Title: Immune Modulating Therapies

Policy #: Rx.01.154

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **abatacept (Orencia® SQ), adalimumab (Humira®), anakinra (Kineret®), apremilast (Otezla®), certolizumab (Cimzia®), etanercept (Enbrel®), golimumab (Simponi®), secukinumab (Cosentyx®), tocilizumab (Actemra SQ®), tofacitinib (Xeljanz [XR]®), methotrexate injection (Otrexup®, Rasuvo®, Reditrex™), ustekinumab (Stelara®), ixekizumab (Taltz®), sarilumab (Kevzara®), brodalumab (Siliq™), rilonacept (Arcalyst®), baricitinib (Olumiant®), guselkumab (Tremfya®), risankizumab-rzaa (Skyrizi™), Upadacitinib (Rinvoq™), ozanimod (Zeposia®), tralokinumab-idrm (Adbry™), deucravacitinib (Sotyktu™), abrocitinib (Cibinqo®), and adalimumab-atto (Amjevita™)** as provided under the member's prescription drug benefit.

Description:

Abatacept (Orencia® SQ) is a selective costimulation modulator, inhibits T-cell (T-lymphocyte) activation by binding to CD80 and CD86, thereby blocking interaction with CD28. This interaction provides a costimulatory signal necessary for full activation of T-lymphocytes. Activated T-lymphocytes are implicated in the pathogenesis of RA and are found in the synovium of patients with RA.

Adalimumab (Humira®) is a recombinant human immunoglobulin G1 (IgG1) monoclonal antibody, which binds specifically to TNF-alpha and blocks its interaction with the p55 and p75 cell surface TNF receptors. Adalimumab also lyses surface TNF-expressing cells in vitro in the presence of a complement. Adalimumab does not bind or inactivate lymphotoxin (TNF-beta). Adalimumab also modulates biological responses that are induced or regulated by TNF, including changes in the levels of adhesion molecules responsible for leukocyte migration (ELAM-1, VCAM-1, and ICAM-1 with a 50% inhibitory concentration of 1 to 2 × 10^{-10}M).

Anakinra (Kineret®) is a recombinant, nonglycosylated form of the human interleukin-1 receptor antagonist (IL-1Ra). It blocks the biologic activity of IL-1 alpha and beta by competitively inhibiting IL-1 binding to the IL-1RI, which is expressed in a wide variety of tissues and organs.

Apremilast (Otezla®) inhibits phosphodiesterase 4 (PDE4) specific for cyclic adenosine monophosphate (cAMP) which results in increased intracellular cAMP levels and regulation of numerous inflammatory mediators (e.g., decreased expression of nitric oxide synthase, TNF-alpha, and interleukin [IL]-23, as well as increased IL-10).

Baricitinib (Olumiant®) is a Janus Kinase (JAK) inhibitor. JAKs are intracellular enzymes which transmit signals arising from cytokine or growth factor-receptor interactions on the cellular membrane to influence cellular processes of hematopoiesis and immune cell function. Within the signaling pathway, JAKs phosphorylate and activate Signal Transducers and Activators of Transcription (STATs) which modulate intracellular activity including gene expression. Baricitinib modulates the signaling pathway at the point of JAKs, preventing the phosphorylation and activation of STATs.

Certolizumab (Cimzia®) is a pegylated humanized antibody Fab. fragment of tumor necrosis factor alpha (TNF-alpha) monoclonal antibody. Certolizumab pegol binds to and selectively neutralizes human TNF-alpha activity.

Etanercept (Enbrel®) is a dimeric soluble form of the p75 TNFR that can bind TNF molecules. Etanercept inhibits binding of TNF-alpha and TNF-beta (lymphotoxin alpha) to cell surface TNFRs, rendering TNF biologically inactive. In in vitro studies, large complexes of etanercept with TNF-alpha were not detected, and cells expressing transmembrane TNF that binds etanercept are not lysed in the presence or absence of complement

Golimumab (Simponi®) is a human monoclonal antibody that binds to both the soluble and transmembrane bioactive forms of human TNF-alpha. This interaction prevents the binding of TNF-alpha to its receptors, thereby inhibiting the biological activity of TNF-alpha (a cytokine protein).

Guselkumab (Tremfya®) is a human monoclonal IgG1gamma antibody that binds to interleukin-23 (IL-23) and inhibits the interaction with its receptor blocker. IL-23 is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Guselkumab inhibits the release of proinflammatory cytokines and chemokines

Ixekizumab (Taltz®) is a humanized IgG4 monoclonal antibody that selectively binds with the interleukin 17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor. IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Ixekizumab inhibits the release of proinflammatory cytokines and chemokines.

Ozanimod (Zeposia®) is a sphingosine 1-phosphate (S1P) receptor modulator that binds with high affinity to S1P receptors 1 and 5. Ozanimod blocks the capacity of lymphocytes to egress from lymph nodes, reducing the number of lymphocytes in peripheral blood. Ozanimod has minimal or no activity on S1P2, S1P3, and S1P4. The mechanism by which ozanimod exerts therapeutic effects in multiple sclerosis and ulcerative colitis is unknown but may involve the reduction of lymphocyte migration into the central nervous system and intestine.

Rilonacept (Arcalyst®) is an interleukin-1 blocker which blocks IL-1β signaling by acting as a soluble decoy receptor that binds IL-1β and prevents its interaction with cell surface receptors. Rilonacept also binds IL-1α and IL-1 receptor antagonist (IL-1ra) with reduced affinity.

Risankizumab-rzaa (Skyrizi™) is a humanized immunoglobulin G1 (IgG1) monoclonal antibody that selectively binds to the p19 subunit of human interleukin 23 (IL-21) cytokine and inhibits its interaction with the IL-23 receptor. IL-23 is a naturally occurring cytokine that is involved in inflammatory and immune responses. Risankizumab-rzaa inhibits the release of pro-inflammatory cytokines and chemokines.

Sarilumab (Kevzara®) is a human recombinant IgG1 monoclonal antibody that binds to the IL-6 receptor and has been shown to inhibit IL-6-mediated signaling through these receptors. IL-6 has been shown to be involved in a variety of inflammatory processes.

Secukinumab (Cosentyx®) is a human IgG1 monoclonal antibody that selectively binds to interleukin-17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor. IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Secukinumab inhibits the release of proinflammatory cytokines and chemokines.

Tocilizumab (Actemra® SQ) is an antagontist of the interleukin-6 (IL-6) receptor. Endogenous IL-6 is induced by inflammatory stimuli and mediates a variety of immunological responses. Inhibition of IL-6 receptors by tocilizumab leads to a reduction in cytokine and acute phase reactant production.

Tofacitinib (Xeljanz®[XR]) inhibits Janus kinase (JAK) enzymes, which are intracellular enzymes involved in stimulating hematopoiesis and immune cell function through a signaling pathway. In response to extracellular cytokine or growth factor signaling, JAKs activate signal transducers and activators of transcription (STATs), which regulate gene expression and intracellular activity. Inhibition of JAKs prevents cytokine- or growth factor–mediated gene expression and intracellular activity of immune cells, reduces circulating CD16/56+ natural killer cells, serum IgG, IgM, IgA, and C-reactive protein, and increases B cells.

Ustekinumab (Stelara®) disrupts IL-12 and IL-23 mediated signaling and cytokine cascades.

Upadacitinib (Rinvoq™) is a Janus kinase (JAK) inhibitor. JAKs are intracellular enzymes which transmit signals arising from cytokine or growth factor-receptor interactions on the cellular membrane to influence cellular processes of hematopoiesis and immune cell function. Within the signaling pathway, JAKs phosphorylate and activate Signal Transducers and Activators of Transcription (STATs) which modulate intracellular activity including gene expression. Upadacitinib modulates the signaling pathway at the point of JAKs, preventing the phosphorylation and activation of STATs. JAK enzymes transmit cytokine signaling through their pairing (e.g., JAK1/JAK2, JAK1/JAK3, JAK1/TYK2, JAK2/JAK2, JAK2/TYK2). In a cell-free isolated enzyme assay, upadacitinib had greater inhibitory potency at JAK1 and JAK2 relative to JAK3 and TYK2. In human leukocyte cellular assays, upadacitinib inhibited cytokine-induced STAT phosphorylation mediated by JAK1 and JAK1/JAK3 more potently than JAK2/JAK2 mediated STAT phosphorylation. However, the relevance of inhibition of specific JAK enzymes to therapeutic effectiveness is not currently known

Ozanimod (Zeposia®) is a sphingosine 1-phosphate (S1P) receptor modulator that binds with high affinity to S1P receptors 1 and 5. Ozanimod blocks the capacity of lymphocytes to egress from lymph nodes, reducing the number of lymphocytes in peripheral blood. Ozanimod has minimal or no activity on S1P2, S1P3, and S1P4. The mechanism by which ozanimod exerts therapeutic effects in multiple sclerosis and ulcerative colitis is unknown but may involve the reduction of lymphocyte migration into the central nervous system and intestine.

Tralokinumab-ldrm (Adbry™) is a human IgG4 monoclonal antibody that specifically binds to human interleukin13 (IL-13) and inhibits its interaction with the IL-13 receptor α1 and α2 subunits (IL-13Rα1 and IL13Rα2). IL-13 is a naturally occurring cytokine of the Type 2

immune response. Tralokinumab-ldrm inhibits the bioactivity of IL-13 by blocking IL-13 interaction with IL-13Rα1/IL-4Rα receptor complex. Tralokinumab-ldrm inhibits IL-13-induced responses including the release of proinflammatory cytokines, chemokines and IgE.

Abrocitinib (Cibinqo®) is a Janus kinase (JAK) inhibitor. Abrocitinib reversibly inhibits JAK1 by blocking the adenosine triphosphate (ATP) binding site. In a cell-free isolated enzyme assay, abrocitinib was selective for JAK1 over JAK2 (28-fold), JAK3 (>340-fold), and tyrosine kinase (TYK) 2 (43-fold), as well as the broader kinome. The relevance of inhibition of specific JAK enzymes to therapeutic effectiveness is not currently known. Both the parent compound and the active metabolites inhibit JAK1 activity in vitro with similar levels of selectivity.

Deucravacitinib (Sotyktu™) is an inhibitor of tyrosine kinase 2 (TYK2). TYK2 is a member of the Janus kinase (JAK) family. Deucravacitinib binds to the regulatory domain of TYK2, stabilizing an inhibitory interaction between the regulatory and the catalytic domains of the enzyme. This results in allosteric inhibition of receptor-mediated activation of TYK2 and its downstream activation of Signal Transducers and Activators of Transcription (STATs) as shown in cell-based assays. JAK kinases, including TYK2, function as pairs of homo- or heterodimers in the JAK-STAT pathways. TYK2 pairs with JAK1 to mediate multiple cytokine pathways and also pairs with JAK2 to transmit signals as shown in cell-based assays. The precise mechanism linking inhibition of TYK2 enzyme to therapeutic effectiveness in the treatment of adults with moderate-to-severe plaque psoriasis is not currently known.

Methotrexate injection (Otrexup™, Rasuvo®, Reditrex™) inhibits dihydrofolic acid reductase. Dihydrofolates must be reduced to tetrahydrofolates by this enzyme before they can be utilized as carriers of 1-carbon groups in the synthesis of purine nucleotides and thymidylate. Therefore, methotrexate interferes with DNA synthesis, repair, and cellular replication. Actively proliferating tissues such as malignant cells, bone marrow, fetal cells, buccal and intestinal mucosa, and cells of the urinary bladder are in general more sensitive to this effect of methotrexate. When cellular proliferation in malignant tissues is greater than in most normal tissues, methotrexate may impair malignant growth without irreversible damage to healthy tissues.The mechanism of action in RA is unknown; it may affect immune function. In psoriasis, the rate of production of epithelial cells in the skin is greatly increased over normal skin. This differential in proliferation rates is the basis for the use of methotrexate to control the psoriatic process.

Methotrexate injection/vial (Otrexup™, Rasuvo®, Reditrex™) are eligible for coverage under both pharmacy and medical benefit.

Adalimumab-atto (Amjevita™) products bind specifically to TNF-alpha and block its interaction with the p55 and p75 cell surface TNF receptors. Adalimumab products also lyse surface TNF expressing cells in vitro in the presence of complement. Adalimumab products do not bind or inactivate lymphotoxin (TNF-beta). TNF is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Elevated concentrations of TNF are found in the synovial fluid of patients with RA, JIA, PsA, and AS and play an important role in both the pathologic inflammation and the joint destruction that are hallmarks of these diseases. Increased concentrations of TNF are also found in psoriasis plaques. In Ps, treatment with AMJEVITA may reduce the epidermal thickness and infiltration of inflammatory cells. The relationship between these pharmacodynamic activities and the mechanism(s) by which adalimumab products exert their clinical effects is unknown.

Clinical evidence demonstrated similar safety and efficacy for the biosimilars and originator product throughout the clinical trials conducted, including switch periods. There were no clinically meaningful differences in immunogenicity between biosimilar and originator products before or after product switching. Observational data was also reviewed adding to the body of experience with biosimilars; this data supported no overall efficacy or safety differences with switching between Humira and its biosimilars over time.

Summary Tables

Table 1: Non-biologics

INDICATION/ AGENT	AS	CD	NOMID/CAPS	PP	PJIA	PA	RA	SJIA	UC	Behcet's Syndrome
Otelza® (apremilast)				X		X				X
Methotrexate injection (i.e Otrexup®, Rasuvo®, Reditrex™)		X		X	X		X			

Table 2: Non-Tumor Necrosis Factor (TNF) Biologics

INDICATION/ AGENT	AS	CD	NOMID	PP	PJIA	PA	RA	SJIA	UC	GCA	CAPS/ FCAS/ MWS	nr-axSpA	DIRA	SSc-ILD	Recurrent pericarditis	MS	ERA	AD	AA
Actemra ® (tocilizumab)					X		X	X		X				x					
Stelara® (ustekinumab)		X		X		X			X										
Cosentyx® (secukinumab)	X			X		X						X					X		
Taltz® (ixekizumab)	X			X		X						X							
Kineret ® (anakinra)			X				X						X						
Orencia ® SQ (abatacept)					X	X	X												
Xeljanz ® [XR] (tofacitinib)	X				X	X	X		X										
Kevzara ® (sarilumab)							X												
Siliq™ (brodalumab)				X															
Tremfya® (guselkumab)				X		X													
Olumiant® (baricitinib)							X												X
Arcalyst® (rilonacept)											X		X		x				
Skyrizi™ (risankizumab-rzaa)		X		X		X													
Rinvoq™ (upadacitinib)	X					X	X		X			X						X	
Zeposia® (ozanimod)									X							X			
Adbry™ (tralokinumab-idrm)																		X	
Cibinqo® (abrocitinib)																		X	
Sotyktu™ (deucravacitinib)				X															

Table 3: Anti-TNF Biologics

INDICATION/ AGENT	AS	CD	HS	NOMID/CAPS	PP	PJIA	PA	RA	SJIA	UC	Uveitis	nr-axSpA
Cimzia® (certolizumab)	X	X			X		X	X				X (with objective signs of inflamm-ation)
Enbrel (etanercept)	X				X (starting at age 4)	X (aged 2 years or older)	X	X				
Humira (adalimumab)	X	X	X		X	X	X	X		X	X	
Simponi (golimumab)	X						X	X		X		
Amjevita (Adalimumab-atto)	X	X	X		X	X	X	X		X		

Legend

ACRONYM	**INDICATION**
AS	Ankylosing Spondylitis
CD	Crohn's Disease
NOMID/CAPS	Neonatal-onset Multisystem Inflammatory Disease/ Cryopyrin-Associated Periodic Syndromes
PP	Plaque Psoriasis
PJIA	Polyarticular Juvenile Idiopathic Arthritis
PA	Psoriatic Arthritis
RA	Rheumatoid Arthritis
SJIA	Systemic Juvenile Idiopathic Arthritis
UC	Ulcerative Colitis
HS	Hidradenitis Suppurativa
GCA	Giant Cell Arteritis
CAPS/ FCAS/ MWS	Cryopyrin-Associated Periodic Syndromes Familial cold Auto-Inflammatory Syndrome (FCAS) and/or Muckle-Wells Syndrome (MWS)
DIRA	Deficiency of Interleukin-1 Receptor Antagonist
nr-axSpA	Non-radiographic Axial Spondyloarthritis
SSc-ILD	Systemic sclerosis-associated interstitial lung disease
MS	Multiple sclerosis
ERA	Enthesitis-related arthritis
AD	Atopic dermatitis
AA	Alopecia Areata

Policy:

Rheumatoid Arthritis (RA)

INITIAL CRITERIA Adalimumab (Humira®), adalimumab-atto (Amjevita™), certolizumab (Cimzia®), golimumab (Simponi®), etanercept (Enbrel®) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe rheumatoid arthritis (RA); and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a rheumatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response of inability to tolerate ONE of the following disease-modifying anti-rheumatic drugs (DMARDS) at maximally indicated doses: methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA Tofacitinib (Xeljanz [XR]® tablets/extended-release tablets) or upadacitinib (Rinvoq™) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe rheumatoid arthritis (RA); and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a rheumatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response of inability to tolerate ONE of the following disease-modifying anti-rheumatic drugs (DMARDS) at maximally indicated doses: methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Member has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Cimzia, Humira/Amjevita, Simponi, Enbrel); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA Anakinra (Kineret®), sarilumab (Kevzara®) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe rheumatoid arthritis (RA); and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a rheumatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response of inability to tolerate ONE of the following disease-modifying anti-rheumatic drugs (DMARDS) at maximally indicated doses: methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine; and
5. ONE of the following:
    a. Both of the following:
        i. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate TWO of the following: adalimumab (Humira®)/adalimumab-atto (Amjevita™), certolizumab (Cimzia®), golimumab (Simponi®), etanercept (Enbrel®), tofacitinib (Xeljanz [XR]® tablets/extended-release tablets) or upadacitinib (Rinvoq™); and
        ii. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate BOTH of the following: abatacept (Orencia® SQ) and tocilizumab (Actemra® SQ); or
    b. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product; and
6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA Baricitinib (Olumiant®) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe rheumatoid arthritis (RA); and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a rheumatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response of inability to tolerate ONE of the following disease-modifying anti-rheumatic drugs (DMARDS) at maximally indicated doses: methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine; and
5. ONE of the following:
    a. Both of the following:

i. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate TWO of the following: adalimumab (Humira®)/adalimumab-atto (Amjevita™), certolizumab (Cimzia®), golimumab (Simponi®), etanercept (Enbrel®), tofacitinib (Xeljanz [XR]® tablets/extended-release tablets) or upadacitinib (Rinvoq™); and
ii. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate BOTH of the following: abatacept (Orencia® SQ) and tocilizumab (Actemra® SQ); or

b. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product; and

6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Member has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Cimzia, Humira, Simponi, Enbrel); and
8. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA Abatacept (Orencia® SQ) or tocilizumab (Actemra® SQ) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe rheumatoid arthritis (RA); and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a rheumatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had an inadequate response or inability to tolerate ONE of the following disease-modifying anti-rheumatic drugs (DMARDS) at maximally indicated doses: methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine; and
5. One of the following:
    a. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate TWO of the following: adalimumab (Humira®)/adalimumab-atto (Amjevita™), certolizumab (Cimzia®), golimumab (Simponi®), etanercept (Enbrel®), tofacitinib (Xeljanz [XR]® tablets/extended-release tablets) or upadacitinib (Rinvoq™) ; or
    b. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product; and
6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Methotrexate injection (i.e., Otrexup™, Rasuvo®, Reditrex™) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of severe, active rheumatoid arthritis (RA); and
2. Prescribed by or in consultation with a rheumatologist; and
3. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had an inadequate response or inability to tolerate oral methotrexate; and
4. For Otrexup™ and Reditrex™ only: paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate Rasuvo®; and
5. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA Adalimumab (Humira®), adalimumab-atto (Amjevita™), certolizumab (Cimzia®), golimumab (Simponi®), tofacitinib (Xeljanz [XR]® tablets/extended-release tablets), upadacitinib (Rinvoq™), anakinra (Kineret®), etanercept (Enbrel®), sarilumab (Kevzara®), baricitinib (Olumiant®), abatacept (Orencia® SQ), tocilizumab (Actemra® SQ), or methotrexate injection (i.e., Otrexup™, Rasuvo®, Reditrex™) is re- approved when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy as evidenced by at least one of the following:
    a. Reduction in total active (swollen and tender) joint count from baseline; or
    b. Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline; and
2. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Reauthorization duration: 2 years

DRUG	DOSE
Adalimumab (Humira®)/adalimumab-atto (Amjevita™)	40 mg every other week; may increase to 40 mg every week or 80 mg every other week in patients not receiving concomitant methotrexate
Certolizumab (Cimzia®)	Loading dose: 400mg (2 injections) week 0, week 2 and week 4 Maintenance dose: 200mg every 2 weeks/400mg every 4 weeks
Golimumab (Simponi®)	50mg once a month

Tofacitinib (Xeljanz®)	5 mg twice daily
Tofacitinib (Xeljanz XR®)	11 mg once daily
Upadacitinib (Rinvoq®)	15mg once daily
Anakinra (Kineret®)	100 mg daily
Etanercept (Enbrel®)	50mg once weekly
Sarilumab (Kevzara®)	200 mg every two weeks
Baricitinib (Olumiant®)	2mg once daily
Abatacept (Orencia SQ®)	125 mg once weekly.
Tocilizumab (Actemra SQ®)	If <100kg: 162mg once every other week; increase to 162 mg once every week based on clinical response. If ≥100kg: 162 mg once every week
Methotrexate	Initial, 7.5 mg once weekly; individualize and adjust dose gradually for optimal response; at doses exceeding 20 mg per week the incidence and severity of toxic reactions are increased

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Ankylosing Spondylitis (AS)

INITIAL CRITERIA: Adalimumab (Humira®), adalimumab-atto (Amjevita™), certolizumab (Cimzia®), etanercept (Enbrel®), or golimumab (Simponi®) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of ankylosing spondylitis (AS); and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a rheumatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had an inadequate response or inability to tolerate two NSAIDS at maximally indicated doses; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA Secukinumab (Cosentyx®) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active ankylosing spondylitis (AS); and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a rheumatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate two NSAIDS at maximally indicated doses; and
5. One of the following:
    a. Both of the following:
        i. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had an inadequate response or inability to tolerate TWO of the following: adalimumab (Humira®)/adalimumab-atto (Amjevita™), certolizumab (Cimzia®), golimumab (Simponi®), etanercept (Enbrel®), tofacitinib (Xeljanz [XR]® tablets/extended-release tablets), or upadacitinib (Rinvoq™); and
        ii. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate ixekizumab (Taltz®); or
    b. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product; and
6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA Ixekizumab (Taltz®) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active ankylosing spondylitis (AS); and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a rheumatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had an inadequate response or inability to tolerate two NSAIDS at maximally indicated doses; and
5. One of the following:
    a. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had an inadequate response or inability to tolerate ONE of the following: adalimumab (Humira®)/adalimumab-atto (Amjevita™), etanercept (Enbrel®), certolizumab (Cimzia®) golimumab (Simponi®), tofacitinib (Xeljanz [XR]® tablets/extended-release tablets), or upadacitinib (Rinvoq™); or
    b. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product; and

6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA Tofacitinib (Xeljanz [XR]® tablets/extended-release tablets) or upadacitinib (Rinvoq™) is approved when ALL of the following are met :

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active ankylosing spondylitis (AS); and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a rheumatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had an inadequate response or inability to tolerate two NSAIDS at maximally indicated doses; and
5. Paid claims or submission of medical records (e.g., chart notes) confirming inadequate response or intolerance to one of more TNF inhibitors (e.g., Cimzia, Humira/Amjevita, Simponi, Enbrel); and
6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonist); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA Adalimumab (Humira®), adalimumab-atto (Amjevita™), certolizumab (Cimzia®), golimumab (Simponi®), Etanercept (Enbrel®), secukinumab (Cosentyx®), tofacitinib (Xeljanz [XR]® tablets/extended-release tablets) or ixekizumab (Taltz®), or upadacitinib (Rinvoq™) is re-approved when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy as evidence by improvement from baseline by at least one of the following:
    a. Disease activity (e.g., pain, fatigue, inflammation, stiffness); or
    b. Lab values (erythrocyte sedimentation rate, C-reactive protein level);or
    c. Axial status (e.g., lumbar spine motion, chest expansion); or
    d. Total active (swollen or tender) joint count; and
2. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Reauthorization duration: 2 years

DRUG	DOSE
Adalimumab (Humira®)/Adalimumab-atto (Amjevita™)	40mg every other week
Certolizumab (Cimzia®)	Loading dose: 400mg (2 injections) week 0, week 2 and week 4 Maintenance dose: 200mg every 2 weeks/400mg every 4 weeks
Golimumab (Simponi®)	50 mg once a month
Tofacitinib (Xeljanz®)	5 mg twice daily
Tofacitinib (Xeljanz XR®)	11 mg once daily
Etanercept (Enbrel®)	50mg once weekly
Ixekizumab (Taltz®)	Loading dose: 160 mg (given as two 80mg injections) at week 0, followed by 80 mg every 4 weeks Maintenance dose: 80 mg every 4 weeks
Secukinumab (Cosentyx®)	Loading dose: 150mg at Weeks 0, 1, 2, 3 and 4 Maintenance dose: 150mg every 4 weeks; may consider a dosage of 300 mg every 4 weeks if active disease persists
Upadacitinib (Rinvoq®)	15 mg PO once daily

Polyarticular Juvenile Idiopathic Arthritic (PJIA)

INITIAL CRITERIA: Adalimumab (Humira®), adalimumab-atto (Amjevita™), or etanercept (Enbrel®) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA); and
2. Member is 2 years of age or older; and
3. Prescribed by or in consultation with a rheumatologist; and

4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had an inadequate response or inability to tolerate ONE of the following DMARDs at maximally indicated doses: methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Tocilizumab (Actemra® SQ), abatacept (Orencia® SQ) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA); and
2. Member is 2 years of age or older; and
3. Prescribed by or in consultation with a rheumatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had an inadequate response or inability to tolerate ONE of the following DMARDs at maximally indicated doses: methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine; and
5. One of the following:
    a. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate TWO of the following: adalimumab (Humira®)/adalimumab-atto (Amjevita™), tofacitinib (Xeljanz® tablets and oral solution), etanercept (Enbrel®): or
    b. Paid claims or submission of medical records (e.g., chart notes) confirming an continuation of therapy with the requested product; and
6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA Tofacitinib (Xeljanz® tablets and oral solution) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis (PJIA); and
2. Member is 2 years of age or older; and
3. Prescribed by or in consultation with a rheumatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had an inadequate response or inability to tolerate ONE of the following DMARDs at maximally indicated doses: methotrexate, hydroxychloroquine, leflunomide, azathioprine, sulfasalazine; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Member had an inadequate response or inability to tolerate one or more TNF inhibitors (e.g., Enbrel®, Humira®/Amjevita™); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Methotrexate injection (i.e., Otrexup™, Rasuvo®, Reditrex™) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA); and
2. Prescribed by or in consultation with a rheumatologist; and
3. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate oral methotrexate; and
4. For Otrexup™ and Reditrex™ only: paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate Rasuvo®; and
5. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA Adalimumab (Humira®), adalimumab-atto (Amjevita™), Tocilizumab (Actemra® SQ), abatacept (Orencia® SQ), tofacitinib (Xeljanz® tablets and oral solution), etanercept (Enbrel®), or methotrexate injection (i.e., Otrexup™, Rasuvo®, Reditrex™) is re-approved when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy as evidenced by at least one of the following:
    a. Reduction in the total active (swollen and tender) joint count from baseline; or
    b. Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline; and
2. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Reauthorization duration: 2 years

DRUG	DOSE

Adalimumab (Humira®), adalimumab-atto (Amjevita™)	Pediatric patients 2 years or older: 10 kg to <15 kg: 10 mg every other week 15 kg to <30 kg: 20 mg every other week ≥30 kg: 40mg every other week
Tocilizumab (Actemra SQ®)	Pediatric patients 2 years or older: <30kg: 162 mg once every three weeks. ≥30 kg: 162mg once every two weeks
Abatacept (Orencia SQ®)	Pediatric patients 2 years or older: 10 kg to < 25 kg: 50 mg once weekly 25 kg to <50 kg: 87.5 mg once weekly ≥50 kg: 125 mg once weekly
Tofacitinib (Xeljanz®) tablet or oral solution	10kg to < 20kg: 3.2mg oral solution twice daily 20kg to <40kg: 4mg oral solution twice daily 40kg or more: 5mg oral tablet or solution twice daily
Etanercept (Enbrel®)	Pediatric patients 2 years or older: ≥63 kg: 50 mg once weekly <63 kg: 0.8 mg/kg once weekly
Methotrexate	Initial, 10 mg/m(2) once weekly; Individualize and adjust dose gradually for optimal response; optimal duration of therapy is unknown

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Psoriatic Arthritis

INITIAL CRITERIA: Adalimumab (Humira®), adalimumab-atto (Amjevita™), etanercept (Enbrel®) certolizumab (Cimzia®), apremilast (Otezla®), golimumab (Simponi®), or guselkumab (Tremfya®), or risankizumab (Skyrizi™), is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active psoriatic arthritis; and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a rheumatologist or dermatologist; and
4. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
5. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Ustekinumab (Stelara®) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active psoriatic arthritis; and
2. Member is 6 years of age or older; and
3. Prescribed by or in consultation with a rheumatologist or dermatologist; and
4. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
5. Dosing and frequency does not exceed maximum FDA recommendation per indicated request

INITIAL CRITERIA: Upadacitinib (Rinvoq™) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active psoriatic arthritis; and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a rheumatologist or dermatologist; and
4. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
5. Paid claims or submission of medical records (e.g., chart notes) confirming the member has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Cimzia, Humira/Amjevita, Simponi, Enbrel); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Tofacitinib (Xeljanz®/Xeljanz® XR tablets/extended-release tablets) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active psoriatic arthritis; and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a rheumatologist or dermatologist; and
4. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
5. Paid claims or submission of medical records (e.g., chart notes) confirming the member has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Cimzia, Humira/Amjevita, Simponi, Enbrel); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Abatacept (Orencia® SQ) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active psoriatic arthritis; and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a rheumatologist or dermatologist; and
4. One of the following:
    a. Paid claims or submission of medical records (e.g., chart notes) confirming the member has had an inadequate response or inability to tolerate TWO of the following: adalimumab (Humira®)/adalimumab-atto (Amjevita™), certolizumab (Cimzia®), ustekinumab (Stelara®), golimumab (Simponi®), etanercept (Enbrel®), guselkumab (Tremfya®), risankizumab (Skyrizi™), tofacitinib (Xeljanz®/Xeljanz® XR tablets/extended-release tablets), or upadacitinib (Rinvoq™); or
    b. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Ixekizumab (Taltz®) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active psoriatic arthritis; and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a rheumatologist or dermatologist; and
4. One of the following:
    a. Paid claims or submission of medical records (e.g., chart notes) confirming the member has had an inadequate response or inability to tolerate ONE of the following: adalimumab (Humira®)/adalimumab-atto (Amjevita™), certolizumab (Cimzia®), ustekinumab (Stelara®), golimumab (Simponi®), etanercept (Enbrel®), guselkumab (Tremfya®), risankizumab (Skyrizi™), tofacitinib (Xeljanz®/Xeljanz® XR tablets/extended-release tablets), or upadacitinib (Rinvoq™); or
    b. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Secukinumab (Cosentyx®) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active psoriatic arthritis; and
2. Member is 2 years of age or older; and
3. Prescribed by or in consultation with a rheumatologist or dermatologist; and
4. One of the following:
    a. All of the following:
        i. Paid claims or submission of medical records (e.g., chart notes) confirming the member has had an inadequate response or inability to tolerate TWO of the following: adalimumab (Humira®)/adalimumab-atto (Amjevita™), certolizumab (Cimzia®), golimumab (Simponi®), ustekinumab (Stelara®), etanercept (Enbrel®), guselkumab (Tremfya®), risankizumab (Skyrizi™), tofacitinib (Xeljanz®/Xeljanz® XR tablets/extended-release tablets), or upadacitinib (Rinvoq™); and
        ii. Paid claims or submission of medical records (e.g., chart notes) confirming the member has had an inadequate response or inability to tolerate BOTH of the following: abatacept (Orencia® SQ) and ixekizumab (Taltz®); or
    b. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Methotrexate injection (i.e., Otrexup®, Rasuvo®, Reditrex™) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of psoriatic arthritis (PsA); and
2. Prescribed by or in consultation with a rheumatologist or dermatologist; and
3. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate oral methotrexate; and
4. For Otrexup™ and Reditrex™ only: Paid claims or submission of medical records (e.g., chart notes) confirming a inadequate response or inability to tolerate Rasuvo®; and
5. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA Adalimumab (Humira®), adalimumab-atto (Amjevita™), certolizumab (Cimzia®), ustekinumab (Stelara®), apremilast (Otezla®), golimumab (Simponi®), guselkumab (Tremfya®), abatacept (Orencia® SQ), tofacitinib (Xeljanz®/Xeljanz® XR tablets/extended-release tablets), Ixekizumab (Taltz®), etanercept (Enbrel®), secukinumab (Cosentyx®), methotrexate injection (i.e., Otrexup®, Rasuvo®, Reditrex™), upadacitinib (Rinvoq™), or risankizumab (Skyrizi™) is re-approved when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy as evidenced by at least one of the following:
    a. Reduction in the total active (swollen and tender) joint count from baseline; or
    b. Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline; or
    c. Reduction in the body surface area involvement from baseline; and
2. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Reauthorization duration: 2 years

DRUG	DOSE
Adalimumab (Humira®), adalimumab-atto (Amjevita™)	40mg every other week
Certolizumab (Cimzia®)	Loading dose: 400mg (2 injections) week 0, week 2 and week 4 Maintenance: 200mg every 2 weeks/400mg every 4 weeks
Ustekinumab (Stelara®)	Adults: 45mg at 0 and 4 weeks, and then 45mg every 12 weeks thereafter. PA with PP or patients weighing >100kg: 90mg at 0 and 4 weeks, and then 90mg every 12 weeks
	Pediatric (6 to 17 years old): Weight-based dosing is recommended at the initial dose, 4 weeks later, then every 12 weeks thereafter <60kg: 0.75mg/kg ≥60kg: 45mg >100kg with co-existent moderate-to-severe plaque psoriasis: 90mg
Apremilast (Otezla®)	Loading: 5-day titration - Starter pack Day 1 10mg, Day 2 20mg, Day 3 30mg, Day 4 40mg, Day 5 60mg Maintenance dose: 30 mg twice daily
Golimumab (Simponi®)	50 mg once a month
Guselkumab (Tremfya®)	Loading dose: 100mg at Week 0, Week 4 Maintenance dose: 100mg every 8 weeks
Abatacept (Orencia SQ®)	125 mg once weekly
Tofacitinib (Xeljanz®)	5 mg twice daily
Tofacitinib Extended-Release (Xeljanz XR®)	11 mg once daily
Ixekizumab (Taltz®)	Loading dose: 160 mg (given as two 80mg injections) at week 0, followed by 80 mg (for psoriatic arthritis patients with coexistent moderate-to-severe plaque psoriasis, use the dosing regimen for adult plaque psoriasis Maintenance dose: 80 mg every 4 weeks
Etanercept (Enbrel®)	50 mg once weekly
Secukinumab (Cosentyx®)	Loading dose: 150mg at Weeks 0, 1, 2, 3 and 4 Maintenance dose: 150mg every 4 weeks; may consider a dosage of 300 mg every 4 weeks if active disease persists
Upadacitinib (Rinvoq®)	15mg once daily
Risankizumab (Skyrizi®)	Loading dose: 150mg at Week 0, Week 4 Maintenance dose: 150mg every 12 weeks
Methotrexate	Initial, 7.5 mg once weekly; individualize and adjust dose gradually for optimal response; at doses exceeding 20 mg per week the incidence and severity of toxic reactions are increased

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Plaque Psoriasis

INITIAL CRITERIA: Adalimumab (Humira®), adalimumab-atto (Amjevita™), guselkumab (Tremfya®), certolizumab (Cimzia®), or risankizumab (Skyrizi™) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe chronic plaque psoriasis; and
2. Member is 18 years of age or older; and

3. Prescribed by or in consultation with a dermatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response of inability to tolerate ONE of the following: topical calcipotriene containing products, topical anthralin, topical steroids, topical immune modulators (Elidel®, Protopic®), topical retinoids; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Apremilast (Otezla®) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of plaque psoriasis; and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a dermatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response of inability to tolerate ONE of the following: topical calcipotriene containing products, topical anthralin, topical steroids, topical immune modulators (Elidel®, Protopic®), topical retinoids; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Ustekinumab (Stelara®) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe chronic plaque psoriasis; and
2. Member is 6 years of age or older; and
3. Prescribed by or in consultation with a dermatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response of inability to tolerate ONE of the following: topical calcipotriene containing products, topical anthralin, topical steroids, topical immune modulators (Elidel®, Protopic®), topical retinoids; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA Secukinumab (Cosentyx™) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe chronic plaque psoriasis; and
2. Member is 6 years of age or older; and
3. Prescribed by or in consultation with a dermatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate ONE of the following: topical calcipotriene containing products, topical anthralin, topical steroids, topical immune modulators (Elidel®, Protopic), topical retinoids; and
5. One of the following:
    a. BOTH of the following:
        i. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate THREE of the following: certolizumab (Cimzia®), adalimumab (Humira®)/adalimumab-atto (Amjevita™), ustekinumab (Stelara®) ,etanercept (Enbrel®), guselkumab (Tremfya®) or risankizumab (Skyrizi™); and
        ii. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate ixekizumab (Taltz®); or
    b. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product; and
6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Ixekizumab (Taltz™) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe chronic plaque psoriasis; and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a dermatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate ONE of the following: topical calcipotriene containing products, topical anthralin, topical steroids, topical immune modulators (Elidel®, Protopic), topical retinoids; and
5. One of the following:
    a. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate ONE of the following: adalimumab (Humira®)/adalimumab-atto (Amjevita™), ustekinumab (Stelara®), etanercept (Enbrel®), certolizumab (Cimzia®), risankizumab (Skyrizi™) or guselkumab (Tremfya®); or

b. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product; and
6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA Etanercept (Enbrel®) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe chronic plaque psoriasis; and
2. Member is 4 years of age or older; and
3. Prescribed by or in consultation with a dermatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate ONE of the following: topical calcipotriene containing products, topical anthralin, topical steroids, topical immune modulators (Elidel®, Protopic), topical retinoids; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonist); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Methotrexate injection (i.e., Otrexup™, Rasuvo®, Reditrex™) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of severe psoriasis; and
2. Member is age 18 years or older; and
3. Prescribed by or in consultation with a dermatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response to ALL other standard therapy (e.g., oral methotrexate, all topical therapy modalities, phototherapy, etc.); and
5. For Otrexup™ and Reditrex™ only: Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate Rasuvo®; and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA Deucravacitinib (Sotyktu™) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe chronic plaque psoriasis; and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a dermatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate ONE of the following: topical calcipotriene containing products, topical anthralin, topical steroids, topical immune modulators (Elidel®, Protopic), topical retinoids; and
5. One of the following:
    a. BOTH of the following:
        i. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate THREE of the following: certolizumab (Cimzia®), adalimumab (Humira®)/adalimumab-atto (Amjevita™), ustekinumab (Stelara®), etanercept (Enbrel®), guselkumab (Tremfya®) or risankizumab (Skyrizi™); and
        ii. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate ixekizumab (Taltz®); or
    b. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product; and
6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA Adalimumab (Humira®), adalimumab-atto (Amjevita™), guselkumab (Tremfya®), certolizumab (Cimzia®), risankizumab (Skyrizi™), apremilast (Otezla®), ustekinumab (Stelara®), secukinumab (Cosentyx™), ixekizumab (Taltz™), etanercept (Enbrel®), deucravacitinib (Sotyktu™) or methotrexate injection (i.e., Otrexup™, Rasuvo®, Reditrex™) is re-approved when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy as evidenced by one of the following:
    a. Reduction in body surface area (BSA) involvement from baseline; or
    b. Improvement in symptoms (e.g., pruritus, inflammation) from baseline; and
2. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Reauthorization duration: 2 years

INITIAL CRITERIA Brodalumab (Siliq™) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe chronic plaque psoriasis; and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a dermatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate ONE of the following: topical calcipotriene containing products, topical anthralin, topical steroids, topical immune modulators (Elidel®, Protopic®), topical retinoids; and
5. One of the following:
    a. BOTH of the following:
        i. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate THREE of the following: adalimumab (Humira®)/adalimumab-atto (Amjevita™), ustekinumab (Stelara®), certolizumab (Cimzia®), etanercept (Enbrel®), risankizumab (Skyrizi), or guselkumab (Tremfya®); and
        ii. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate ixekizumab (Taltz®); or
    b. Paid claims or submission of medical records (e.g., chart notes) confirming continuation of therapy with the requested product; and
6. Member has been evaluated for depression and suicidal ideations using the Patient Health Questionnaire (PHQ)-9; and
7. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonist); and
8. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 16 weeks

REAUTHORIZATION CRITERIA Brodalumab (Siliq™) is re-approved when ALL of the following are met:

1. Member has positive response to therapy with brodalumab (Siliq®) as evidenced by one of the following:
    a. Reduction of the body surface area (BSA) involvement from baseline; or
    b. Improvement in symptoms (e.g., pruritus, inflammation) from baseline; and
2. Member has been evaluated for depression and suicidal ideations using the Patient Health Questionnaire (PHQ)-9; and
3. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Reauthorization duration: 1 year

DRUG	DOSE
Adalimumab (Humira®), adalimumab-atto (Amjevita™)	Loading dose: 80mg on day 1, 40mg every other week starting 1 week after the initial dose Maintenance dose: 40mg every other week
Certolizumab (Cimzia®)	Loading dose: 400mg (2 injections) week 0, week 2 and week 4 Maintenance dose: 200mg every 2 weeks/400mg every 4 weeks
Ustekinumab (Stelara®)	Adult: (Weight ≤100kg): Loading dose: 45mg week 0 and week 4 Maintenance dose: 45mg every 12 weeks (Weight > 100kg): Loading dose: 90mg week 0 and week 4 Maintenance dose: 90mg every 12 weeks
	Psoriasis Pediatric Patients (6 to 17 years old): Weight-based dosing is recommended at the initial dose, 4 weeks later, then every 12 weeks thereafter <60kg: 0.75mg/kg 60kg to 100kg: 45mg >100kg: 90mg
Apremilast (Otezla®)	Loading: 5-day titration - Starter pack Day 1 10mg, Day 2 20mg, Day 3 30mg, Day 4 40mg, Day 5 60mg 30 mg twice daily
Guselkumab (Tremfya®)	100 mg at weeks 0, 4, and then every 8 weeks thereafter.
Ixekizumab (Taltz®)	Adult: Loading dose: 160 mg (two 80mg injections) subQ at week 0, followed by 80 mg at weeks 2, 4, 6, 8, 10, and 12 Maintenance dose: 80 mg every 4 weeks
	Pediatric: <25kg: 40mg at week 0, followed by 20mg every 4 weeks 25kg to 50kg: 80mg at week 0, followed by 40mg every 4 weeks >50kg: 160mg (two 80mg injections) at week 0, followed by 80mg every 4 weeks
Etanercept (Enbrel®)	loading dose: 50 mg twice weekly for 3 months

	Maintenance dose: 50mg weekly
Secukinumab (Cosentyx®)	Loading dose: 300mg at Weeks 0, 1, 2, 3 and 4 Maintenance dose: 300mg every 4 weeks; some patients may only need 150 mg
Risankizumab (Skyrizi®)	Loading dose: 150mg at Week 0, Week 4 Maintenance dose: 150mg every 12 weeks
Brodalumab (Siliq®)	Initial: 210 mg at weeks 0, 1, and 2 Maintenance dose: 210 mg once every 2 weeks. (Continuing treatment beyond 16 weeks in patients without an adequate response is not likely to result in greater success).
Deucravacitinib (Sotyktu™)	6 mg orally once daily
Methotrexate	10 to 25 mg once weekly; adjust dose gradually for optimal response, generally not exceeding 30 mg/week

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Crohn's Disease

INITIAL CRITERIA: Adalimumab (Humira®), adalimumab-atto (Amjevita™), certolizumab (Cimzia®), ustekinumab (Stelara®), or risankizumab (Skyrizi®) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe Crohn's disease; and
2. Member is 6 years of age or older (adalimumab/adalimumab-atto) or 18 years of age or older (certolizumab, risankizumab and ustekinumab); and
3. Prescribed by or in consultation with a gastroenterologist; and
4. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
5. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate one drug from any of TWO of the following groups:
    a. Corticosteroids: budesonide (Entocort® EC), prednisone, hydrocortisone, methylprednisolone; or
    b. Aminosalicylates: sulfasalazine, mesalamine (Asacol®, Rowasa®, Canasa®, Pentasa®); or
    c. Immunomodulators: azathioprine, 6-mercaptopurine, cyclosporine, tacrolimus (Prograf®), methotrexate; or
    d. Antibiotics: metronidazole, levofloxacin; and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Methotrexate injection (i.e., Otrexup™, Rasuvo®, Reditrex™) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe Crohn's disease; and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a gastroenterologist; and
4. For Otrexup™ and Reditrex™ only: Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate Rasuvo®; and
5. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA Adalimumab (Humira®), adalimumab-atto (Amjevita™), certolizumab (Cimzia®), ustekinumab (Stelara®), risankizumab (Skyrizi ®), methotrexate injection (i.e., Otrexup™, Rasuvo®, Reditrex™) is re-approved when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following:
    a. Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline; or
    b. Reversal of high fecal output state; and
2. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Reauthorization duration: 2 years

DRUG	**DOSE**
Adalimumab (Humira®), adalimumab-atto (Amjevita™)	Adults: Loading dose: 160mg on day 1, 80mg on day 15, 40mg every other week starting on day 29 Maintenance dose: 40mg every 2 weeks
	Pediatric Patients 6 Years of Age and Older:

	17 kg to <40 kg: 80mg on day 1, 40mg on day 15, 20mg every other week starting on day 29 ≥40 kg: 160mg on day 1, 80mg on day 15, 40mg every other week starting on day 29
Certolizumab (Cimzia®)	Loading dose: 400mg (2 injections) week 0, week 2 and week 4 Maintenance dose: 200mg every 2 weeks/400mg every 4 weeks
Risankizumab (Skyrizi®)	Maintenance dose: 180mg or 360mg administered subcutaneously at week 12, and every 8 weeks thereafter after the IV induction.
Ustekinumab (Stelara®)	Maintenance dose: 90 mg every 8 weeks; begin maintenance dosing 8 weeks after the IV induction dose.
Methotrexate	25mg per week

Ulcerative Colitis (UC)

INITIAL CRITERIA: Ustekinumab (Stelara®), or golimumab (Simponi®) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe ulcerative colitis (UC); and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a gastroenterologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate ONE of the following medications: corticosteroids, azathioprine, 6-mercaptopurine; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Adalimumab (Humira®), adalimumab-atto (Amjevita™) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe ulcerative colitis (UC); and
2. Member is 5 years of age or older; and
3. Prescribed by or in consultation with a gastroenterologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate ONE of the following medications: corticosteroids, azathioprine, 6-mercaptopurine; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Ozanimod (Zeposia®) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe ulcerative colitis (UC); and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a gastroenterologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate ONE of the following medications: corticosteroids, azathioprine, 6-mercaptopurine; and
5. One of the following:
    a. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate TWO of the following adalimumab (Humira®)/adalimumab-atto (Amjevita™), ustekinumab (Stelara®), golimumab (Simponi®), upadacitinib (Rinvoq®) or tofacitinib (Xeljanz®/Xeljanz® XR); or
    b. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product; and
6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 2 years

INITIAL CRITERIA: Tofacitinib (Xeljanz®/Xeljanz® XR tablets/extended-release tablets), or upadacitinib (Rinvoq®) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe ulcerative colitis (UC); and

2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a gastroenterologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate ONE of the following medications: corticosteroids, azathioprine, 6-mercaptopurine; and
5. One of the following:
    a. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate ONE of more TNF inhibitors (Humira/Amjevita, Simponi®); or
    b. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product; and
6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA Adalimumab (Humira®), adalimumab-atto (Amjevita™), ustekinumab (Stelara®), or golimumab (Simponi®), or tofacitinib (Xeljanz® /Xeljanz® XR tablets/extended-release tablets), upadacitinib (Rinvoq®) or ozanimod (Zeposia®) is re-approved when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy as evidenced by at least one of the following:
    a. Improvement in intestinal inflammation (e.g., mucosal healing, improvement in lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline; or
    b. Reversal of high fecal output state; and
2. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Reauthorization duration: 2 years

DRUG	DOSE
Adalimumab (Humira®), Adalimumab-atto (Amjevita™)	Adults: Loading dose: 160mg on day 1, 80mg on day 15, 40mg every other week starting on day 29 Maintenance dose: 40mg every other week
	Pediatric Patients 5 Years of Age and Older: 20 kg to <40 kg: 80mg on day 1, 40mg on day 8, 40mg on day 15, 40mg every other week or 20mg every week starting on day 29 ≥40 kg: 160mg on day 1, 80mg on day 8, 80mg on day 15, 80mg every other week or 40mg every week starting on day 29
Golimumab (Simponi®)	Induction: 200 mg at week 0, then 100 mg at week 2 Maintenance dose: 100 mg every 4 weeks.
Ustekinumab (Stelara®)	Maintenance dose: 90 mg every 8 weeks; begin maintenance dosing 8 weeks after the IV induction dose.
Tofacitinib (Xeljanz®)	Loading dose: 10mg twice daily for 8 weeks; may continue for up to 16 weeks Maintenance dose: 5mg twice daily
Tofacitinib Extended-Release (Xeljanz® XR)	Loading dose: 22mg once daily for 8 weeks; may continue for up to 16 weeks Maintenance dose: 11mg once daily
Ozanimod (Zeposia®)	Initial dose: 0.23 mg PO once daily on days 1 through 4; then 0.46 mg once daily on days 5 through 7 Maintenance dose: 0.92 mg once daily starting on day 8
Updacitinib (Rinvoq®)	Initial dose: 45 mg ER PO once daily for 8 weeks Maintenance dose: 15mg ER PO once daily; 30 mg ER once daily may be considered for patients with refractory, severe, or extensive disease. Discontinue if an adequate response is not achieved with 30 mg.

Cryopyrin-Associated Periodic Syndromes (CAPS)

INITIAL CRITERIA: Anakinra (Kineret®) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of Neonatal-Onset Multisystem Inflammatory Disease (NOMID); and
2. Prescribed by or in consultation with a rheumatologist or other appropriate specialist; and
3. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
4. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA Anakinra (Kineret®) is re-approved when BOTH of the following are met:

1. Documentation of positive clinical response to therapy; and
2. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Reauthorization duration: 2 years

INITIAL CRITERIA: Rilonacept (Arcalyst®) is approved when there ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of Cryopyrin-Associated Periodic Syndromes including Familial cold Auto-Inflammatory Syndrome(FCAS) and/or Muckle-Wells Syndrome (MWS); and
2. Prescribed by or in consultation with an immunologist, allergist, dermatologist, rheumatologist, neurologist, or other medical specialist; and
3. Member is 12 years of age or older; and
4. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
5. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA rilonacept (Arcalyst®) is re-approved when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy as evidenced by one of the following:
    a. Improvement in rash, fever, joint pain, headache, or conjunctivitis; or
    b. Decreased number of disease flare days; or
    c. Normalization of inflammatory markers (C-reactive protein [CRP], erythrocyte sedimentation rate [ESR], serum amyloid A [SAA]); or
    d. Corticosteroid dose reduction; or
    e. Improvement in MD global score or active joint count; and
2. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Reauthorization duration: 2 years

DRUG	**DOSE**
Anakinra (Kineret®)	1 to 2 mg/kg once daily; may increase in 0.5 to 1 mg/kg increments to MAX 8 mg/kg/day; may split into 2 daily doses
Rilonacept (Arcalyst®)	Adults: Loading dose: 320 mg (160 mg at 2 different sites on the same day) maintenance dose: 160 mg SUBQ once weekly
	Pediatric patients 12 years to 17 years: Loading dose: 4.4mg/kg, up to a maximum of 320 mg, delivered as 1 or 2 injections (not to exceed 2 mL/injection) Maintenance dose: 2.2 mg/kg, up to a maximum of 160 mg (2 mL) injection, once weekly

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Hidradenitis Suppurativa

INITIAL CRITERIA: Adalimumab (Humira®) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley stage II or III); and
2. Prescribed by or in consultation with a dermatologist; and
3. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
4. Member is 12 years of age or older; and
5. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA Adalimumab (Humira®) is re-approved when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy; and
2. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Reauthorization duration: 2 years

DRUG	DOSE
Adalimumab (Humira®)	Adults: Loading dose: 160mg on day 1, 80mg on day 15, 40mg every other week starting on day 29 Maintenance dose: 40mg every other week
	Adolescents 12 years of age and older: 30kg to <60kg: 80mg on day 1, 40mg on day 8, 40mg every other week for subsequent doses >60kg: 160mg on day 1, 80mg on day 15, 40mg every week or 80mg every other week starting on day 29 and subsequent doses

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Uveitis

INITIAL CRITERIA: Adalimumab (Humira®), adalimumab-atto (Amjevita™) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of non-infectious intermediate, posterior, or panuveitis; and
2. Prescribed by or in consultation with an ophthalmologist or rheumatologist; and
3. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate ophthalmic and oral corticosteroids; and
4. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
5. Member is 2 years of age or older; and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA Adalimumab (Humira®), adalimumab-atto (Amjevita™) is re-approved when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy; and
2. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Reauthorization duration: 2 years

DRUG	DOSE
Adalimumab (Humira®), adalimumab-atto (Amjevita™)	Adults: Loading dose: 80mg on day 1, 40mg every other week starting 1 week after the initial dose Maintenance dose: 40mg every other week
	Pediatric patients 2 years or older: 10 kg to <15 kg: 10 mg every other week 15 kg to <30 kg: 20 mg every other week ≥30 kg: 40mg every other week

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Giant Cell Arteritis

INITIAL CRITERIA: Tocilizumab (Actemra® SQ) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of Giant Cell Arteritis; and
2. Prescribed by or in consultation with a rheumatologist; and
3. Member is 18 years of age or older; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming that the member had inadequate response or inability to tolerate a glucocorticoid (i.e., prednisone); and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA Tocilizumab (Actemra® SQ) is re-approved when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy; and
2. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Reauthorization duration: 2 years

DRUG	DOSE
Tocilizumab (Actemra® SQ)	162 mg given once every week

Systemic Juvenile Idiopathic Arthritis

INITIAL CRITERIA: Tocilizumab (Actemra® SQ) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active systemic juvenile idiopathic arthritis (SIJA); and
2. Prescribed by or in consultation with a rheumatologist; and
3. Member is 2 years of age or older; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate ONE of the following conventional therapies at maximally indicated doses:
    a. Non-steroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen); or
    b. Systemic glucocorticoid (e.g., prednisone)
    c. DMARDs (e.g., leflunomide, methotrexate); and
5. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA Tocilizumab (Actemra® SQ) is re-approved when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy as evidenced by at least one of the following:
    a. Reduction in the total active (swollen and tender) joint count from baseline; or
    b. Improvement in clinical features or symptoms (e.g., pain, fever, inflammation, rash, lymphadenopathy, serositis) from baseline; and
2. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Reauthorization duration: 2 years

DRUG	DOSE
Tocilizumab (Actemra® SQ)	<30kg: 162mg every two weeks. ≥30kg: 162 every week.

Non-radiographic axial spondyloarthritis (nr-axSpA)

INITIAL CRITERIA: Certolizumab (Cimzia®) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation; and
2. Member has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacrolitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints); and
3. Member is 18 years of age or older; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming inadequate response or inability to tolerate two different NSAIDs (e.g., diclofenac, meloxicam, naproxen) at maximally indicated doses; and
5. Prescribed by or in consultation with a rheumatologist; and
6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA Upadacitinib (Rinvoq™) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation; and
2. Member has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacrolitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints); and
3. Member is 18 years of age or older; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming inadequate response or inability to tolerate two different NSAIDs (e.g., diclofenac, meloxicam, naproxen) at maximally indicated doses; and
5. Prescribed by or in consultation with a rheumatologist; and
6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Member has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Cimzia); and
8. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Ixekizumab (Taltz®) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation; and
2. Member has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacrolitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints); and
3. Member is 18 years of age or older; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming inadequate response or inability to tolerate two different NSAIDs (e.g., diclofenac, meloxicam, naproxen) at maximally indicated doses; and
5. Prescribed by or in consultation with a rheumatologist; and
6. One of the following:
    a. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate ONE of the following: certolizumab (Cimzia®) or upadacitinib (Rinvoq™); or
    b. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product; and
7. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
8. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Secukinumab (Cosentyx®) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation; and
2. Member has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacrolitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints); and
3. Member is 18 years of age or older; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming inadequate response or inability to tolerate two different NSAIDs (e.g., diclofenac, meloxicam, naproxen) at maximally indicated doses; and
5. Prescribed by or in consultation with a rheumatologist; and
6. One of the following:

    a. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate ALL of the following: certolizumab (Cimzia®), upadacitinib (Rinvoq™) and Ixekizumab (Taltz®); or
    b. Paid claims or submission of medical records (e.g., chart notes) confirming a continuation of therapy with the requested product; and
7. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
8. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA Certolizumab (Cimzia®), upadacitinib (Rinvoq™), ixekizumab (Taltz®), or secukinumab (Cosentyx®) is re-approved when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following:
    a. Disease activity (e.g., pain, fatigue, inflammation, stiffness); or
    b. Lab values (erythrocyte sedimentation rate, C-reactive protein level); or
    c. Function; or
    d. Axial status (e.g., lumbar spine motion, chest expansion); or
    e. Total active (swollen and tender) joint count; and
2. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Reauthorization duration: 2 years

DRUG	DOSE
Certolizumab (Cimzia®)	Loading dose: 400mg (2 injections) week 0, week 2 and week 4 Maintenance dose: 200mg every 2 weeks/400mg every 4 weeks
Ixekizumab (Taltz®)	80 mg every 4 weeks
Secukinumab (Cosentyx®)	Loading dose: 150mg at Weeks 0, 1, 2, 3 and 4 Maintenance dose: 150mg every 4 weeks
Upadacitinib (Rinvoq®)	15 mg once daily

Ulcer of the mouth associated with Behcet's syndrome

INITIAL CRITERIA: Apremilast (Otezla®) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of ulcer of the mouth associated with Behcet's syndrome; and
2. Member has active oral ulcers; and
3. Member is 18 years of age or older; and
4. Prescribed by or in consultation with a rheumatologist or dermatologist; and
5. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate systemic corticosteroids, topical corticosteroids or topical sucralfate; and
6. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA Apremilast (Otezla®) is re-approved when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy as evidenced by ONE of the following:
    a. Reduction in pain from oral ulcers from baseline; or
    b. Reduction in number of oral ulcers from baseline; and
2. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Reauthorization duration: 2 years

DRUG	DOSE

Apremilast (Otezla®)	Loading dose: 5-day titration - Starter pack Day 1 10mg, Day 2 20mg, Day 3 30mg, Day 4 40mg, Day 5 60mg Maintenance dose: 30 mg twice daily

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Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

INITIAL CRITERIA: Rilonacept (Arcalyst®) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes) confirming the use for the maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA); and
2. Member is currently in remission (e.g., no fever, skin rash, and bone pain; no radiological evidence of active bone lesions; C-reactive protein [CRP] less than 5 mg/L); and
3. Member weights at least 10kg; and
4. Prescribed by or in consultation with a rheumatologist or pediatric specialist; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonist); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Anakinra (Kineret®) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA); and
2. Prescribed by or in consultation with a rheumatologist or pediatric specialist; and
3. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonist) ; and
4. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA Rilonacept (Arcalyst®) or anakinra (Kineret®) is re-approved when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy; and
2. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Reauthorization duration: 2 years

DRUG	DOSE
Rilonacept (Arcalyst®)	Adults and pediatric patients weighing 10 kg or more: 4.4mg/kg up to a maximum of 320 mg (160 mg at 2 different sites on the same day) once weekly
Anakinra (Kineret®)	1 to 2 mg/kg daily; adjust dose in 0.5 to 1 mg/kg increments as needed to a maximum of 8 mg/kg daily

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Recurrent pericarditis

INITIAL CRITERIA: Rilonacept (Arcalyst®) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming use for the treatment of recurrent pericarditis as evidenced by at least 2 episodes that occur a minimum of 4 to 6 weeks apart and reduction in risk of recurrence; and
2. Member is 12 years of age or older; and
3. Submission of medical records (e.g., chart notes) confirming inadequate response or inability to tolerate at least one of the following:
    a. NSAID (e.g., ibuprofen, naproxen); or
    b. Colchicine; or
    c. Corticosteroids (e.g., prednisone); and
4. Prescribed by or in consultation with a cardiologist; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA Rilonacept (Arcalyst®) is re-approved when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy; and
2. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Reauthorization duration: 2 years

DRUG	DOSE
Rilonacept (Arcalyst®)	Initial dose: 320mg given as 2 separate injections (160 [2mL] per injection) on the same day at 2 different sites. Maintenance dose: 160mg once weekly. (Begin maintenance dose 1 week following loading dose).

Systemic sclerosis-associated interstitial lung disease (SSc-ILD)

INITIAL CRITERIA: Tocilizumab (Actemra®) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) confirmed by a High-Resolution CT scan or biopsy; and
2. Member is 18 years of age or older; and
3. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate one of the following:
    a. Mycophenolate; or
    b. Cyclophosphamide; or
    c. Azathioprine; and
4. Prescribed by or in consultation with a pulmonologist; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA Tocilizumab (Actemra®) is re-approved when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy; and
2. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Reauthorization duration: 2 years

DRUG	DOSE
Tocilizumab (Actemra®)	162mg once every week

Active enthesitis-related arthritis (ERA)

INITIAL CRITERIA: Secukinumab (Cosentyx®) is approved when ALL of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of active enthesitis-related arthritis (ERA); and
2. Member is 4 years of age or older; and
3. Prescribed by or in consultation with a rheumatologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate TWO nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally indicated doses; and
5. No concurrent therapy with any other biologic DMARD (i.e., tumor necrosis factor antagonists); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Secukinumab (Cosentyx®) is re-approved when BOTH of the following are met:

1. There is documentation of positive clinical response to therapy as evidenced by at least one of the following:
    a. Reduction in the total active (swollen and tender) joint count from baseline; or
    b. Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline; and
2. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Reauthorization duration: 2 years

DRUG	DOSE
Secukinumab (Cosentyx®)	Pediatrics 4 years or older: <50kg: 75mg at weeks 0, 1, 2, 3, 4, followed by 75mg every 4 weeks ≥50kg: 150mg at weeks 0, 1, 2, 3, 4 followed by 150mg every 4 weeks

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Atopic dermatitis (AD)

INITIAL CRITERIA: Upadacitinib (Rinvoq™) is approved when ALL of the following are met:

1. Diagnosis of refractory, moderate to severe atopic dermatitis; and
2. Member is 12 years of age or older; and
3. Prescribed by or in consultation with a dermatologist, allergist or immunologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate ONE of the following:
    a. Topical steroids, medium potency or higher; or
    b. Topical tacrolimus; or
    c. Topical pimecrolimus; or
    d. Eucrisa™; and
5. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate ONE systemic drug product for the treatment of atopic dermatitis (example include, but are not limited to Adbry [tralokinumab-Idrm], Dupixent [dupilumab], etc.); and
6. No concurrent therapy with any other biologic agents (e.g., JAK inhibitors); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Abrocitinib (Cibinqo™) is approved when ALL of the following are met:

1. Diagnosis of refractory, moderate to severe atopic dermatitis; and
2. Member is 18 years of age or older; and
3. Prescribed by or in consultation with a dermatologist, allergist or immunologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate ONE of the following:
    a. Topical steroids, medium potency or higher; or
    b. Topical tacrolimus; or
    c. Topical pimecrolimus; or
    d. Eucrisa™; and
5. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate ONE systemic drug product for the treatment of atopic dermatitis (examples include, but are not limited to Adbry [tralokinumab-Idrm], Dupixent [dupilumab], etc.); and
6. No concurrent therapy with any other biologic agents (e.g., JAK inhibitors); and
7. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

INITIAL CRITERIA: Tralokinumab-idrm (Adbry™) is approved when ALL of the following are met:

1. Member is 18 years of age or older; and
2. Diagnosis of moderate-severe atopic dermatitis; and
3. Prescribed by or in consultation with a dermatologist, allergist or immunologist; and
4. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate ONE of the following:
    a. Topical steroids, medium potency or higher; or
    b. Topical tacrolimus; or
    c. Topical pimecrolimus; or
    d. Eucrisa ™; and
5. No concurrent therapy with any other biologic agents; and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Upadacitinib (Rinvoq™), abrocitinib (Cibinqo™), or tralokinumab-idrm (Adbry™) is re-approved when BOTH of the following are met:

1. Documentation of positive clinical response to therapy (e.g., reduction in body surface area involvement, reduction in pruritus severity); and
2. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Reauthorization duration: 2 years

DRUG	DOSE
Upadacitinib (Rinvoq®)	Pediatric Patients 12 Years of Age and Older Weighing at Least 40 kg and Adults Less Than 65 Years of Age: 15 mg PO once daily; may increase to 30 mg once daily if inadequate response Adults 65 Years of Age and Older: 15 mg PO once daily
Tralokinumab-idrm (Adbry®)	600 mg SQ (four 150-mg injections) followed by 300 mg SQ (two 150 mg injections) every other week. After 16 weeks of treatment, for patient with body weight below 100 kg who achieved clear or almost clear skin, may consider 300 mg SQ every 4 weeks
Abrocitinib (Cibinqo®)	100 mg PO once daily. If inadequate response is not achieved after 12 weeks, consider increasing to 200mg PO once daily. Discontinue if inadequate response after dosage increase

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Multiple sclerosis (MS)

INITIAL CRITERIA: Ozanimod (Zeposia®) is approved when BOTH of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions); and
2. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Ozanimod (Zeposia®) is re-approved when both of the following are met:

1. Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression); and
2. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Reauthorization duration: 2 years

DRUG	DOSE
Ozanimod (Zeposia®)	Initial dose: 0.23 mg PO once daily on days 1 through 4; then 0.46 mg once daily on days 5 through 7 Maintenance dose: 0.92 mg once daily starting on day 8

Alopecia Areata (AA)

INITIAL CRITERIA: Baricitinib (Olumiant®) is approved when all of the following are met:

1. Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of alopecia areata; and
2. Member has at least 50% scalp hair loss; and
3. Other causes of hair loss have been rules out (e.g., androgenetic alopecia, trichotillomania, tinea capitis, psoriasis); and
4. Prescribed by or in consultation with a dermatologist; and
5. No concurrent therapy with any other biological agent (e.g., JAK inhibitors); and
6. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Baricitinib (Olumiant ®) is re-approved when BOTH of the following are met:

1. Documentation of positive clinical response to therapy; and
2. Dosing and frequency does not exceed maximum FDA recommendation per indication requested

Reauthorization duration: 2 years

DRUG	DOSE
Baricitinib (Olumiant®)	Initial dose: 2mg PO once daily; may increase to 4mg PO once daily if inadequate response or in patients with nearly complete or complete scalp hair loss; decrease dose to 2mg PO daily after adequate response

Black Box Warning as shown in the drug Prescribing Information:

Abrocitinib (Cibinqo®)

WARNING: SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE), and THROMBOSIS

- Increased risk of serious bacterial, fungal, viral and opportunistic infections leading to hospitalization or death, including tuberculosis (TB). Discontinue treatment with CIBINQO if serious or opportunistic infection occurs. Test for latent TB before and during therapy; treat latent TB prior to use. Monitor all patients for active TB during treatment, even patients with initial negative latent TB test.
- Higher rate of all-cause mortality, including sudden cardiovascular death, with another JAK inhibitor vs. TNF blockers in rheumatoid arthritis (RA) patients. CIBINQO is not approved for use in RA patients.
- Malignancies have occurred with CIBINQO. Higher rate of lymphomas and lung cancers with another JAK inhibitor vs. TNF blockers in RA patients.
- MACE has occurred with CIBINQO. Higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) with another JAK inhibitor vs. TNF blockers in RA patients.
- Thrombosis has occurred with CIBINQO. Increased incidence of pulmonary embolism, venous and arterial thrombosis with another JAK inhibitor vs. TNF blockers.

Adalimumab (Humira®)/Adalimumab-atto (Amjevita™)

SERIOUS INFECTIONS

- Patients treated with HUMIRA are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.
- Discontinue HUMIRA if a patient develops a serious infection or sepsis.
- Reported infections include:
    - Active tuberculosis (TB), including reactivation of latent TB. Patients with TB have frequently presented with disseminated or extrapulmonary disease. Test patients for latent TB before HUMIRA use and during therapy. Initiate treatment for latent TB prior to HUMIRA use.
    - Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.
    - Bacterial, viral and other infections due to opportunistic pathogens, including Legionella and Listeria.
- Carefully consider the risks and benefits of treatment with HUMIRA prior to initiating therapy in patients with chronic or recurrent infection.
- Monitor patients closely for the development of signs and symptoms of infection during and after treatment with HUMIRA, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

MALIGNANCY

- Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers including HUMIRA. Post-marketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers including HUMIRA. These cases have had a very aggressive disease course and have been fatal. The majority of reported TNF blocker cases have occurred in patients with Crohn's disease or ulcerative colitis and the majority were in adolescent and young adult males. Almost all these patients had received treatment with azathioprine or 6-mercaptopurine (6–MP) concomitantly with a TNF blocker at or prior to diagnosis. It is uncertain whether the occurrence of HSTCL is related to use of a TNF blocker or a TNF blocker in combination with these other immunosuppressants.

Baricitinib (Olumiant®)

SERIOUS INFECTIONS

- Patients treated with OLUMIANT are at risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.
- If a serious infection develops, interrupt OLUMIANT until the infection is controlled.
  Reported infections include:

    - Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Patients should be tested for latent tuberculosis before initiating OLUMIANT and during therapy. Treatment for latent infection should be considered prior to OLUMIANT use.
    - Invasive fungal infections, including candidiasis and pneumocystosis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.
    - Bacterial, viral, and other infections due to opportunistic pathogens.
- The risks and benefits of treatment with OLUMIANT should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection.
- Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with OLUMIANT including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

MALIGNANCIES

Lymphoma and other malignancies have been observed in patients treated with OLUMIANT.

THROMBOSIS

Thrombosis, including deep venous thrombosis and pulmonary embolism, has been observed at an increased incidence in patients treated with OLUMIANT compared to placebo. In addition, there were cases of arterial thrombosis. Many of these adverse events were serious and some resulted in death. Patients with symptoms of thrombosis should be promptly evaluated.

Brodalumab (Siliq™)

SUICIDAL IDEATION AND BEHAVIOR

Suicidal ideation and behavior, including completed suicides, have occurred in patients treated with SILIQ. Prior to prescribing SILIQ, weigh the potential risks and benefits in patients with a history of depression and/or suicidal ideation or behavior. Patients with new or worsening suicidal ideation and behavior should be referred to a mental health professional, as appropriate. Advise patients and caregivers to seek medical attention for manifestations of suicidal ideation or behavior, new onset or worsening depression, anxiety, or other mood changes

Because of the observed suicidal behavior in subjects treated with SILIQ, SILIQ is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the SILIQ REMS Program.

Certolizumab (Cimzia®)

SERIOUS INFECTIONS

- Patients treated with CIMZIA are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.
- CIMZIA should be discontinued if a patient develops a serious infection or sepsis.
- Reported infections include:
    - Active tuberculosis, including reactivation of latent tuberculosis. Patients with tuberculosis have frequently presented with disseminated or extrapulmonary disease. Patients should be tested for latent tuberculosis before CIMZIA use and during therapy. Treatment for latent infection should be initiated prior to CIMZIA use.
    - Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Empiric anti-fungal therapy should be considered in patients at risk for invasive fungal infections who develop severe systemic illness.
    - Bacterial, viral and other infections due to opportunistic pathogens, including Legionella and Listeria.
- The risks and benefits of treatment with CIMZIA should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection.
- Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with CIMZIA, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

MALIGNANCY

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which CIMZIA is a member. CIMZIA is not indicated for use in pediatric patients.

Etanercept (Enbrel®)

SERIOUS INFECTIONS

- Patients treated with Enbrel are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.
- Enbrel should be discontinued if a patient develops a serious infection or sepsis.
- Reported infections include:
    - Active tuberculosis, including reactivation of latent tuberculosis. Patients with tuberculosis have frequently presented with disseminated or extrapulmonary disease. Patients should be tested for latent tuberculosis before Enbrel use and during therapy. Treatment for latent infection should be initiated prior to Enbrel use.
    - Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Empiric anti-fungal therapy should be considered in patients at risk for invasive fungal infections who develop severe systemic illness.
    - Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.
- The risks and benefits of treatment with Enbrel should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection.
- Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with Enbrel, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

MALIGNANCIES

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including Enbrel.

Golimumab (Simponi®)

SERIOUS INFECTIONS

- Patients treated with SIMPONI® are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.
- Discontinue SIMPONI if a patient develops a serious infection.
- Reported infections with TNF blockers, of which SIMPONI is a member, include:
    - Active tuberculosis, including reactivation of latent tuberculosis. Patients with tuberculosis have frequently presented with disseminated or extrapulmonary disease. Test patients for latent tuberculosis before SIMPONI use and during therapy. Initiate treatment for latent TB prior to SIMPONI use.
    - Invasive fungal infections including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric antifungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.
    - Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.
- Consider the risks and benefits of treatment with SIMPONI prior to initiating therapy in patients with chronic or recurrent infection.
- Monitor patients closely for the development of signs and symptoms of infection during and after treatment with SIMPONI, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

MALIGNANCY

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which SIMPONI is a member.

Sarilumab (Kevzara®)

- Patients treated with Kevzara® are at increased risk for developing serious infections that may lead to hospitalization or death. Opportunistic infections have also been reported in patients receiving Kevzara®. Most patients who developed infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.
- Avoid use of Kevzara® in patients with an active infection.
- Reported infections include:
    - Active tuberculosis, which may resent with pulmonary or extrapulmonary disease. Patients should be tested for latent tuberculosis before Kevzara® use and during therapy. Treatment for latent infection should be initiated prior to Kevzara® use.
    - Invasive fungal infections, such as candidiasis, and pneumocystis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.
    - Bacterial, viral and other infections due to opportunistic pathogens.
- Closely monitor patients for signs and symptoms of infection during treatment with Kevzara®. If a serious infection develops, interrupt Kevzara® until the infection is controlled.
- Consider the risks and benefits of treatment with Kevzara® prior to initiating therapy in patients with chronic or recurrent infection.

Tocilizumab (Actemra® SQ)

- Patients treated with ACTEMRA are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.
- If a serious infection develops, interrupt ACTEMRA until the infection is controlled.
- Reported infections include:
    - Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Patients should be tested for latent tuberculosis before ACTEMRA use and during therapy. Treatment for latent infection should be initiated prior to ACTEMRA use.
    - Invasive fungal infections, including candidiasis, aspergillosis, and pneumocystis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.
    - Bacterial, viral and other infections due to opportunistic pathogens.
- The risks and benefits of treatment with ACTEMRA should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection.
- Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with ACTEMRA, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

Tofacitinib (Xeljanz [XR]®)

SERIOUS INFECTIONS

- Patients treated with XELJANZ/XELJANZ XR/XELJANZ Oral Solution are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.
- If a serious infection develops, interrupt XELJANZ/XELJANZ XR/XELJANZ Oral Solution until the infection is controlled.
- Reported infections include:
    - Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Patients should be tested for latent tuberculosis before XELJANZ/XELJANZ XR/XELJANZ Oral Solution use and during therapy. Treatment for latent infection should be initiated prior to XELJANZ/XELJANZ XR/XELJANZ Oral Solution use.
    - Invasive fungal infections, including cryptococcosis and pneumocystosis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.
    - Bacterial, viral, including herpes zoster, and other infections due to opportunistic pathogens.
- The risks and benefits of treatment with XELJANZ/XELJANZ XR/XELJANZ Oral Solution should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection.
- Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with XELJANZ/XELJANZ XR/XELJANZ Oral Solution, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

MORTALITY

Rheumatoid arthritis patients 50 years of age and older with at least one cardiovascular (CV) risk factor treated with XELJANZ 10 mg twice a day had a higher rate of all-cause mortality, including sudden CV death, compared to those treated with XELJANZ 5 mg given twice daily or TNF blockers in a large, ongoing, postmarketing safety study.

MALIGNANCIES

Lymphoma and other malignancies have been observed in patients treated with XELJANZ. Epstein Barr Virus-associated post-transplant lymphoproliferative disorder has been observed at an increased rate in renal transplant patients treated with XELJANZ and concomitant immunosuppressive medications.

THROMBOSIS

Thrombosis, including pulmonary embolism, deep venous thrombosis, and arterial thrombosis, has been observed at an increased incidence in rheumatoid arthritis patients who were 50 years of age and older with at least one CV risk factor treated with XELJANZ 10 mg twice daily compared to XELJANZ 5 mg twice daily or TNF blockers in a large, ongoing postmarketing safety study. Many of these events were serious and some resulted in death. Avoid XELJANZ/XELJANZ XR in patients at risk. Discontinue XELJANZ/XELJANZ XR and promptly evaluate patients with symptoms of thrombosis.

For patients with ulcerative colitis, use XELJANZ at the lowest effective dose and for the shortest duration needed to achieve/maintain therapeutic response.

Methotrexate (Otrexup™, Rasuvo®, Reditrex™)

- Serious toxic reactions and death have been reported with the use of methotrexate. Patients should be closely monitored for bone marrow, liver, lung, skin, and kidney toxicities.
- Methotrexate has been reported to cause fetal death and/or congenital anomalies and is contraindicated in pregnancy.
- Unexpectedly severe (sometimes fatal) bone marrow suppression, aplastic anemia, and gastrointestinal toxicity have been reported with concomitant administration of methotrexate (usually in high dosage) along with some nonsteroidal anti-inflammatory drugs (NSAIDs).
- Hepatotoxicity, fibrosis, and cirrhosis may occur after prolonged use.
- Methotrexate may cause interstitial pneumonitis at any time during therapy and has been reported at low doses. Pulmonary symptoms (especially a dry, nonproductive cough) may require interruption of treatment and careful investigation.
- Diarrhea, ulcerative stomatitis, hemorrhagic enteritis, and death from intestinal perforation may occur.
- Severe, occasionally fatal, skin reactions have been reported.
- Potentially fatal opportunistic infections may occur.

Upadacitinib (Rinvoq™)

SERIOUS INFECTIONS

- Patients treated with RINVOQ are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.
- If a serious infection develops, interrupt RINVOQ until the infection is controlled.
- Reported infections include:
    - Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Patients should be tested for latent tuberculosis before RINVOQ use and during therapy. Treatment for latent infection should be considered prior to RINVOQ use.
    - Invasive fungal infections, including cryptococcosis and pneumocystosis.
    - Bacterial, viral, including herpes zoster, and other infections due to opportunistic pathogens.
- The risks and benefits of treatment with RINVOQ should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection.
- Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with RINVOQ, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

MALIGNANCIES

Lymphoma and other malignancies have been observed in patients treated with RINVOQ

THROMBOSIS

Thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis have occurred in patients treated with Janus kinase inhibitors used to treat inflammatory conditions. Many of these adverse events were serious and some resulted in death. Consider the risks and benefits prior to treating patients who may be at increased risk. Patients with symptoms of thrombosis should be promptly evaluated and treated appropriately.

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

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Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Actemra® SQ	tocilizumab
Cimzia®	certolizumab
Cosentyx™	secukinumab
Enbrel®	etanercept
Humira®	adalimumab
Kineret®	anakinra
Simponi®	golimumab
Orencia®	abatacept
Otezla®	apremilast
Xeljanz [XR]®	tofacitinib
Otrexup®, Rasuvo™, Reditrex™	methotrexate
Taltz™	ixekizumab
Kevzara®	sarilumab
Siliq™	brodalumab
Stelara®	ustekinumab
Tremfya®	guselkumab
Olumiant®	baricitinib
Arcalyst®	rilonacept
Skyrizi™	risankizumab-rzaa
Rinovq™	upadacitinib
Zeposia®	ozanimod
Adbry®	Tralokinumab-idrm
Cibinqo®	Abrocitinib
Sotyktu™	Deucravacitinib
Amjevita™	Adalimumab-atto

Cross References:

Off-Label Use Rx.01.33

Policy Version Number: 37.00

P&T Approval Date: March 16, 2023

Policy Effective Date: July 01, 2023

Next Required Review Date: March 17, 2023