstrated an inadequate response to at least two of the following agents or the provider has indicated clinical inappropriateness of all of the following:
 - i. Corticosteroids (e.g., prednisone)
 - ii. 5-Aminosalicylates (e.g., sulfasalazine)
 - iii. 6-mercaptopurine, azathioprine and/or cyclosporine
 - iv. Methotrexate
 - b. The Member has tried and failed treatment with another biological agent for the treatment of Crohn's disease or ulcerative colitis
 - c. The Member is moderate to high risk as 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
 - d. The Member is new to the plan and has been stable on Humira prior to enrollment

Hidradenitis suppurativa

1. Documented diagnosis of hidradenitis suppurativa
- AND**
2. Documentation of Hurley Stage II or III disease and with at least three abscesses or inflammatory nodules
- AND**
3. The prescribing physician is a dermatologist
- AND**
4. The Member is 12 years of age or older
- AND**
5. Documentation of **one (1) of the following**:
 - a. The Member has demonstrated an inadequate response to at least three of the following conventional treatments:
 - i. Local hygiene and ordinary hygiene
 - ii. Weight reduction in patients who are obese
 - iii. Use of ordinary soaps and antiseptic and antiperspirant agents (e.g., aluminum chloride hexahydrate)
 - iv. Application of warm compresses with sodium chloride solution or Burow's solution
 - v. Laser hair removal
 - vi. Cessation of cigarette smoking
 - vii. Medical anti-inflammatory or antiandrogen therapy such as oral or topical antibiotics, intralesional triamcinolone, spironolactone, or finasteride
 - b. The Member is new to the plan and has been stable on Humira prior to enrollment

Plaque Psoriasis

1. Documented diagnosis of plaque psoriasis
- AND**
2. The prescribing physician is a dermatologist
- AND**
3. Documentation of **one (1) of the following**:
 - a. The Member has demonstrated an inadequate response to phototherapy and at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - i. Soriatane (acitretin)
 - ii. Cyclosporine
 - iii. Methotrexate
 - b. The Member has tried and failed treatment with another biological for the treatment of plaque psoriasis
 - c. The Member is new to the plan and has been stable on Humira prior to enrollment

Polyarticular juvenile idiopathic arthritis and Psoriatic arthritis

1. Documented diagnosis of one of the following:
 - a. Polyarticular juvenile idiopathic arthritis
 - b. Psoriatic arthritis
- AND**
2. The prescribing physician is a rheumatologist
- AND**
3. Documentation of **one (1) of the following**:
 - a. The Member has demonstrated an inadequate response to at least one of the following or the provider has indicated clinical inappropriateness of all of the following:
 - i. Azathioprine
 - ii. Gold therapy
 - iii. Hydroxychloroquine
 - iv. Methotrexate
 - v. Penicillamine
 - vi. Sulfasalazine
 - vii. Cyclosporine
 - viii. Leflunomide
 - b. The Member has tried and failed treatment with another biological agent for the treatment of polyarticular juvenile idiopathic arthritis or psoriatic arthritis
 - c. The Member is new to the plan and has been stable on Humira prior to enrollment

Rheumatoid Arthritis

1. Documented diagnosis of rheumatoid arthritis
- AND**
2. The prescribing physician is a rheumatologist
- AND**
3. Documentation of **one (1) of the following:**
 - a. The Member has demonstrated an inadequate response to at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - i. Azathioprine
 - ii. Gold therapy
 - iii. Hydroxychloroquine
 - iv. Methotrexate
 - v. Penicillamine
 - vi. Sulfasalazine
 - vii. Cyclosporine
 - viii. Leflunomide
 - b. The Member has tried and failed treatment with another biological agent for the treatment of rheumatoid arthritis
 - c. The Member is new to the plan and has been stable on Humira prior to enrollment

Uveitis

1. Documented diagnosis of non-infectious intermediate, posterior and panuveitis
- AND**
2. The prescribing physician is a uveitis specialist (e.g., ophthalmologist, ocular immunologist, rheumatologist)
- AND**
3. Documentation of **one (1) of the following:**
 - a. The Member has demonstrated an inadequate response to conventional therapy:
 - i. Periocular, intraocular, or systemic corticosteroids
 - ii. Immunosuppressive drugs (e.g., methotrexate)
 - b. The Member is new to the plan and has been stable on Humira prior to enrollment

3. 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. The prescribing physician is a rheumatologist
- AND**
3. Documentation of **one (1) of the following:**
 - a. The Member demonstrated an inadequate response to at least one nonsteroidal anti-inflammatory drug or the provider has indicated clinical inappropriateness with nonsteroidal anti-inflammatory drugs
 - b. The Member has tried and failed treatment with another biological agent for the treatment of ankylosing spondylitis
 - c. The Member is new to the plan and has been stable on Taltz prior to enrollment

Non-radiographic Axial Spondyloarthritis

1. Documented diagnosis of non-radiographic axial spondyloarthritis
- AND**
2. The prescribing physician is a rheumatologist
- AND**
3. The Member is 18 years of age or older
- AND**
4. Documentation of objective signs of inflammation
- AND**
5. Documented trial and failure with, or intolerance to at least one nonsteroidal anti-inflammatory drug

Plaque psoriasis

1. Documented diagnosis of plaque psoriasis
- AND**
2. The prescribing physician is a dermatologist
- AND**
3. The Member is 6 years of age or older
- AND**
4. Documentation of **one (1) of the following:**
 - a. The Member has demonstrated an inadequate response to phototherapy and at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - i. Soriatane (acitretin)
 - ii. Cyclosporine
 - iii. Methotrexate
 - b. The Member has tried and failed treatment with another biological agent for the treatment of plaque psoriasis
 - c. The Member is new to the plan and has been stable on Taltz prior to enrollment

Psoriatic arthritis

1. Documented diagnosis of psoriatic arthritis
- AND**
2. The prescribing physician is a rheumatologist
- AND**
3. The Member is 18 years of age or older
- AND**
4. Documentation of **one (1) of the following:**
 - a. The Member has demonstrated an inadequate response to at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - i. Azathioprine
 - ii. Gold therapy
 - iii. Hydroxychloroquine
 - iv. Methotrexate
 - v. Penicillamine
 - vi. Sulfasalazine
 - vii. Cyclosporine
 - viii. Leflunomide
 - b. The Member has tried and failed treatment with another biological agent for the treatment of psoriatic arthritis
 - c. The Member is new to the plan and has been stable on Taltz prior to enrollment

4. *Xeljanz (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. The prescribing physician is a rheumatologist **AND**
3. The Member is 18 years of age or older **AND**
4. Documentation of **one (1) of the following:**
 - a. The Member has demonstrated an inadequate response to at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - i. Azathioprine
 - ii. Gold therapy
 - iii. Hydroxychloroquine
 - iv. Methotrexate
 - v. Penicillamine
 - vi. Sulfasalazine
 - vii. Cyclosporine
 - viii. Leflunomide
 - b. The Member has tried and failed treatment with another biological agent for the treatment of psoriatic arthritis
 - c. The Member is new to the plan and has been stable on Xeljanz prior to enrollment

Rheumatoid arthritis

1. Documented diagnosis of rheumatoid arthritis **AND**
2. The prescribing physician is a rheumatologist **AND**
3. The Member is 18 years of age or older **AND**
4. Documentation of **one (1) of the following:**
 - a. The Member has demonstrated an inadequate response to at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - i. Azathioprine
 - ii. Gold therapy
 - iii. Hydroxychloroquine
 - iv. Methotrexate
 - v. Penicillamine
 - vi. Sulfasalazine
 - vii. Cyclosporine
 - viii. Leflunomide
 - b. The Member has tried and failed treatment with another biological agent for the treatment of rheumatoid arthritis
 - c. The Member is new to the plan and has been stable on Xeljanz prior to enrollment

Ulcerative colitis

1. Documented diagnosis of ulcerative colitis **AND**
2. The prescribing physician is a gastroenterologist **AND**
3. The Member is 18 years of age or older **AND**
4. Documentation of **one (1) of the following:**
 - a. Member has demonstrated an inadequate response to at least two of the following agents or the provider has indicated clinical inappropriateness of all of the following:
 - i. Corticosteroids (e.g., prednisone)
 - ii. 5-Aminosalicylates (e.g., sulfasalazine)
 - iii. 6-mercaptopurine, azathioprine and/or cyclosporine
 - iv. Methotrexate
 - b. The Member is moderate to high risk as 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
 - c. The Member has tried and failed treatment with another biological agent for the treatment of ulcerative colitis
 - d. The Member is new to the plan and has been stable on Xeljanz prior to enrollment

NON-PREFERRED PRODUCTS

1. Actemra (tocilizumab) (subcutaneous and intravenous)

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 severe or life-threatening chimeric antigen receptor T cell-induced cytokine release syndrome

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. The prescribing physician is a rheumatologist or neurologist
AND
3. The Member is 18 years of age or older
AND
4. The Member has demonstrated an inadequate response to at least one of the following agents or the provider has indicated clinical inappropriateness with corticosteroids:
 - a. Corticosteroids (e.g., prednisone)
 - b. Immunosuppressants (e.g., methotrexate)

Polyarticular juvenile idiopathic arthritis

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

1. Documented diagnosis of polyarticular juvenile idiopathic arthritis
AND
2. The prescribing physician is a rheumatologist
AND
3. The Member is two years of age or older
AND
4. The Member has demonstrated an inadequate response to at least one of the following or the provider has indicated clinical inappropriateness of all of the following:
 - a. Azathioprine
 - b. Gold therapy
 - c. Hydroxychloroquine
 - d. Methotrexate
 - e. Penicillamine
 - f. Sulfasalazine
 - g. Cyclosporine
 - h. Leflunomide**AND**
5. The Member has tried and failed treatment with both of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. 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. The prescribing physician is a rheumatologist
AND
3. The Member is two years of age or older
AND
4. The Member has demonstrated an inadequate response to both of the following agents or the provider has indicated clinical inappropriateness with both of the following:
 - a. Corticosteroids (e.g., prednisone)
 - b. Methotrexate

Rheumatoid arthritis

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

1. Documented diagnosis of rheumatoid arthritis
AND
2. The prescribing physician is a rheumatologist
AND
3. The Member is 18 years of age or older
AND
4. The Member has demonstrated an inadequate response to at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - a. Azathioprine
 - b. Gold therapy
 - c. Hydroxychloroquine
 - d. Methotrexate
 - e. Penicillamine
 - f. Sulfasalazine
 - g. Cyclosporine
 - h. Leflunomide**AND**
5. The Member has tried and failed treatment with at least two of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira
 - c. Xeljanz

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. The prescribing physician is a rheumatologist
AND
3. Documentation the Member demonstrated an inadequate response to at least one nonsteroidal anti-inflammatory drug or the provider has indicated clinical inappropriateness with nonsteroidal anti-inflammatory drugs
AND
4. The Member has tried and failed treatment with at least two of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira
 - c. Taltz

Crohn's disease

1. Documented diagnosis of Crohn's disease
AND
2. The prescribing physician is a gastroenterologist
AND
3. Documentation of **one (1) of the following:**
 - a. Member has demonstrated an inadequate response to at least two of the following agents or the provider has indicated clinical inappropriateness of all of the following:
 - i. Corticosteroids (e.g., prednisone)
 - ii. 5-Aminosalicylates (e.g., sulfasalazine)
 - iii. 6-mercaptopurine, azathioprine and/or cyclosporine
 - iv. Methotrexate
 - b. The Member is moderate to high risk as 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
AND
4. The Member has tried and failed treatment with the following agent or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Humira

Non-radiographic Axial Spondyloarthritis

1. Documented diagnosis of non-radiographic axial spondyloarthritis
AND
2. The prescribing physician is a rheumatologist
AND
3. The Member is 18 years of age or older
AND
4. Documentation of objective signs of inflammation
AND
5. Documented trial and failure with, or intolerance to at least one nonsteroidal anti-inflammatory drug

Plaque psoriasis

1. Documented diagnosis of plaque psoriasis
- AND**
2. The prescribing physician is a dermatologist
- AND**
3. Documentation the Member has demonstrated an inadequate response to phototherapy and at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - a. Soriatane (acitretin)
 - b. Cyclosporine
 - c. Methotrexate
- AND**
4. The Member has tried and failed treatment with at least two of following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira
 - c. Taltz

Psoriatic arthritis

1. Documented diagnosis of psoriatic arthritis
- AND**
2. The prescribing physician is a rheumatologist
- AND**
3. Documentation the Member has demonstrated an inadequate response to at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - a. Azathioprine
 - b. Gold therapy
 - c. Hydroxychloroquine
 - d. Methotrexate
 - e. Penicillamine
 - f. Sulfasalazine
 - g. Cyclosporine
 - h. Leflunomide
- AND**
4. The Member has tried and failed treatment with at least two of following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira
 - c. Taltz
 - d. Xeljanz

Rheumatoid arthritis

1. Documented diagnosis of rheumatoid arthritis
- AND**
2. The prescribing physician is a rheumatologist
- AND**
3. The Member has demonstrated an inadequate response to at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - a. Azathioprine
 - b. Gold therapy
 - c. Hydroxychloroquine
 - d. Methotrexate
 - e. Penicillamine
 - f. Sulfasalazine
 - g. Cyclosporine
 - h. Leflunomide
- AND**
4. The Member has tried and failed treatment with at least two of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira
 - c. Xeljanz

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. The prescribing physician is a rheumatologist
AND
3. The Member is 18 years of age or older
AND
4. Documentation the Member demonstrated an inadequate response to at least one nonsteroidal anti-inflammatory drug or the provider has indicated clinical inappropriateness with nonsteroidal anti-inflammatory drugs
AND
5. The Member has tried and failed treatment with at least two of following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira
 - c. Taltz

Non-radiographic Axial Spondyloarthritis

1. Documented diagnosis of non-radiographic axial spondyloarthritis
AND
2. The prescribing physician is a rheumatologist
AND
3. The Member is 18 years of age or older
AND
4. Documentation of objective signs of inflammation
AND
5. Documented trial and failure with, or intolerance to at least one nonsteroidal anti-inflammatory drug

Plaque psoriasis

1. Documented diagnosis of plaque psoriasis
AND
2. The prescribing physician is a dermatologist
AND
3. The Member is 18 years of age or older
AND
4. Documentation the Member has demonstrated an inadequate response to phototherapy and at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - a. Soriatane (acitretin)
 - b. Cyclosporine
 - c. Methotrexate**AND**
5. The Member has tried and failed treatment with at least two of following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira
 - c. Taltz

Psoriatic arthritis

1. Documented diagnosis of psoriatic arthritis
- AND**
2. The prescribing physician is a rheumatologist
- AND**
3. The Member is 18 years of age or older
- AND**
4. Documentation the Member has demonstrated an inadequate response to at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - a. Azathioprine
 - b. Gold therapy
 - c. Hydroxychloroquine
 - d. Methotrexate
 - e. Penicillamine
 - f. Sulfasalazine
 - g. Cyclosporine
 - h. Leflunomide
- AND**
5. The Member has tried and failed treatment with at least two of following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira
 - c. Taltz
 - d. Xeljanz

4. Entyvio (vedolizumab)

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

Crohn's disease and Ulcerative colitis

1. Documented diagnosis Crohn's disease

AND

2. The prescribing physician is a gastroenterologist

AND

3. Documentation of **one (1) of the following:**

- a. Member has demonstrated an inadequate response to at least two of the following agents or the provider has indicated clinical inappropriateness of all of the following:

- i. Corticosteroids (e.g., prednisone)
- ii. 5-Aminosalicylates (e.g., sulfasalazine)
- iii. 6-mercaptopurine, azathioprine and/or cyclosporine
- iv. Methotrexate

- b. The Member is moderate to high risk as 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

AND

4. The Member has tried and failed treatment with the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:

- a. Humira
- b. If ulcerative colitis: Xeljanz

Crohn's disease and Ulcerative colitis

1. Documented diagnosis of ulcerative colitis

AND

2. The prescribing physician is a gastroenterologist

AND

3. Documentation of **one (1) of the following:**

- a. Member has demonstrated an inadequate response to at least two of the following agents or the provider has indicated clinical inappropriateness of all of the following:

- i. Corticosteroids (e.g., prednisone)
- ii. 5-Aminosalicylates (e.g., sulfasalazine)
- iii. 6-mercaptopurine, azathioprine and/or cyclosporine
- iv. Methotrexate

- b. The Member is moderate to high risk as 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

AND

4. The Member has tried and failed treatment with both of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:

- a. Humira
- b. Xeljanz

5. 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 plaque psoriasis
AND
2. The prescribing physician is a dermatologist
AND
3. The Member is 18 years of age or older
AND
4. Documentation the Member has demonstrated an inadequate response to phototherapy and at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - a. Soriatane (acitretin)
 - b. Cyclosporine
 - c. Methotrexate**AND**
4. The Member has tried and failed treatment with at least two of following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira
 - c. Taltz

6. 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
AAND
2. The prescribing physician is a rheumatologist
AND
3. Documentation the Member demonstrated an inadequate response to at least one nonsteroidal anti-inflammatory drug or the provider has indicated clinical inappropriateness with nonsteroidal anti-inflammatory drugs
AND
4. The Member has tried and failed treatment with at least two of following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira
 - c. Taltz

Crohn's disease - non-fistulizing disease

1. Documented diagnosis of Crohn's disease
AND
2. The prescribing physician is a gastroenterologist
AND
3. Documentation the Member has demonstrated an inadequate response to at least two of the following agents or the provider has indicated clinical inappropriateness of all of the following:
 - a. Corticosteroids (e.g., prednisone)
 - b. 5-Aminosalicylates (e.g., sulfasalazine)
 - c. 6-mercaptopurine, azathioprine and/or cyclosporine
 - d. Methotrexate**AND**
4. Documentation of **one (1) of the following:**
 - a. The Member has tried and failed treatment with the following agent or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - i. Humira
 - b. The Member is new to the plan and has been stable on the requested drug prior to enrollment and the prescribing physician has documented that changing to Humira would result in adverse clinical outcomes

Crohn's disease - fistulizing disease

1. Documented diagnosis of Crohn's disease
- AND**
2. Documentation of fistulizing disease
- AND**
3. The prescribing physician is a gastroenterologist
- AND**
4. Documentation of **one (1) of the following**:
 - a. The Member has demonstrated an inadequate response to an appropriate trial with at least two of the following or the provider has indicated clinical inappropriateness of all of the following:
 - i. Corticosteroids (e.g., prednisone)
 - ii. 5-Aminosalicylates (e.g., sulfasalazine)
 - iii. 6-mercaptopurine (6-MP) and/or azathioprine
 - iv. Methotrexate
 - b. The provider has indicated severe/refractory perianal disease or recent or planned surgical resection
 - c. The Member has tried and failed treatment with another biological agent indicated for the treatment of Crohn's disease

Plaque psoriasis

1. Documented diagnosis of plaque psoriasis
- AND**
2. The prescribing physician is a dermatologist
- AND**
3. Documentation the Member has demonstrated an inadequate response to phototherapy and at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - a. Soriatane (acitretin)
 - b. Cyclosporine
 - c. Methotrexate
- AND**
4. The Member has tried and failed treatment with at least two of following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira
 - c. Taltz

Psoriatic arthritis

1. Documented diagnosis of psoriatic arthritis
- AND**
2. The prescribing physician is a rheumatologist
- AND**
3. The Member has demonstrated an inadequate response to at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - a. Azathioprine
 - b. Gold therapy
 - c. Hydroxychloroquine
 - d. Methotrexate
 - e. Penicillamine
 - f. Sulfasalazine
 - g. Cyclosporine
 - h. Leflunomide
- AND**
4. The Member has tried and failed treatment with at least two of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira
 - c. Taltz
 - d. Xeljanz

Rheumatoid arthritis

1. Documented diagnosis of rheumatoid arthritis
- AND**
2. The prescribing physician is a rheumatologist
- AND**
3. The Member has demonstrated an inadequate response to at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - a. Azathioprine
 - b. Gold therapy
 - c. Hydroxychloroquine
 - d. Methotrexate
 - e. Penicillamine
 - f. Sulfasalazine
 - g. Cyclosporine
 - h. Leflunomide
- AND**
4. The Member has tried and failed treatment with at least two of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira
 - c. Xeljanz

Ulcerative colitis

1. Documented diagnosis of ulcerative colitis
- AND**
2. The prescribing physician is a gastroenterologist
- AND**
3. Documentation of **one (1) of the following:**
 - a. Member has demonstrated an inadequate response to at least two of the following agents or the provider has indicated clinical inappropriateness of all of the following:
 - i. Corticosteroids (e.g., prednisone)
 - ii. 5-Aminosalicylates (e.g., sulfasalazine)
 - iii. 6-mercaptopurine, azathioprine and/or cyclosporine
 - iv. Methotrexate
 - b. The Member is moderate to high risk as 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
- AND**
4. The Member has tried and failed treatment with both of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Humira
 - b. Xeljanz

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, contraindication, or clinical inappropriateness with all infliximab biosimilars

7. 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 rheumatoid arthritis
AND
2. The prescribing physician is a rheumatologist
AND
3. The Member is 18 years of age or older
AND
4. The Member has demonstrated an inadequate response to at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - a. Azathioprine
 - b. Gold therapy
 - c. Hydroxychloroquine
 - d. Methotrexate
 - e. Penicillamine
 - f. Sulfasalazine
 - g. Cyclosporine
 - h. Leflunomide**AND**
5. The Member has tried and failed treatment with at least two of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira
 - c. Xeljanz

8. 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 rheumatoid arthritis

AND

2. The prescribing physician is a rheumatologist

AND

3. The Member is 18 years of age or older

AND

4. The Member has demonstrated an inadequate response to at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:

- a. Azathioprine
- b. Gold therapy
- c. Hydroxychloroquine
- d. Methotrexate
- e. Penicillamine
- f. Sulfasalazine
- g. Cyclosporine
- h. Leflunomide

AND

5. The Member has tried and failed treatment with at least two of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:

- a. Enbrel
- b. Humira
- c. Xeljanz

9. Olumiant (baricitinib)

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

Rheumatoid arthritis

1. Documented diagnosis of rheumatoid arthritis
- AND**
2. The prescribing physician is a rheumatologist
- AND**
3. The Member is 18 years of age or older
- AND**
4. The Member has demonstrated an inadequate response to at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - a. Azathioprine
 - b. Gold therapy
 - c. Hydroxychloroquine
 - d. Methotrexate
 - e. Penicillamine
 - f. Sulfasalazine
 - g. Cyclosporine
 - h. Leflunomide
- AND**
5. The Member has tried and failed treatment with at least two of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira
 - c. Xeljanz

10. Orenzia (abatacept)

The plan may authorize coverage of **Orenzia (intravenous or subcutaneous injection)** for Members when the following criteria are met:

Polyarticular juvenile idiopathic arthritis

1. Documented diagnosis of polyarticular juvenile idiopathic arthritis
AND
2. The prescribing physician is a rheumatologist
AND
3. Documentation the Member has demonstrated an inadequate response to at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - a. Azathioprine
 - b. Gold therapy
 - c. Hydroxychloroquine
 - d. Methotrexate
 - e. Penicillamine
 - f. Sulfasalazine
 - g. Cyclosporine
 - h. Leflunomide**AND**
4. The Member has tried and failed treatment with both of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira

Psoriatic arthritis

1. Documented diagnosis of psoriatic arthritis
AND
2. The prescribing physician is a rheumatologist
AND
3. Documentation the Member has demonstrated an inadequate response to at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - a. Azathioprine
 - b. Gold therapy
 - c. Hydroxychloroquine
 - d. Methotrexate
 - e. Penicillamine
 - f. Sulfasalazine
 - g. Cyclosporine
 - h. Leflunomide**AND**
4. The Member has tried and failed treatment with at least two of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira
 - c. Taltz
 - d. Xeljanz

Rheumatoid arthritis

1. Documented diagnosis of rheumatoid arthritis
- AND**
2. The prescribing physician is a rheumatologist
- AND**
3. The Member is 18 years of age or older
- AND**
4. The Member has demonstrated an inadequate response to at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - a. Azathioprine
 - b. Gold therapy
 - c. Hydroxychloroquine
 - d. Methotrexate
 - e. Penicillamine
 - f. Sulfasalazine
 - g. Cyclosporine
 - h. Leflunomide
- AND**
5. The Member has tried and failed treatment with at least two of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira
 - c. Xeljanz

11. 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 Behcet's disease
- AND**
2. Documentation of active oral ulcers
- AND**
3. Prescribed by or in consultation with a rheumatologist
- AND**
4. The Member has tried and failed treatment with at least two of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with
 - a. Azathioprine
 - b. Colchicine
 - c. Corticosteroids (topical or systemic)
 - d. Sucralfate

Plaque psoriasis

1. Documented diagnosis of plaque psoriasis
- AND**
2. The prescribing physician is a dermatologist
- AND**
3. The Member is 18 years of age or older
- AND**
4. Documentation the Member has demonstrated an inadequate response to phototherapy and at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - a. Soriatane (acitretin)
 - b. Cyclosporine
 - c. Methotrexate
- AND**
5. The Member has tried and failed treatment with at least two of following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira
 - c. Taltz

Psoriatic arthritis

1. Documented diagnosis of psoriatic arthritis
- AND**
2. The prescribing physician is a rheumatologist
- AND**
3. The Member is 18 years of age or older
- AND**
4. Documentation the Member has demonstrated an inadequate response to at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - a. Azathioprine
 - b. Gold therapy
 - c. Hydroxychloroquine
 - d. Methotrexate
 - e. Penicillamine
 - f. Sulfasalazine
 - g. Cyclosporine
 - h. Leflunomide
- AND**
5. The Member has tried and failed treatment with at least two of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira
 - c. Taltz
 - d. Xeljanz

12. 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 rheumatoid arthritis

AND

2. The prescribing physician is a rheumatologist

AND

3. The Member has demonstrated an inadequate response to at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:

- a. Azathioprine
- b. Gold therapy
- c. Hydroxychloroquine
- d. Methotrexate
- e. Penicillamine
- f. Sulfasalazine
- g. Cyclosporine
- h. Leflunomide

AND

4. The Member has tried and failed treatment with at least two of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:

- a. Enbrel
- b. Humira
- c. Xeljanz

13. Siliq (brodalumab)

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

Plaque psoriasis

1. Documented diagnosis of plaque psoriasis
- AND**
2. The prescribing physician is a dermatologist
- AND**
3. The Member is 18 years of age or older
- AND**
4. Documentation the Member has demonstrated an inadequate response to phototherapy and at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - a. Soriatane (acitretin)
 - b. Cyclosporine
 - c. Methotrexate
- AND**
5. The Member has tried and failed treatment with at least two of following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira
 - c. Taltz

**14. Simponi (golimumab) and Simponi Aria (golimumab)
Ankylosing spondylitis**

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

1. Documented diagnosis of ankylosing spondylitis
AND
2. The prescribing physician is a rheumatologist
AND
3. Documentation the Member demonstrated an inadequate response to at least one nonsteroidal anti-inflammatory drug or the provider has indicated clinical inappropriateness with nonsteroidal anti-inflammatory drugs
AND
4. The Member has tried and failed treatment with at least two of following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira
 - c. Taltz

Psoriatic arthritis

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

1. Documented diagnosis of psoriatic arthritis
AND
2. The prescribing physician is a rheumatologist
AND
3. The Member has demonstrated an inadequate response to at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - a. Azathioprine
 - b. Gold therapy
 - c. Hydroxychloroquine
 - d. Methotrexate
 - e. Penicillamine
 - f. Sulfasalazine
 - g. Cyclosporine
 - h. Leflunomide**AND**
4. The Member has tried and failed treatment with at least two of following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira
 - c. Taltz
 - d. Xeljanz

Rheumatoid arthritis

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

1. Documented diagnosis of rheumatoid arthritis
AND
2. The prescribing physician is a rheumatologist
AND
3. The Member has demonstrated an inadequate response to at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - a. Azathioprine
 - b. Gold therapy
 - c. Hydroxychloroquine
 - d. Methotrexate
 - e. Penicillamine
 - f. Sulfasalazine
 - g. Cyclosporine
 - h. Leflunomide**AND**
4. The Member has tried and failed treatment with at least two of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira
 - c. Xeljanz

Ulcerative colitis

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

1. Documented diagnosis of ulcerative colitis
AND
2. The prescribing physician is a gastroenterologist
AND
3. Documentation of **one (1) of the following:**
 - a. Member has demonstrated an inadequate response to at least two of the following agents or the provider has indicated clinical inappropriateness of all of the following:
 - i. Corticosteroids (e.g., prednisone)
 - ii. 5-Aminosalicylates (e.g., sulfasalazine)
 - iii. 6-mercaptopurine, azathioprine and/or cyclosporine
 - iv. Methotrexate
 - b. The Member is moderate to high risk as 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**AND**
4. The Member has tried and failed treatment with both of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Humira
 - b. Xeljanz

15. 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 plaque psoriasis
AND
2. The prescribing physician is a dermatologist
AND
3. The Member is 18 years of age or older
AND
4. Documentation the Member has demonstrated an inadequate response to phototherapy and at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - a. Soriatane (acitretin)
 - b. Cyclosporine
 - c. Methotrexate**AND**
5. The Member has tried and failed treatment with at least two of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira
 - c. Taltz

16. Stelara (ustekinumab) (intravenous and subcutaneous)

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

Crohn's disease

1. Documented diagnosis of Crohn's disease
- AND**
2. The prescribing physician is a gastroenterologist
- AND**
3. Documentation of **one (1) of the following:**
 - a. Member has demonstrated an inadequate response to at least two of the following agents or the provider has indicated clinical inappropriateness of all of the following:
 - i. Corticosteroids (e.g., prednisone)
 - ii. 5-Aminosalicylates (e.g., sulfasalazine)
 - iii. 6-mercaptopurine (6-MP), azathioprine and/or cyclosporine
 - iv. Methotrexate
 - b. The Member is moderate to high risk as 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
- AND**
4. The Member has tried and failed treatment with the following agent or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Humira

Plaque psoriasis

1. Documented diagnosis of plaque psoriasis
- AND**
2. The prescribing physician is a dermatologist
- AND**
3. The Member is 6 years of age or older
- AND**
4. Documentation the Member has demonstrated an inadequate response to phototherapy and at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - a. Soriatane (acitretin)
 - b. Cyclosporine
 - c. Methotrexate
- AND**
5. The Member has tried and failed treatment with at least two of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira
 - c. Taltz

Psoriatic arthritis

1. Documented diagnosis of psoriatic arthritis
- AND**
2. The prescribing physician is a rheumatologist
- AND**
3. The Member has demonstrated an inadequate response to at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - a. Azathioprine
 - b. Gold therapy
 - c. Hydroxychloroquine
 - d. Methotrexate
 - e. Penicillamine
 - f. Sulfasalazine
 - g. Cyclosporine
 - h. Leflunomide
- AND**
4. The Member has tried and failed treatment with at least two of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira
 - c. Taltz
 - d. Xeljanz

Ulcerative Colitis

1. Documented diagnosis of ulcerative colitis
- AND**
2. The prescribing physician is a gastroenterologist
- AND**
3. Documentation of **one (1) of the following:**
 - a. Member has demonstrated an inadequate response to at least two of the following agents or the provider has indicated clinical inappropriateness of all of the following:
 - i. Corticosteroids (e.g., prednisone)
 - ii. 5-Aminosalicylates (e.g., sulfasalazine)
 - iii. 6-mercaptopurine (6-MP), azathioprine and/or cyclosporine
 - iv. Methotrexate
 - b. The Member is moderate to high risk as 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
- AND**
4. The Member has tried and failed treatment with both of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Humira
 - b. Xeljanz

17. Tremfya (guselkumab)

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

Plaque psoriasis

1. Documented diagnosis of plaque psoriasis
AND
2. The prescribing physician is a dermatologist
AND
3. The Member is 18 years of age or older
AND
4. Documentation the Member has demonstrated an inadequate response to phototherapy and at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - a. Soriatane (acitretin)
 - b. Cyclosporine
 - c. Methotrexate**AND**
5. The Member has tried and failed treatment with at least two of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira
 - c. Taltz

Psoriatic arthritis

1. Documented diagnosis of psoriatic arthritis
AND
2. The prescribing physician is a rheumatologist
AND
3. The Member is 18 years of age or older
AND
4. The Member has demonstrated an inadequate response to at least one of the following agents or the provider has indicated clinical inappropriateness with all of the following:
 - a. Azathioprine
 - b. Gold therapy
 - c. Hydroxychloroquine
 - d. Methotrexate
 - e. Penicillamine
 - f. Sulfasalazine
 - g. Cyclosporine
 - h. Leflunomide**AND**
5. The Member has tried and failed treatment with at least two of the following agents or the provider has indicated clinical inappropriateness with or contraindication to treatment with:
 - a. Enbrel
 - b. Humira
 - c. Taltz
 - d. Xeljanz

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.
- Maximal doses of methotrexate are defined as 15 to 25 mg per week depending on the patient's tolerance.
- For the diagnosis of plaque psoriasis, 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	Starter 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 (vedolizumab) 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, Oencia, Simponi, and Stelara (Crohn’s disease and psoriatic arthritis only) Updated duration of approval to life of plan for Enbrel, Cimzia, Kevzara, Kineret, Oencia, 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. Oencia 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 prerequisite 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. September 15, 2020: Updated the age requirements of Stelara for psoriasis based on expanded indication for use in patients at least 6 years of age.

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.