Pharmacy Policy Bulletin: J-1049 Chronic Inflammatory Diseases - Commercial National Select Formulary	
Number: J-1049	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☐ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1. or 2.):** **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization (Leqselvi, Litfulo, Olumiant, Otezla, Xeljanz, Xeljanz XR, Rinvoq, Sotyktu, Velsipity, Zeposia) **2.** Miscellaneous Specialty Drugs Injectable = Yes w/ Prior Authorization (Adalimumab, Bimzelx, Cosentyx SC, Enbrel, Entyvio SC, Cimzia, Ilumya, Kevzara, Kineret, Omvoh SC, Orencia SC, Siliq, Simponi SC, Skyrizi SC, Taltz, Tocilizumab SC, Tremfya, Ustekinumab SC, Zymfentra) **Quantity Limits (1., 2., 3., or 4.):** **1.** Rx Mgmt Quantity Limits = Safety/Specialty **2.** Rx Mgmt Quantity Limits = Safety/Specialty + Dose Opt **3.** Rx Mgmt Quantity Limits = Safety/Specialty + Dose Opt + Watchful **4.** Rx Mgmt Performance = MRxC = Yes
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** Applies to Commercial National Select formulary only
Version: J-1049-049	**Original Date:** 12/02/2020
Effective Date: 10/08/2025	**Review Date:** 09/17/2025

Drugs Product(s):	• Abrilada (adalimumab-afzb) • Actemra (tocilizumab) subcutaneous (SC) • Amjevita (adalimumab-atto) • Bimzelx (bimekizumab-bkzx) • Cimzia (certolizumab) • Cosentyx (secukinumab) SC • Cyltezo (adalimumab-adbm) • Enbrel (etanercept) • Entyvio (vedolizumab) SC

	• Hadlima (adalimumab-bwwd) • Hulio (adalimumab-fkjp) • Humira (adalimumab) • Hyrimoz (adalimumab-adaz) • Idacio (adalimumab-aacf) • Ilumya (tildrakizumab) • Imuldosa (ustekinumab-srlf) • Kevzara (sarilumab) • Kineret (anakinra) • Leqselvi (deuroxolitinib) • Litfulo (ritlecitinib) • Olumiant (baricitinib) • Omvoh (mirikizumab-mrkz) SC • Orencia (abatacept) SC • Otezla (apremilast) • Otulfi (ustekinumab-aauz) SC • Pyzchiva (ustekinumab-ttwe) SC • Rinvoq (upadacitinib) ER oral tablet • Rinvoq LQ (upadacitinib) oral solutionSelarsdi (ustekinumab-aekn) SC • Siliq (brodalumab) • Simlandi (adalimumab-ryvk) • Simponi (golimumab) SC • Skyrizi (risankizumab) SC • Sotyktu (deucravacitinib) • Stelara (ustekinumab) SC • Steqeyma (ustekinumab-stba) SC • Taltz (ixekizumab) • Tremfya (guselkumab) SC • Tyenne (tocilizumab-aazg) SC • Velsipity (etrasimod) • Wezlana (ustekinumab-aaub) SC • Xeljanz, Xeljanz XR (tofacitinib) • Yesintek (ustekinumab-kfce) SC • Yuflyma (adalimumab-aaty) • Yusimry (adalimumab-aqvh) • Zeposia (ozanimod) • Zymfentra (infliximab-dyyb) SC

FDA-Approved Indication(s):	• **Actemra SC**
	  ○ Treatment of adult patients with moderately to severely active **rheumatoid arthritis** (RA) who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs)
	  ○ Treatment of adult patients with **giant cell arteritis** (GCA)
	  ○ Slowing the rate of decline in pulmonary function in adult patients with **systemic sclerosis-associated interstitial lung disease** (SSc-ILD)
	  ○ Treatment of **polyarticular juvenile idiopathic arthritis** (PJIA) in patients 2 years of age and older
	  ○ Treatment of patients 2 years of age and older with active **systemic juvenile idiopathic arthritis** (SJIA)
	• **Adalimumab Biosimilars**
	  ○ Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active **rheumatoid arthritis** (RA)

	○ Reducing signs and symptoms of moderately to severely active **polyarticular juvenile idiopathic arthriti**s (PJIA) in pediatric patients 2 years of age and older ○ Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active **psoriatic arthritis** (PsA) ○ Reducing signs and symptoms in adult patients with active **ankylosing spondylitis** (AS) ○ Treatment of moderately to severely active **Crohn's disease** (CD) in adults and pediatric patients 6 years of age and older. ○ Treatment of moderately to severely active **ulcerative colitis** (UC) in adult patients. ○ Treatment of adult patients with moderate to severe chronic **plaque psoriasis** (PsO) who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. ○ Treatment of moderate to severe **hidradenitis suppurativa** (HS) in adult patients. ○ Treatment of non-infectious **intermediate, posterior, and panuveitis** (UV) in adult patients. • **Bimzelx** ○ Treatment of moderate to severe **plaque psoriasis** (PsO) in adults who are candidates for systemic therapy or phototherapy ○ Treatment of adults with active **psoriatic arthritis** (PsA) ○ Treatment of adults with active **non-radiographic axial spondyloarthritis** (nr-axSpA) with objective signs of inflammation ○ Treatment of adults with active **ankylosing spondylitis** (AS) ○ Treatment of adults with moderate to severe **hidradenitis suppurativa** (HS) • **Cimzia** ○ Treatment of adult patients with moderately to severely active **rheumatoid arthritis** (RA) ○ Treatment of adult patients with active **ankylosing spondylitis** (AS) ○ Treatment of adult patients with active **psoriatic arthritis** (PsA) ○ Reducing signs and symptoms and maintaining clinical remission in adult patients with moderately to severely active **Crohn's disease** (CD) who have had an inadequate response to conventional therapy ○ Treatment of adult patients with moderate to severe chronic **plaque psoriasis** (PsO) who are candidates for systemic therapy or phototherapy ○ Treatment of adults with active **non-radiographic axial spondyloarthritis** (nr-axSpA) with objective signs of inflammation ○ Treatment of active **polyarticular juvenile idiopathic arthritis** (PJIA) in patients 2 years of age and older • **Cosentyx SC** ○ Treatment of adult patients with active **ankylosing spondylitis** (AS) ○ Treatment of active **psoriatic arthritis** (PsA) in patients 2 years of age and older ○ Treatment of moderate to severe **plaque psoriasis** (PsO) in patients 6 years and older who are candidates for systemic therapy or phototherapy ○ Treatment of adult patients with active **non-radiographic axial spondyloarthritis** (nr-axSpA) with objective signs of inflammation ○ Treatment of active **enthesitis-related arthritis** (ERA) in patients 4 years of age and older

	○ Treatment of adults with moderate to severe **hidradenitis suppurativa** (HS) • **Enbrel** ○ Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active **rheumatoid arthritis** (RA) ○ Reducing signs and symptoms in adult patients with active **ankylosing spondylitis** (AS) ○ Reducing signs and symptoms of moderately to severely active **polyarticular juvenile idiopathic arthritis** (PJIA) in pediatric patients 2 years of age and older ○ Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active **psoriatic arthritis** (PsA) ○ Treatment of patients 4 years or older with chronic moderate to severe **plaque psoriasis** (PsO) who are candidates for systemic or phototherapy ○ Treatment of active **juvenile psoriatic arthritis** (JPsA) in pediatric patients 2 years of age and older • **Entyvio SC** ○ Treatment of moderately to severely active **ulcerative colitis** (UC) in adults ○ Treatment of moderately to severely active **Crohn's disease** (CD) in adults • **Humira** ○ Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active **rheumatoid arthritis** (RA) ○ Reducing signs and symptoms in adult patients with active **ankylosing spondylitis** (AS) ○ Reducing signs and symptoms of moderately to severely active **polyarticular juvenile idiopathic arthritis** (PJIA) in pediatric patients 2 years of age and older ○ Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active **psoriatic arthritis** (PsA) ○ Treatment of adult patients with moderate to severe chronic **plaque psoriasis** (PsO) who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate ○ Treatment of moderately to severely active **Crohn's disease** (CD) in adults and pediatric patients 6 years of age and older ○ Treatment of moderately to severely active **ulcerative colitis** (UC) in adults and pediatric patients 5 years of age and older ○ Treatment of moderate to severe **hidradenitis suppurativa (HS)** in adults and pediatrics patients 12 years of age and older ○ Treatment of non-infectious **intermediate, posterior and panuveitis (UV)** in adults and pediatric patients 2 years of age and older • **Ilumya** ○ Treatment of adult patients with moderate-to-severe **plaque psoriasis** (PsO) who are candidates for systemic therapy or phototherapy • **Kevzara**

	○ Treatment of adult patients with moderately to severely active **rheumatoid arthritis** (RA) who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs) ○ Treatment of adult patients with **polymyalgia rheumatica** (PMR) who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper ○ Treatment of patients who weigh 63 kg or greater with active **polyarticular juvenile idiopathic arthritis** (pJIA) • **Kineret** ○ Reducing signs and symptoms and slowing the progression of structural damage in moderately to severely active **rheumatoid arthritis** (RA), in patients 18 years of age or older who have failed one or more disease-modifying antirheumatic drugs (DMARDs) ○ Treatment of **neonatal-onset multisystem inflammatory disease** (NOMID) ○ Treatment of **Deficiency of Interleukin-1 Receptor Antagonist** (DIRA) • **Leqselvi** ○ Treatment of adults with severe **alopecia areata (AA)** • **Litfulo** ○ Treatment of severe **alopecia areata** (AA) in adults and adolescents 12 years and older. • **Olumiant** ○ Treatment of adults with moderate to severely active **rheumatoid arthritis** (RA) who have had an inadequate response to one or more tumor necrosis factor (TNF) blockers ○ Treatment of **coronavirus disease 2019 (COVID-19)** in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). ○ Treatment of adult patients with severe **alopecia areata** (AA) • **Omvoh SC** ○ Treatment of moderately to severely active **ulcerative colitis** (UC) in adults ○ Treatment of moderately to severely active **Crohn's disease** (CD) in adults • **Orencia SC** ○ Treatment of adult patients with moderately to severely active **rheumatoid arthritis** (RA) ○ Treatment of moderately to severely active **polyarticular juvenile idiopathic arthritis** (PJIA) in pediatric patients 2 years of age and older ○ Treatment of patients 2 years of age and older with active **psoriatic arthritis** (PsA) • **Otezla** ○ Treatment of adult patients with active **psoriatic arthritis** (PsA) ○ Treatment of adult patients with **plaque psoriasis** (PsO) who are candidates for systemic therapy or phototherapy ○ Pediatric patients 6 years of age and older and weighing at least 20 kg with active **psoriatic arthritis (PsA)** ○ Pediatric patients 6 years of age and older and weighing at least 20 kg with moderate to severe **plaque psoriasis** (PsO) who are candidates for phototherapy or systemic therapy ○ Treatment of adult patients with oral ulcers associated with **Behçet's Disease** • **Rinvoq ER tablet**

	○ Treatment of adult patients with moderately to severely active **rheumatoid arthritis** (RA) who have had an inadequate response or intolerance to one or more TNF blockers ○ Treatment of adults and pediatric patients 2 years of age and older with active **psoriatic arthritis** (PsA) who have had an inadequate response or intolerance to one or more TNF blockers. ○ Treatment of adults and pediatric patients 12 years of age and older with refractory, moderate to severe **atopic dermatitis** (AD) whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable. ○ Treatment of adults with moderately to severely active **ulcerative colitis** (UC) who have had an inadequate response or intolerance to one or more TNF blockers. ○ Treatment of adults with moderately to severely active **Crohn's disease** (CD) who have had an inadequate response or intolerance to one or more TNF blockers. ○ Treatment of adults with active **ankylosing spondylitis** (AS) who have had an inadequate response or intolerance to one or more TNF blockers ○ Treatment of adults with active **non-radiographic axial spondyloarthritis** (nr-axSpA) with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy ○ Treatment of patients 2 years of age and older with active **polyarticular juvenile idiopathic arthritis** (PJIA) who have had an inadequate response or intolerance to one or more TNF blockers. ○ Treatment of adults with **giant cell arteritis** (GCA). • **Rinvoq LQ** ○ Treatment of adults and pediatric patients 2 years of age and older with active **psoriatic arthritis** (PsA) who have had an inadequate response or intolerance to one or more TNF blockers. ○ Treatment of patients 2 years of age and older with active **polyarticular juvenile idiopathic arthritis** (PJIA) who have had an inadequate response or intolerance to one or more TNF blockers • **Siliq** ○ Treatment of adult patients with moderate to severe **plaque psoriasis** (PsO) who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies • **Simponi SC** ○ Treatment of adult patients with moderately to severely active **rheumatoid arthritis** (RA) in combination with methotrexate ○ Treatment of adult patients with active **ankylosing spondylitis** (AS) ○ Treatment of adult patients with active **psoriatic arthritis** (PsA) alone, or in combination with methotrexate ○ Treatment of adult patients with moderately to severely active **ulcerative colitis** (UC) who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine for inducing and maintaining clinical response, improving endoscopic appearance of the mucosa during induction, inducing clinical remission, and achieving and sustaining clinical remission in induction responders • **Skyrizi SC** ○ Treatment of adult patients with moderate-to-severe **plaque psoriasis** (PsO) who are candidates for systemic therapy or phototherapy ○ Treatment of active **psoriatic arthritis** (PsA) in adults ○ Treatment of moderately to severely active **Crohn's disease** (CD) in adults

	○ Treatment of moderately to severely active **ulcerative colitis** (UC) in adults • **Sotyktu** ○ Treatment of adults with moderate-to-severe **plaque psoriasis** (PsO) who are candidates for systemic therapy or phototherapy. • **Taltz** ○ Treatment of adult patients with active **psoriatic arthritis** (PsA) ○ Treatment of patients 6 years of age or older with moderate to severe **plaque psoriasis** (PsO) who are candidates for systemic therapy or phototherapy ○ Treatment of adult patients with active **ankylosing spondylitis** (AS) ○ Treatment of adult patients with active **non-radiographic axial spondyloarthritis** (nr-axSpA) with objective signs of inflammation • **Tremfya** ○ Treatment of adult patients with active **psoriatic arthritis** (PsA) ○ Treatment of adult patients with moderate-to-severe **plaque psoriasis** (PsO) who are candidates for systemic therapy or phototherapy ○ Treatment of moderately to severely active **ulcerative colitis** (UC) in adult patients ○ Treatment of moderately to severely active **Crohn's disease** (CD) in adult patients • **Tyenne SC** ○ Treatment of adult patients with moderately to severely active **rheumatoid arthritis (RA)** who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs). ○ Treatment of adult patients with **giant cell arteritis (GCA).** ○ Treatment of patients 2 years of age and older with active **polyarticular juvenile idiopathic arthritis (PJIA).** ○ Treatment of patients 2 years of age and older with **active systemic juvenile idiopathic arthritis (SJIA).** • **Ustekinumab SC** ○ Treatment of patients 6 years of age or older with active **psoriatic arthritis** (PsA) ○ Treatment of patients 6 years of age or older with moderate to severe **plaque psoriasis** (PsO) who are candidates for systemic therapy or phototherapy ○ Treatment of adult patients with moderately to severely active **Crohn's disease** (CD) ○ Treatment of adult patients with moderately to severely active **ulcerative colitis** (UC) • **Velsipity** ○ Treatment of moderately to severely active **ulcerative colitis** (UC) in adults. • **Xeljanz** ○ Treatment of adult patients with moderately to severely active **rheumatoid arthritis** (RA) who have had an inadequate response or intolerance to one or more TNF blockers. ○ Xeljanz tablet and Xeljanz oral solution only: Treatment of active **polyarticular course juvenile idiopathic arthritis** (pcJIA) in patients 2 years of age and older who have had an inadequate response or intolerance to one or more TNF blockers. ○ Treatment of adult patients with active **psoriatic arthritis** (PsA) who have had an inadequate response or intolerance to one or more TNF blockers.

	○ Treatment of adult patients with moderately to severely active **ulcerative colitis** (UC), who have had an inadequate response or intolerance to one or more TNF blockers. ○ Treatment of adult patients with active **ankylosing spondylitis** (AS) who have had an inadequate response or intolerance to one or more TNF blockers. • **Zeposia** ○ Treatment of relapsing forms of **multiple sclerosis** (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. ○ Treatment of moderately to severely active **ulcerative colitis** (UC) in adults. • **Zymfentra** ○ Maintenance treatment of adults with moderately to severely active **ulcerative colitis** (UC) following treatment with an infliximab product administered intravenously. ○ Maintenance treatment of adults with moderately to severely active **Crohn's disease** (CD) following treatment with an infliximab product administered intravenously.

Background:	• **Kevzara, Tocilizumab** ○ Kevzara and Tocilizumab are recombinant humanized interleukin-6 (**IL-6**) receptor inhibitors that works to inhibit IL-6 mediated actions at soluble and membrane bound IL-6 receptors. Inhibiting the signaling pathway can lead to inhibition of activated T- and B-cells, lymphocytes, monocytes, and fibroblasts. IL-6 is also produced by synovial and endothelial cells which has an effect on the inflammatory process. • **Bimzelx, Cosentyx, Siliq, Taltz** ○ Bimzelx, Cosentyx, Siliq, and Taltz are human IgG1 monoclonal antibodies. Cosentyx and Taltz selectively bind to the interleukin-17A (**IL-17A**) cytokine and inhibits its interaction with the IL-17 receptor. Siliq binds with the **IL-17 receptor**. Bimzelx binds to **IL-17A, IL-17F, and IL-17AF**. IL-17 is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. • **Adalimumab, Enbrel, Infliximab, Cimzia, Simponi** ○ Enbrel, adalimumab, infliximab, Cimzia, and Simponi are tumor necrosis factor (**TNF**) inhibitors, which results in an interference in the production of downstream inflammatory mediators, including interleukin-1, prostaglandins, platelet activating factor, and nitric oxide. TNF, a naturally occurring cytokine, mediates inflammation and modulates cellular immune responses. • **Otezla** ○ Otezla is an oral phosphodiesterase 4 (**PDE-4**) inhibitor specific for cyclic adenosine monophosphate (cAMP). PDE4 regulates immune and inflammatory processes through control of intracellular cAMP levels and downstream protein kinase A pathways. The production of a number of key inflammatory cytokines is affected by PDE4 including interferon (IFN)γ, tumor necrosis factor (TNF)α, interleukin (IL)-12, and IL-23, thus shaping the immune response. PDE4 inhibition results in increased intracellular cAMP levels and an inhibitory effect on multiple cytokines involved in the inflammatory process. • **Ustekinumab** ○ Ustekinumab is a human immunoglobulin G (IgG) monoclonal antibody that binds with high affinity and specificity to the p40 subunit, which is part of both interleukin (IL)-12 and IL-23. **IL-12** and **IL-23** are naturally

occurring cytokines that are involved in inflammatory and immune responses, such as natural killer cell activation and CD4+ T-cell differentiation and activation. Ustekinumab binding to the p40 subunit prevents IL-12 and IL-23 from binding to the IL-12 receptor which is the ligand binding subunit of the receptor complexes. Prevention of IL-12 and IL-23 from binding to their respective complexes disrupts IL-12 and IL-23 transduction.

- **Leqselvi, Litfulo, Olumiant, Xeljanz, Rinvoq**
  - Leqselvi, Litfulo, Olumiant, Xeljanz, and Rinvoq are orally bioavailable, small-molecule inhibitors of the Janus kinase (**JAK**) family. These medications modulate the signaling pathway at the point of JAKs, preventing the phosphorylation and activation of Signal Transducers and Activators of Transcription (STATs), which modulate intracellular activity including gene expression.
- **Kineret**
  - Kineret blocks interleukin 1 (**IL-1**) alpha and beta by competitively inhibiting IL-1 binding to the interleukin-1 type I receptor (IL-1RI), which is expressed in a wide variety of tissues and organs. IL-1 production is induced in response to inflammatory stimuli and mediates various physiologic responses including inflammatory and immunological responses.
- **Orencia**
  - Orencia is a fully human recombinant fusion protein categorized as a co-stimulatory or second-signal blocker of **T cell** activation. Orencia disrupts the activation pathway of T cells causing a disturbance in key mechanisms of inflammation and progressive joint destruction.
- **Ilumya, Omvoh, Tremfya, Skyrizi**
  - Ilumya, Omvoh, Tremfya, and Skyrizi are human monoclonal antibodies that selectively antagonize interleukin 23 (**IL-23**) to inhibit the release of pro-inflammatory cytokines and chemokines.
- **Sotyktu**
  - Sotyktu is an inhibitor of tyrosine kinase 2 **(TYK2)**, a member of the Janus kinase (JAK) family, and results in inhibition of downstream activation of Signal Transducers and Activators of Transcription (STATs). This results in inhibition of interleukin (IL)-12, IL-23 and type 1 interferon (IFN) pathways which are implicated in multiple immune-mediated diseases.
- **Velsipity, Zeposia**
  - Zeposia is a sphingosine 1-phosphate **(S1P)** receptor modulator that binds with high affinity to S1P receptors 1 and 5, and Velsipity is a S1P receptor that binds with high affinity to S1P receptors 1, 4, and 5. They block the capacity of lymphocytes to egress from lymph nodes, reducing the number of lymphocytes in peripheral blood. The exact mechanism by which S1P receptor modulators exert therapeutic effects in MS (Zeposia only) and UC are unknown, but may involve the reduction of lymphocyte migration into the central nervous system (CNS) and intestine.
- **Entyvio**
  - Entyvio is a humanized monoclonal antibody that specifically binds to the α4β7 **integrin** and blocks the interaction of α4β7 integrin with mucosal addressin cell adhesion molecule-1 (MAdCAM-1) and inhibits the migration of memory T-lymphocytes across the endothelium into inflamed gastrointestinal parenchymal tissue. The interaction of the α4β7 integrin with MAdCAM-1 has been implicated as an important contributor

to the chronic inflammation that is a hallmark of inflammatory bowel disease.

- Coding of quantity limitations is at the maintenance threshold.
- Claims for quantities of exceeding the maintenance therapy limitations will reject at point of sale.
- Patient Level Authorization (PLA) will be needed for authorized quantities of pre-filled syringes that exceed maintenance therapy limitations (specifically, induction therapy).
- Prescribing Considerations:
    - The member should be under the supervision of a rheumatologist, gastroenterologist, dermatologist, neurologist, or ophthalmologist.
    - Leqselvi, Litfulo, Xeljanz, Olumiant, and Rinvoq should not be used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants such as azathioprine or cyclosporine.
    - Tocilizumab, Cimzia, Enbrel, adalimumab, Kevzara, Leqselvi, Litfulo, Olumiant, infliximab, Simponi, Simponi Aria, Xeljanz, and Rinvoq have a black box warning for risk of serious infections leading to hospitalization or death. If a serious infection develops, interrupt the CID product until the infection is controlled. Cimzia, Enbrel, adalimumab, Leqselvi, Litfulo, Olumiant, infliximab, Simponi, Simponi Aria, Xeljanz and Rinvoq have a black box warning for lymphoma and other malignancies. Leqselvi, Litfulo, Olumiant, Xeljanz, and Rinvoq have a black box warning for thrombosis (specifically, deep vein thrombosis, pulmonary embolism, arterial tuberculosis), higher rate of all-cause mortality compared to TNF blockers in RA, including sudden cardiovascular death, and higher rate of major adverse cardiovascular events (MACE) defined as cardiovascular death, myocardial infarction, and stroke) compared to TNF blockers in RA. To note, the black box warnings for Leqselvi, Litfulo, Rinvoq, and Olumiant for mortality, malignancy, MACE, and thrombosis were due to the warnings added to Xeljanz and considered to be a JAK inhibitor class warning. Siliq has a black box warning and REMS program for suicidal ideation and behavior. The goal of the Siliq REMS program is to mitigate the observed risk of suicidal ideation and behavior by ensuring that prescribers and patients are educated about the risk of suicidal ideation and behavior. Bimzelx, Cosentyx, Entyvio, Ilumya, Kineret, Omvoh, Orencia, Sotyktu, ustekinumab, Taltz, and Tremfya do not have any black box warnings.
    - While taking a biologic DMARD, the member is currently not using a JAK inhibitor or another biologic DMARD (for example, Enbrel, Kineret, adalimumab, Cimzia, Orencia, tocilizumab, Simponi, or ustekinumab).
    - Zeposia and Velsipity require assessments prior to initiation including a complete blood count (CBC), electrocardiogram (ECG), liver functions tests, and ophthalmic evaluations (if increased risk of macular edema). Zeposia and Velsipity are contraindicated in patients who have, in the last 6 months, experienced myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure. Zeposia and Velsipity are also contraindicated in patients with presence of Mobitz type II second-degree or third-degree atrioventricular block, sick sinus syndrome, sino-atrial block (unless the patient has a functioning pacemaker). Zeposia is contraindicated in severe untreated sleep apnea, or concomitant use of a monoamine oxidase inhibitor.
    - The American Gastroenterology Association (AGA) has recommended against long-term corticosteroid use and starting thiopurine based

	regimens in pregnant patients for inflammatory bowel diseases (Crohn's Disease and Ulcerative Colitis). o When treating Behçet's disease, triamcinolone in Orabase, fluocinonide gel, or clobetasol gel can be utilized as an attempt to control the oral flares as needed without the need for systemic medications that have more side effects and are more expensive. If this is not sufficient, colchicine can be used, recognizing that this once inexpensive medication is now quite costly, and many patients find the associated diarrhea intolerable. Otezla may be a good maintenance therapy option for patients that try and fail either a topical corticosteroid product or colchicine. o Absolute contraindications to phototherapy (for example, PUVA, UVB) include dysplastic naevus syndrome, systemic lupus erythematosus, dermatomyositis, genetic skin cancer syndromes, Bloom syndrome, Cockayne syndrome, patients unwilling or unable to comply with safety procedures, and patients who are medically unfit and unable to stand (for example, severe cardiovascular or respiratory disease). o Absolute contraindications to methotrexate therapy include pregnancy, nursing, alcoholism, alcoholic liver disease or other chronic liver diseases, immunodeficiency syndromes, bone marrow hypoplasia, leukopenia, thrombocytopenia, or significant anemia. History of or current use of greater than moderate alcohol consumption is not a contraindication to methotrexate therapy, but a risk factor for methotrexate-associated hepatotoxicity. o Systemic drugs for atopic dermatitis (AD) include monoclonal antibodies administered subcutaneously (SC), such as Dupixent (dupilumab) and Adbry (tralokinumab). Other oral systemic therapy includes off-label use of cyclosporine, methotrexate (MTX), mycophenolate mofetil (MMF), and azathioprine (AZA). Oral immunomodulatory therapy is typically reserved for a subset of patients when topical regimens and/or phototherapy do not adequately control the disease, or when quality of life is substantially impacted. o The recommended induction dose of Rinvoq ER tablets for UC is 45 mg once daily for 8 weeks; CD is 45 mg once daily for 12 weeks. The recommended maintenance dosage for UC or CD is 15 mg once daily. A maintenance dosage of 30 mg once daily may be considered for patients with refractory, severe, or extensive UC or CD. o Olumiant for treatment of COVID-19 in hospitalized patients should only be administered in an inpatient setting for 14 days or until hospital discharge, and coverage would be bundled with the overall inpatient stay. Use in the outpatient setting for COVID-19 is not FDA-approved at this time. o For alopecia areata, Olumiant 2 mg once daily is recommended. Dosage can be increased to 4 mg once daily if the response to 2 mg is not adequate. For patients with nearly complete or complete scalp hair loss, with or without substantial eyelash or eyebrow hair loss, consider treating with 4 mg once daily. Olumiant 4 mg is not indicated for the treatment of RA. o A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences in safety, purity and effectiveness from the reference product. A biosimilar may have fewer indications than the innovator due to unexpired patent exclusivity that prevents other manufacturers from obtaining approval for all indications. However, per the FDA clinical activity of a biosimilar is expected to be similar in all clinical settings for which the innovator product has been tested and is approved.

	○ Tocilizumab in PMR without GCA is not an FDA-approved indication, however, clinical efficacy is supported by a systematic review with meta-analysis (Farinango et al.; n = 8 studies) and individual studies demonstrating tocilizumab in combination with glucocorticoids can be an effective therapeutic option. SEMAPHORE (randomized, double-blind, parallel-group, placebo-controlled, international, phase 3 trial) demonstrated a significantly greater percentage of tocilizumab patients with a C-reactive protein (CRP) level < 10 with reduced prednisone requirements at week 24. PMR-SPARE (randomized, double-blind, multi-center, international, phase 2/3 clinical trial) demonstrated tocilizumab 162 mg weekly is superior to placebo in achieving glucocorticoid-free remission at 16 and 24 weeks in patients with new-onset PMR, reduced the occurrence of relapses and the cumulative glucocorticoid dose ○ There is no dosage form for Cimzia that allows for patient self-administration for doses below 200 mg. Doses less than 200 mg require administration by a health care professional using the vial kit.

Approval Criteria

Table 1. Summary of Preferred Products Given by Oral or Subcutaneous (SC) Administration by Indication

	RA	AS	PJIA	PsA	PsO	CD	UC	nr-axSpA	HS
Step 1 Preferred	• Enbrel • Adalimumab[6]	• Enbrel • Adalimumab[6] • Taltz	• Enbrel • Adalimumab[6]	• Enbrel • Adalimumab[6] • Otezla • Skyrizi SC^ • Ustekinumab SC[9] • Taltz • Tremfya SC	• Enbrel • Adalimumab[6] • Otezla • Skyrizi SC^ • Sotyktu • Ustekinumab SC[9] • Taltz • Tremfya SC	• Adalimumab[6] • Omvoh SC • Skyrizi SC* • Ustekinumab SC[9] • Tremfya SC • Zymfentra	• Adalimumab[6] • Omvoh SC • Skyrizi SC* • Ustekinumab SC[9] • Tremfya SC • Velsipity • Zymfentra	• Cimzia • Taltz	• Adalimumab[6] • Cosentyx SC
Step 2a Non-Preferred (directed to **ONE** Step 1 agent)	• tocilizumab SC[1,8] • Rinvoq tablets • Xeljanz/ Xeljanz XR tablets	• Rinvoq tablets[3] • Xeljanz/ Xeljanz XR tablets[3]	• tocilizumab SC[1-2,8] • Rinvoq tablets/ Rinvoq LQ • Xeljanz tablets/ oral solution	• Rinvoq tablets/ Rinvoq LQ[3] • Xeljanz/ Xeljanz XR tablets[3]	--	• Cimzia[1] • Rinvoq tablets[1]	• Rinvoq tablets[1] • Simponi SC[1] • Xeljanz/ Xeljanz XR tablets[1]	• Rinvoq tablets[5]	--
Step 2b Non-Preferred (directed to **ONE** step 1 agent)	--	• Bimzelx	--	• Bimzelx	• Bimzelx	--	--	• Bimzelx	• Bimzelx

Step 3a Non-Preferred (directed to **TWO** Step 1 or 2a agents)[7]	• Cimzia • Kevzara • Kineret • Olumiant • Orencia SC • Simponi SC	• Cimzia • Simponi SC • Cosentyx SC[4]	• Cimzia • Kevzara • Orencia SC	• Cimzia • Cosentyx SC[4] • Simponi SC • Orencia SC	• Cimzia • Cosentyx SC[4] • Ilumya • Siliq	• Entyvio SC	• Entyvio SC	• Cosentyx SC[4]	--
Step 3b Non-Preferred (directed to **TWO** Step 1 agents)	--	--	--	--	--	--	• Zeposia	--	--

[1] Directed to adalimumab specifically.
[2] Tocilizumab SC will require a trial of adalimumab first for Polyarticular Juvenile Idiopathic Arthritis (PJIA) indication.
[3] Directed specifically to Enbrel or adalimumab.
[4] No grandfathering.
[5] Directed to Cimzia specifically.
[6] A trial of any preferred adalimumab product counts as one (1) adalimumab preferred product. See Table 2 for preferred adalimumab products.
[7] Documentation required. The prescriber must provide written documentation supporting the trial of Preferred Products. Documentation may include, but is not limited to, chart notes, prescription claims records, and/or prescription receipts.
[8] A trial of preferred tocilizumab product counts as one (1) tocilizumab preferred product. See Table 2 for preferred tocilizumab products.
[9] A trial of preferred ustekinumab product counts as one (1) ustekinumab preferred product. See Table 2 for preferred ustekinumab products.
^ Pen or syringe.
* On-body injector.

Table 2. Summary of Preferred Biosimilars

Drug Name	Formulary Name	Preferred	Non-Preferred
adalimumab	• **Commercial National Select**	• Humira [00074] labeler • Cyltezo • Hyrimoz [61314] labeler • Simlandi • adalimumab-adaz • adalimumab-adbm [00597] labeler	• Abrilada • adalimumab-aacf • adalimumab-aaty • adalimumab-adbm [82009] labeler • adalimumab-fkjp • adalimumab-ryvk • Amjevita • Idacio • Hadlima • Hulio • Humira [83457] labeler • Hyrimoz [83457] labeler • Yuflyma • Yusimry
Tocilizumab SC	• **Commercial National Select**	• Actemra SC	• Tyenne SC
Ustekinumab SC	• **Commercial National Select**	• Stelara SC • Yesintek SC	• Imuldosa • Otulfi • Pyzchiva • Selarsdi • Steqeyma SC • ustekinumab • ustekinumab-aekn • ustekinumab-ttwe • Wezlana SC

- A request for a non-preferred adalimumab product should be directed to preferred adalimumab products. There is no clinical exception criteria for non-preferred adalimumab products.
- A request for a non-preferred tocilizumab SC product should be directed to Actemra SC. There is no clinical exception criteria for non-preferred tocilizumab products.
- A request for a non-preferred ustekinumab SC product should be directed to preferred ustekinumab products. There is no clinical exception criteria for non-preferred ustekinumab products.
- Any additional biosimilars not listed for a formulary are non-preferred until indicated otherwise.

I. adalimumab (See Table 2 for Preferred Products)

A. Initial Authorization

1. Rheumatoid Arthritis (RA) (ICD-10: M05, M06)

When a benefit, coverage of a preferred adalimumab product may be approved when all of the following criteria are met **(a. through d.)**:

a. The member is 18 years of age or older.
b. The member has a diagnosis of moderate to severe RA.
c. The medication is prescribed by or in consultation with a rheumatologist.
d. The member has experienced therapeutic failure or intolerance to at least one (1) non-biologic DMARD (for example, methotrexate, leflunomide, sulfasalazine, cyclosporine), or all non-biologic DMARDs are contraindicated.

2. Ankylosing Spondylitis (AS) (ICD-10: M45, excluding M45.A)

When a benefit, coverage of a preferred adalimumab product may be approved when all of the following criteria are met **(a., b., and c.)**:

a. The member is 18 years of age or older.
b. The member has a diagnosis of AS.
c. The medication is prescribed by or in consultation with a rheumatologist.

3. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (ICD-10: M08.4)

When a benefit, coverage of a preferred adalimumab product may be approved when all of the following criteria are met **(a. through d.)**:

a. The member is 2 years of age or older.
b. The member has a diagnosis of moderate to severe PJIA.
c. The medication is prescribed by or in consultation with a rheumatologist.
d. The member meets one (1) of the following criteria **(i. or ii.)**:
  i. The member has experienced therapeutic failure or intolerance to at least one (1) non-biologic DMARD (for example, methotrexate, leflunomide, sulfasalazine, cyclosporine), or all non-biologic DMARDs are contraindicated.
  ii. The member requires initial biologic therapy due to involvement of high-risk joints (for example, cervical spine, wrist, or hip), high disease activity, and/or those judged by their physician to be at high risk of disabling joint damage.

4. Psoriatic Arthritis (PsA) (ICD-10: L40.5)

a. Spinal or axial PsA

When a benefit, coverage of a preferred adalimumab product may be approved when all of the following criteria are met **(i. through iv.):**

i. The member is 18 years of age or older.
ii. The member has a diagnosis of spinal or axial PsA.
iii. The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
iv. The member has experienced therapeutic failure or intolerance to at least one (1) nonsteroidal anti-inflammatory drug (NSAID), or all NSAIDs are contraindicated.

b. PsA without spinal or axial disease

When a benefit, coverage of a preferred adalimumab product may be approved when all of the following criteria are met **(i. through iv.)**:

- **i.** The member is 18 years of age or older.
- **ii.** The member has a diagnosis of PsA without spinal disease.
- **iii.** The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
- **iv.** The member has experienced therapeutic failure or intolerance to at least one (1) non-biologic DMARD (for example, methotrexate, leflunomide, sulfasalazine, cyclosporine), or all non-biologic DMARDs are contraindicated.

c. Enthesitis and/or dactylitis associated PsA

When a benefit, coverage of a preferred adalimumab product may be approved when all of the following criteria are met **(i. through iv.)**:

- **i.** The member is 18 years of age or older.
- **ii.** The member has a diagnosis of enthesitis and/or dactylitis associated with PsA.
- **iii.** The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
- **iv.** The member has experienced therapeutic failure or intolerance to at least one (1) NSAID or a local glucocorticoid injection, or all NSAIDs and all local glucocorticoid injections are contraindicated.

5. Plaque Psoriasis (PsO) (ICD-10: L40, excluding L40.5)

When a benefit, coverage of a preferred adalimumab product may be approved when all of the following criteria are met **(a. through d.)**:

- **a.** The member is 18 years of age or older.
- **b.** The member has a diagnosis of moderate to severe PsO.
- **c.** The medication is prescribed by or in consultation with a dermatologist or rheumatologist.
- **d.** The member meets one (1) of the following criteria **(i., ii., or iii.)**:
  - **i.** The member has experienced therapeutic failure or intolerance to phototherapy (for example, PUVA, UVB).
  - **ii.** The member has experienced therapeutic failure or intolerance to at least one (1) systemic therapy (for example, methotrexate).
  - **iii.** The member is contraindicated to both phototherapy and systemic therapy.

6. Crohn's Disease (CD) (ICD-10: K50)

When a benefit, coverage of a preferred adalimumab product may be approved when all of the following criteria are met **(a., b., and c.)**:

- **a.** The member is 6 years of age or older.
- **b.** The member has a diagnosis of moderate to severe CD.
- **c.** The medication is prescribed by or in consultation with a gastroenterologist.

7. Ulcerative Colitis (UC) (ICD-10: K51)

When a benefit, coverage of a preferred adalimumab product may be approved when all of the following criteria are met **(a., b., and c.)**:

- **a.** The member is 5 years of age or older.
- **b.** The member has a diagnosis of moderate or severe UC.
- **c.** The medication is prescribed by or in consultation with a gastroenterologist.

8. Hidradenitis Suppurativa (HS) (ICD-10: L73.2)

When a benefit, coverage of a preferred adalimumab product may be approved when all of the following criteria are met **(a., b., and c.)**:

- **a.** The member is 12 years of age or older.
- **b.** The member has a diagnosis of moderate to severe HS.
- **c.** The medication is prescribed by or in consultation with a dermatologist.

9. Uveitis (UV) (ICD-10: H44.1)

When a benefit, coverage of a preferred adalimumab product may be approved when all of the following criteria are met **(a. through d.)**:

a. The member is 2 years of age or older.
b. The member has a diagnosis of non-infectious intermediate, posterior or panuveitis.
c. The medication is prescribed by or in consultation with an ophthalmologist.
d. The member has experienced therapeutic failure or intolerance to at least one (1) immunosuppressant (for example, azathioprine, 6-mercaptopurine), or immunosuppressants are contraindicated.

B. Reauthorization

When a benefit, reauthorization of a preferred adalimumab product may be approved when the following criterion is met **(1.)**:

1. The member has demonstrated disease stability or a beneficial response to therapy.

C. Quantity Limitations

When prior authorization is approved, adalimumab prefilled syringes, pens, or auto-injectors may be authorized in quantities as follows:

Diagnosis	Induction Therapy	Maintenance Therapy
RA, AS, PsA	N/A	Two (2) prefilled pens/syringes (40 mg/0.4 mL or 40 mg/0.8 mL) every four (4) weeks
RA*	N/A	Four (4) prefilled pen/syringes (40 mg/0.4 mL or 40 mg/0.8 mL) every four (4) weeks (Without concurrent methotrexate therapy) -OR- Two (2) prefilled pens/syringes (80 mg/0.8 mL) every four (4) weeks (Without concurrent methotrexate therapy)
PJIA, pediatric UV	N/A	Two (2) prefilled pens/syringes (40 mg/0.4 mL or 40 mg/0.8 mL) every four (4) weeks
chronic PSO	Four (4) prefilled pens/syringes (40 mg/0.4 mL or 40 mg/0.8 mL) within the first four (4) weeks of therapy -OR- One (1) starter package kit	Two (2) prefilled pens/syringes (40 mg/0.4 mL or 40 mg/0.8 mL) every four (4) weeks -OR- Four (4) prefilled pens/syringes (40 mg/0.4 mL or 40 mg/0.8 mL) every four (4) weeks†
adult CD	Six (6) prefilled pens/syringes (40 mg/0.4 mL or 40 mg/0.8 mL) within the first four (4) weeks of therapy -OR-	Two (2) prefilled pens/syringes (40 mg/0.4 mL or 40 mg/0.8 mL) every four (4) weeks -OR- Four (4) prefilled pens/syringes (40 mg/0.4 mL or 40 mg/0.8 mL) every four (4) weeks†

	Three (3) prefilled pens/syringes (80 mg/0.8 mL) within the first four (4) weeks of therapy -OR- One (1) starter package kit	
pediatric CD (37 lbs - 88 lbs)	Three (3) prefilled pens/syringes (40 mg/0.4 mL or 40 mg/0.8 mL) within the first four (4) weeks of therapy -OR- One (1) starter package kit	Two (2) prefilled pens/syringes (20 mg/0.2 mL or 20 mg/0.4 mL) every four (4) weeks -OR- Four (4) prefilled pens/syringes (20 mg/0.2 mL or 20 mg/0.4 mL) every four (4) weeks†
pediatric CD (≥ 88 lbs)	Six (6) prefilled pens/syringes (40 mg/0.4 mL or 40 mg/0.8 mL) within the first four (4) weeks of therapy -OR- Three (3) prefilled pens/syringes (80 mg/0.8 mL) within the first four (4) weeks of therapy -OR- One (1) starter package kit	Two (2) prefilled pens/syringes (40 mg/0.4 mL or 40 mg/0.8 mL) every four (4) weeks -OR- Four (4) prefilled syringes (40 mg/0.4 mL or 40 mg/0.8 mL) every four (4) weeks†
adult UC	Six (6) prefilled pens/syringes (40 mg/0.4 mL or 40 mg/0.8 mL) within the first four (4) weeks of therapy -OR- Three (3) prefilled pens/syringes (80 mg/0.8 mL) within the first four (4) weeks of therapy -OR- One (1) starter package kit	Two (2) prefilled pens/syringes (40 mg/0.4 mL or 40 mg/0.8 mL) every four (4) weeks -OR- Four (4) prefilled pens/syringes (40 mg/0.4 mL or 40 mg/0.8 mL) every four (4) weeks†
pediatric UC (44 lbs - 88 lbs)	Four (4) prefilled pens/syringes (40 mg/0.4 mL or 40 mg/0.8 mL) within the first four (4) weeks of therapy	Two (2) prefilled pens/syringes(40 mg/0.4 mL or 40 mg/0.8 mL) every four (4) weeks -OR- Four (4) prefilled pens/syringes (20 mg/0.4 mL or 20 mg/0.2 mL) every four (4) weeks††
pediatric UC (≥ 88 lbs)**	Eight (8) prefilled pens/syringes (40 mg/0.4 mL or 40 mg/0.8 mL)	Four (4) prefilled pens/syringes(40 mg/0.4 mL or 40 mg/0.8 mL) every four (4) weeks

	within the first four (4) weeks of therapy -OR- Four (4) prefilled pens/syringes (80 mg/0.8 mL) within the first four (4) weeks of therapy -OR- One (1) starter package kit	-OR- Two (2) prefilled pens/syringes (80 mg/0.8 mL) every four (4) weeks
HS in adults and adolescents (12 years and older) ≥ 60 kg*	Seven (7) prefilled pens/syringes (40 mg/0.4 mL or 40 mg/0.8 mL) within the first four (4) weeks of therapy -OR- Four (4) prefilled pens/syringes (80 mg/0.8 mL) within the first four (4) weeks of therapy -OR- One (1) starter package kit	Four (4) prefilled pens/syringes (40 mg/0.4 mL or 40 mg/0.8 mL) every four (4) weeks -OR- Two (2) prefilled pens/syringes (80 mg/0.8 mL) every four (4) weeks
HS in adolescents (12 years and older) 30 kg to < 60 kg*	Five (5) prefilled pens/syringes (40 mg/0.4 mL or 40 mg/0.8 mL) within the first four (4) weeks of therapy -OR- One (1) starter package kit	Two (2) prefilled pens/syringes (40 mg/0.4 mL or 40 mg/0.8 mL) every four (4) weeks
adult UV	Four (4) prefilled pens/syringes (40 mg/0.4 mL or 40 mg/0.8 mL) within the first four (4) weeks of therapy -OR- One (1) starter package kit	Two (2) prefilled pens/syringes (40 mg/0.4 mL or 40 mg/0.8 mL) every four (4) weeks

N/A=not applicable

- *Patients diagnosed with rheumatoid arthritis (without concurrent methotrexate therapy) or hidradenitis suppurativa may receive weekly dosing of adalimumab prefilled syringes. Patient Level Authorization (PLA) input – Retail: 4 syringes; Mail: 12 syringes
- ** Continuation of pediatric UC dosing in patients who turn 18 years of age may be approved when documentation of stability or beneficial response to therapy.
- Coding of quantity level limitations is at the maintenance therapy threshold <u>except for RA, HS, and pediatric UC weekly dosing administration</u>.
- †Four (4) prefilled syringes every four (4) weeks may be approved when there is clinical documentation that treatment with two (2) prefilled syringes every four (4) weeks was ineffective.
- †† Only adalimumab 20 mg prefilled syringe may be approved for every week dosing.

- Adalimumab starter packs have a quantity limit of 1 kit per 274 days but can be billed as a quantity/dispensing size of 2, 3, 4, or 6 pens or syringes depending on indication.

II. Bimzelx (bimekizumab-bkzx)

A. Initial Authorization

1. Plaque Psoriasis (PsO) (ICD-10: L40, excluding L40.5)

When a benefit, coverage of Bimzelx may be approved when all of the following criteria are met **(a. through e.)**:

a. The member is 18 years of age or older.

b. The member has a diagnosis of moderate to severe PsO.

c. The medication is prescribed by or in consultation with a dermatologist or rheumatologist.

d. The member meets one (1) of the following criteria **(i., ii., or iii.)**:

i. The member has experienced therapeutic failure or intolerance to phototherapy (for example, PUVA, UVB).

ii. The member has experienced therapeutic failure or intolerance to at least one (1) systemic therapy (for example, methotrexate).

iii. The member is contraindicated to both phototherapy and systemic therapy.

e. The member has experienced therapeutic failure or intolerance to at least **one (1)** step 1 preferred agent for the treatment of PsO (see **Table 1**).

2. Psoriatic Arthritis (PsA) (ICD-10: L40.5)

a. Spinal or axial PsA

When a benefit, coverage of Bimzelx may be approved when all of the following criteria are met **(i. through v.)**:

i. The member is 18 years of age or older.

ii. The member has a diagnosis of spinal or axial PsA.

iii. The medication is prescribed by or in consultation with a rheumatologist or dermatologist.

iv. The member has experienced therapeutic failure or intolerance to at least one (1) nonsteroidal anti-inflammatory drug (NSAID), or all NSAIDs are contraindicated.

v. The member has experienced therapeutic failure or intolerance to at least **one (1)** step 1 preferred agent for the treatment of PsA (see **Table 1**).

b. PsA without spinal or axial disease

When a benefit coverage of Bimzelx may be approved when all of the following criteria are met **(i. through v.)**:

i. The member is 18 years of age or older.

ii. The member has a diagnosis of PsA without spinal disease.

iii. The medication is prescribed by or in consultation with a rheumatologist or dermatologist.

iv. The member has experienced therapeutic failure or intolerance to at least one (1) non-biological DMARD (for example, methotrexate, leflunomide, sulfasalazine, cyclosporine) or all non-biological DMARDs are contraindicated.

v. The member has experienced therapeutic failure or intolerance to at least **one (1)** step 1 preferred agent for the treatment of PsA (see **Table 1**).

c. Enthesitis and/or dactylitis associated PsA

When a benefit, coverage of Bimzelx may be approved when all of the following criteria are met **(i. through v.**):

i. The member is 18 years of age or older.

ii. The member has a diagnosis of enthesitis and/or dactylitis associated with PsA.

iii. The medication is prescribed by or in consultation with a rheumatologist or dermatologist.

iv. The member has experienced therapeutic failure or intolerance to at least one (1) NSAID or a local glucocorticoid injection, or all NSAIDs and all local glucocorticoid injections are contraindicated
v. The member has experienced therapeutic failure or intolerance to at least **one (1)** step 1 preferred agent for the treatment of PsA (see **Table 1**).

3. **Non-radiographic Axial Spondyloarthritis (nr-axSpA) (ICD-10: M45.A)**
When a benefit, coverage of Bimzelx may be approved when all of the following criteria are met **(a. through d.)**:
a. The member is 18 years of age or older.
b. The member has a diagnosis of nr-axSpA.
c. The medication is prescribed by or in consultation with a rheumatologist.
d. The member has experienced therapeutic failure or intolerance to at least **one (1)** step 1 preferred agent for the treatment of nr-axSpA (see **Table 1**).

4. **Ankylosing spondylitis (AS) (ICD-10: M45, excluding M45.A)**
When a benefit, coverage of Bimzelx may be approved when all of the following criteria are met (a. through d.):
a. The member is 18 years of age or older.
b. The member has a diagnosis of AS.
c. The medication is prescribed by or in consultation with a rheumatologist.
d. The member has experienced therapeutic failure or intolerance to at least **one (1)** step 1 preferred agent for the treatment of AS (see **Table 1).**

5. **Hidradenitis Suppurativa (HS) (ICD-10: L73.2)**
When a benefit, coverage of Bimzelx may be approved when all the following criteria are met **(a. through d.)**:
a. The member is 18 years of age or older.
b. The member has a diagnosis of moderate to severe HS.
c. The medication is prescribed by or in consultation with a dermatologist.
d. The member has experienced therapeutic failure or intolerance to at least **one (1)** step 1 preferred agent for the treatment of HS (see **Table 1**).

B. Reauthorization
When a benefit, reauthorization of Bimzelx may be approved when the following criterion is met **(1.)**:
1. The member has demonstrated disease stability or a beneficial response to therapy.

Dosing
In addition to the initial authorization and reauthorization criteria outlined above for a diagnosis of PsO or PsA with coexistent PsO, documentation that member weight and prescribed Bimzelx dose is consistent with dosing below:

- **PsO or PsA with Coexistent PsO**
  a. < 120 kg (264 lbs): 320 mg initially and every 4 weeks for the first 16 weeks, followed by 320 mg every 8 weeks.
  b. ≥ 120 kg (264 lbs) **(a. or b.)**:
    a. 320 mg initially and every 4 weeks for the first 16 weeks, followed by 320 mg every 8 weeks.
    b. 320 mg initially and every 4 weeks for the first 16 weeks, followed by 320 mg every 4 weeks.

C. Quantity Limitations
When prior authorization is approved, Bimzelx may be authorized in quantities as follows:

Diagnosis	Induction Therapy	Maintenance Therapy
PsO (< 120 kg)[1]	Five (5) autoinjectors/prefilled syringes (320 mg/2 mL) within the first sixteen (16) weeks of therapy	One (1) autoinjector/prefilled syringe (320 mg/2 mL) every eight (8) weeks
PsO (≥ 120 kg)[1]	Five (5) autoinjectors/prefilled syringes (320 mg/2 mL) within the first sixteen (16) weeks of therapy	One (1) autoinjector/prefilled syringe (320 mg/2 mL) every four (4) weeks -OR- One (1) autoinjector/prefilled syringe (320 mg/2 mL) every eight (8) weeks
PsA[1]	N/A	One (1) autoinjector/prefilled syringe (160 mg/mL) every four (4) weeks
Nr-axSpA	N/A	One (1) autoinjector/prefilled syringe (160 mg/mL) every four (4) weeks
AS	N/A	One (1) autoinjector/prefilled syringe (160 mg/mL) every four (4) weeks
HS[2]	Eight (8) autoinjectors/prefilled syringes (320 mg/2 mL) within the first sixteen (16) weeks of therapy	One (1) autoinjector/prefilled syringe (320 mg/2 mL) every four (4) weeks

[1] See dosing criteria – coding of quantity level limitations is at the maintenance therapy threshold; however, patients weighing ≥ 120 kg may consider a dose of 320 mg every 4 weeks after Week 16.
[2] Patients diagnosed with hidradenitis suppurativa may receive 320 mg every 4 weeks dosing of Bimzelx. Patient Level Authorization (PLA) input – Retail: 1 syringe per 21 days; Mail: 3 syringes per 63 days.

III. Cimzia (certolizumab)

A. Initial Authorization

1. Rheumatoid Arthritis (RA) (ICD-10: M05, M06)
When a benefit, coverage of Cimzia may be approved when all of the following criteria are met **(a. through e.)**:

- **a.** The member is 18 years of age or older.
- **b.** The member has a diagnosis of moderate to severe RA.
- **c.** The medication is prescribed by or in consultation with a rheumatologist.
- **d.** The member has experienced therapeutic failure or intolerance to at least one (1) non-biologic DMARD (for example, methotrexate, leflunomide, sulfasalazine, cyclosporine), or all non-biologic DMARDs are contraindicated.
- **e.** The member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for the treatment of RA (see **Table 1**).

2. Ankylosing Spondylitis (AS) (ICD-10: M45, excluding M45.A)
When a benefit, coverage of Cimzia may be approved when all of the following criteria are met **(a. through d.)**:

- **a.** The member is 18 years of age or older.

b. The member has a diagnosis of AS.
c. The medication is prescribed by or in consultation with a rheumatologist.
d. The member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for the treatment of AS (see **Table 1**).

3. Psoriatic Arthritis (PsA) (ICD-10: L40.5)

a. Spinal or axial PsA

When a benefit, coverage of Cimzia may be approved when all of the following criteria are met **(i. through v.)**:

i. The member is 18 years of age or older.
ii. The member has a diagnosis of spinal or axial PsA.
iii. The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
iv. The member has experienced therapeutic failure or intolerance to at least one (1) nonsteroidal anti-inflammatory drug (NSAID), or all NSAIDs are contraindicated.
v. The member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for the treatment of PsA (see **Table 1**).

b. PsA without spinal or axial disease

When a benefit, coverage of Cimzia may be approved when all of the following criteria are met **(i. through v.)**:

i. The member is 18 years of age or older.
ii. The member has a diagnosis of PsA without spinal disease.
iii. The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
iv. The member has experienced therapeutic failure or intolerance to at least one (1) non-biologic DMARD (for example, methotrexate, leflunomide, sulfasalazine, cyclosporine), or all non-biologic DMARDs are contraindicated.
v. The member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for the treatment of PsA (see **Table 1**).

c. Enthesitis and/or dactylitis associated PsA

When a benefit, coverage of Cimzia may be approved when all of the following criteria are met **(i. through v.)**:

i. The member is 18 years of age or older.
ii. The member has a diagnosis of enthesitis and/or dactylitis associated with PsA.
iii. The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
iv. The member has experienced therapeutic failure or intolerance to at least one (1) NSAID or a local glucocorticoid injection, or all NSAIDs and all local glucocorticoid injections are contraindicated.
v. The member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for the treatment of PsA (see **Table 1**).

4. Crohn's Disease (CD) (ICD-10: K50)

When a benefit, coverage of Cimzia may be approved when all of the following criteria are met **(a. through d.)**:

a. The member is 18 years of age or older.
b. The member has a diagnosis of moderate to severe CD.
c. The medication is prescribed by or in consultation with a gastroenterologist.
d. The member has experienced therapeutic failure or intolerance to a preferred **adalimumab product** for the treatment of CD (see **Table 1**).

5. Plaque Psoriasis (PsO) (ICD-10: L40, excluding L40.5)

When a benefit, coverage of Cimzia may be approved when all of the following criteria are met **(a. through e.)**:

a. The member is 18 years of age or older.
b. The member has a diagnosis of moderate to severe PsO.

c. The medication is prescribed by or in consultation with a dermatologist or rheumatologist.
d. The member meets one (1) of the following criteria **(i., ii., or iii.)**:
  i. The member has experienced therapeutic failure or intolerance to phototherapy (for example, PUVA, UVB).
  ii. The member has experienced therapeutic failure or intolerance to at least one (1) systemic therapy (for example, methotrexate).
  iii. The member is contraindicated to both phototherapy and systemic therapy.
e. The member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for the treatment of PsO (see **Table 1**).

6. Non-radiographic Axial Spondyloarthritis (nr-axSpA) (ICD-10: M45.A)
When a benefit, coverage of Cimzia may be approved when all of the following criteria are met **(a., b., and c.)**:
a. The member is 18 years of age or older.
b. The member has a diagnosis of nr-axSpA.
c. The medication is prescribed by or in consultation with a rheumatologist.

7. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (ICD-10: M08.4)
When a benefit, coverage of Cimzia may be approved when all of the following criteria are met **(a. through e.)**:
a. The member is 2 years of age or older.
b. The member has a diagnosis of active PJIA.
c. The medication is prescribed by or in consultation with a rheumatologist.
d. The member meets one (1) of the following criteria **(i. or ii.)**:
  i. The member has experienced therapeutic failure or intolerance to at least one (1) non-biologic DMARD (for example, methotrexate, leflunomide, sulfasalazine, cyclosporine), or all non-biologic DMARDs are contraindicated.
  ii. The member requires initial biologic therapy due to involvement of high-risk joints (for example, cervical spine, wrist, or hip), high disease activity, and/or those judged by their physician to be at high risk of disabling joint damage.
e. The member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for the treatment of PJIA (see **Table 1**).

B. Reauthorization
When a benefit, reauthorization of Cimzia may be approved when the following criterion is met **(1.)**:
1. The member has demonstrated disease stability or a beneficial response to therapy.

C. Quantity Limitations
When prior authorization is approved, Cimzia may be authorized in quantities as follows:

Diagnosis	Induction Therapy	Maintenance Therapy
RA, AS, PsA, CD, nr-axSpA	Ten (10) syringes in first twelve (12) weeks of therapy -OR- One (1) starter package kit	Two (2) syringes every four (4) weeks
PsO	Six (6) syringes in first four (4) weeks of therapy	Two (2) syringes or four (4) syringes every four (4) weeks
PJIA 10 to < 20 kg	N/A	N/A

PJIA 20 to < 40 kg	Three (3) syringes in the first four (4) weeks of therapy	N/A
PJIA ≥ 40 kg	Six (6) syringes in the first four (4) weeks of therapy -OR- One (1) starter package kit	Two (2) syringes every four (4) weeks

- To note, starter package kits are coded for quantity level limitations of one (1) kit per 365 days.
- Coding of quantity level limitations is at the maintenance therapy threshold except for PsO.
- Doses for PJIA less than 200 mg require administration by a health care professional using the vial kit.

IV. Cosentyx (secukinumab) SC

A. Initial Authorization

1. Ankylosing Spondylitis (AS) (ICD-10: M45, excluding M45.A)

When a benefit, coverage of Cosentyx SC may be approved when all of the following criteria are met **(a. through d.)**:

a. The member is 18 years of age or older.
b. The member has a diagnosis of AS.
c. The medication is prescribed by or in consultation with a rheumatologist.
d. The member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for the treatment of AS (see **Table 1**). Note: A trial of Cimzia, an infliximab product (for example, Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts

2. Psoriatic Arthritis (PsA) (ICD-10: L40.5)

a. Spinal or axial PsA

When a benefit, coverage of Cosentyx SC may be approved when all of the following criteria are met **(i. through v.)**:

i. The member is 2 years of age or older.
ii. The member has a diagnosis of spinal or axial PsA.
iii. The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
iv. The member has experienced therapeutic failure or intolerance to at least one (1) nonsteroidal anti-inflammatory drug (NSAID), or all NSAIDs are contraindicated.
v. The member meets one (1) of the following criteria **(A) or B))**:
A) If the member is 18 years of age or older, the member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for PsA (see **Table 1**). Note: A trial of Cimzia, an infliximab product (for example, Remicade, biosimilars), or Simponi (subcutaneous or Aria) also counts toward a trial of a TNFi.
B) If the member is less than 18 years of age, the member has experienced therapeutic failure or intolerance to **one (1)** of the following preferred agents **(1) or 2))**. Note: A trial of another TNFi counts towards a trial of Enbrel.
1) Enbrel
2) preferred ustekinumab SC product

b. PsA without spinal or axial disease

When a benefit, coverage of Cosentyx SC may be approved when all of the following criteria are met **(i. through v.)**:

i. The member is 2 years of age or older.
ii. The member has a diagnosis of PsA without spinal disease.

iii. The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
iv. The member has experienced therapeutic failure or intolerance to at least one (1) non-biologic DMARD (for example, methotrexate, leflunomide, sulfasalazine, cyclosporine), or all non-biologic DMARDs are contraindicated.
v. The member meets one (1) of the following criteria **(A) or B))**:
A) If the member is 18 years of age or older, the member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for PsA (see **Table 1**). Note: A trial of Cimzia, an infliximab product (for example, Remicade, biosimilars), or Simponi (subcutaneous or Aria) also counts toward a trial of a TNFi.
B) If the member is less than 18 years of age, the member has experienced therapeutic failure or intolerance to **one (1)** of the following preferred agents **(1) or 2))**. Note: A trial of another TNFi counts towards a trial of Enbrel.
1) Enbrel
2) preferred ustekinumab SC product

c. Enthesitis and/or dactylitis associated PsA
When a benefit, coverage of Cosentyx SC may be approved when all of the following criteria are met **(i. through v.)**:
i. The member is 2 years of age or older.
ii. The member has a diagnosis of enthesitis and/or dactylitis associated with PsA.
iii. The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
iv. The member has experienced therapeutic failure or intolerance to at least one (1) NSAID or a local glucocorticoid injection, or all NSAIDs and all local glucocorticoid injections are contraindicated.
v. The member meets one (1) of the following criteria **(A) or B))**:
A) If the member is 18 years of age or older, the member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for PsA (see **Table 1**). Note: A trial of Cimzia, an infliximab product (for example, Remicade, biosimilars), or Simponi (subcutaneous or Aria) also counts toward a trial of a TNFi.
B) If the member is less than 18 years of age, the member has experienced therapeutic failure or intolerance to **one (1)** of the following preferred agents **(1) or 2))**. Note: A trial of another TNFi counts towards a trial of Enbrel.
1) Enbrel
2) preferred ustekinumab SC product

3. Plaque Psoriasis (PsO), including Scalp Psoriasis (ICD-10: L40, excluding L40.5)
When a benefit, coverage of Cosentyx SC may be approved when all of the following criteria are met **(a. through e.)**:
a. The member is 6 years of age or older.
b. The member has a diagnosis of moderate to severe PsO.
c. The medication is prescribed by or in consultation with a dermatologist or rheumatologist.
d. The member meets one (1) of the following criteria **(i., ii., or iii.)**:
i. The member has experienced therapeutic failure or intolerance to phototherapy (for example, PUVA, UVB).
ii. The member has experienced therapeutic failure or intolerance to at least one (1) systemic therapy (for example, methotrexate).
iii. The member is contraindicated to both phototherapy and systemic therapy.
e. The member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for PsO (see **Table 1**).

4. Non-radiographic Axial Spondyloarthritis (nr-axSpA) (ICD-10: M45.A)

When a benefit, coverage of Cosentyx SC may be approved when all of the following criteria are met **(a. through d.)**:

a. The member is 18 years of age or older.
b. The member has a diagnosis of nr-axSpA.
c. The medication is prescribed by or in consultation with a rheumatologist.
d. The member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for nr-axSpA (see **Table 1**). Note: A trial of Enbrel, adalimumab, an infliximab Product (for example, Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts

5. Enthesitis-Related Arthritis (ERA) (ICD-10: M08.80)

When a benefit, coverage of Cosentyx SC may be approved when all of the following criteria are met **(a., b, and c.)**:

a. The member is 4 years of age or older.
b. The member has a diagnosis of active ERA.
c. The medication is prescribed by or in consultation with a rheumatologist.

6. Hidradenitis Suppurativa (HS) (ICD-10: L73.2)

When a benefit, coverage of Cosentyx SC may be approved when all of the following criteria are met **(a., b., and c.)**:

a. The member is 18 years of age or older.
b. The member has a diagnosis of moderate to severe HS.
c. The medication is prescribed by or in consultation with a dermatologist.

B. Reauthorization

When a benefit, reauthorization of Cosentyx SC may be approved when the following criteria are met **(1. and 2.)**:

1. The member has demonstrated disease stability or a beneficial response to therapy.
2. The member meets one (1) of the following criteria **(a. through e.)**:
a. If the request is for AS, the member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for the treatment of AS (see **Table 1**). Note: A trial of Cimzia, an infliximab product (for example, Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts
b. If the request is for PsA and the member is less than 18 years of age, the member has experienced therapeutic failure or intolerance to **one (1)** of the following preferred agents: Enbrel or preferred ustekinumab SC product. Note: A trial of another TNFi counts towards a trial of Enbrel.
c. If the request is for PsA and the member is 18 years of age or older, the member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for PsA (see Table 1). Note: A trial of Cimzia, an infliximab product (for example, Remicade, biosimilars), or Simponi (subcutaneous or Aria) also counts toward a trial of a TNFi.
d. If the request is for PsO, the member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for PsO (see Table 1).
e. If the request is for nr-axSpA, the member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for nr-axSpA (see Table 1). Note: A trial of Enbrel, adalimumab, an infliximab Product (for example, Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts

C. Quantity Limitations

When prior authorization is approved, Cosentyx SC may be authorized in quantities as follows:

Diagnosis	Induction Therapy	Maintenance Therapy

AS	One (1) or Five (5) (150 mg/mL) pens/prefilled syringes within the first four (4) weeks of therapy	One (1) (150 mg/mL or 300 mg/2mL) or Two (2) (150 mg/mL) pens/prefilled syringes every four (4) weeks
Adult PsA[4]	One (1) or Five (5) (150 mg/mL) pens/prefilled syringes within the first four (4) weeks of therapy	One (1) (150 mg/mL or 300 mg/2mL) or Two (2) (150 mg/mL) pens/prefilled syringes every four (4) weeks
ERA and Pediatric PsA (≥ 50 kg)[1,2]	Five (5) (150 mg/mL) pens/prefilled syringes within the first four (4) weeks of therapy	One (1) (150 mg/mL) pen/prefilled syringe every four (4) weeks
ERA and Pediatric PsA (≥ 15 kg to < 50 kg)[1]	Five (5) (75 mg/mL) prefilled syringes within the first four (4) weeks of therapy	One (1) (75mg/mL) prefilled syringe every four (4) weeks
Adult PsO with or without PsA, scalp PsO[1,3]	Five (5) (300 mg/2mL) or Ten (10) (150 mg/mL) pens/prefilled syringes within the first four (4) weeks of therapy	One (1) (150 mg/mL or 300 mg/2mL) or Two (2) (150 mg/mL) pens/prefilled syringes every four (4) weeks
Pediatric PsO (≥ 50 kg)[1,2]	Five (5) (150 mg/mL) pens/prefilled syringes within the first four (4) weeks of therapy	One (1) (150 mg/mL) pen/prefilled syringe every four (4) weeks
Pediatric PsO (< 50 kg)[1]	Five (5) (75 mg/mL) prefilled syringes within the first four (4) weeks of therapy	One (1) (75mg/mL) prefilled syringe every four (4) weeks
nr-axSpA	One (1) or Five (5) (150 mg/mL) pens/prefilled syringes within the first four (4) weeks of therapy	One (1) (150 mg/mL) pen/prefilled syringe every four (4) weeks
HS[5,6]	Five (5) (300 mg/2mL) or Ten (10) (150 mg/mL) pens/prefilled syringes within the first four (4) weeks of therapy	One (1) (300 mg/mL) pen/prefilled syringe or Two (150 mg/mL) pens/prefilled syringes every four (4) weeks

[1] Pediatric patients with PsO or PsA may require 3 pens/prefilled syringes within a four (4) week time frame if switching from pediatric dosing (75 mg/mL) to adult dosing (300 mg/2 mL).

[2] Pediatric patients with PsO, PsA, or ERA (≥ 50 kg) are subject to dose optimization of one (1) pen/prefilled syringe (150 mg/mL) every four (4) weeks.

[3] Adult patients < 50 kg with PsO are subject to adult dosing recommendations and quantity limits.

[4] For adult PsA patients with coexistent moderate to severe PsO, use the dosing for adult PsO.

[5] Two (2) (300 mg/mL) pens/prefilled syringes or Four (150 mg/mL) pens/prefilled syringes every four (4) weeks may be approved when there is clinical documentation that treatment with 300 mg every 4 weeks was ineffective.

[6] Cosentyx UnoReady Pen (300 mg/2mL) is subject to a quantity limit of 1 pen per 21 days (retail) or 3 pens per 63 days (mail). All Cosentyx products, except COSENTYX SNRDY 300MG DOSE-2PEN, are subject to cumulative limit of 2 pens/syringes per 21 days (retail) or 6 pens/syringes per 63 days (mail). If Cosentyx UnoReady Pen is approved, both quantity limit rules will require overrides for appropriate induction therapy.

- COSENTYX SNRDY 300MG DOSE-2PEN is subject to a QL of retail: 2 pens/21 days and mail: 6 pens/42 days.

V. Enbrel (etanercept)

A. Initial Authorization

1. Rheumatoid Arthritis (RA) (ICD-10: M05, M06)

When a benefit, coverage of Enbrel may be approved when all of the following criteria are met **(a. through d.)**:

- **a.** The member is 18 years of age or older.
- **b.** The member has a diagnosis of moderate to severe RA.
- **c.** The medication is prescribed by or in consultation with a rheumatologist.
- **d.** The member has experienced therapeutic failure or intolerance to at least one (1) non-biologic DMARD (for example, methotrexate, leflunomide, sulfasalazine, cyclosporine), or all non-biologic DMARDs are contraindicated.

2. Ankylosing Spondylitis (AS) (ICD-10: M45, excluding M45.A)

When a benefit, coverage of Enbrel may be approved when all of the following criteria are met **(a., b., and c.)**:

- **a.** The member is 18 years of age or older.
- **b.** The member has a diagnosis of AS.
- **c.** The medication is prescribed by or in consultation with a rheumatologist.

3. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (ICD-10: M08.4)

When a benefit, coverage of Enbrel may be approved when all of the following criteria are met **(a. through d.)**:

- **a.** The member is 2 years of age or older.
- **b.** The member has a diagnosis of moderate to severe PJIA.
- **c.** The medication is prescribed by or in consultation with a rheumatologist.
- **d.** The member meets one (1) of the following criteria **(i. or ii.)**:
  - **i.** The member has experienced therapeutic failure or intolerance to at least one (1) non-biologic DMARD (for example, methotrexate, leflunomide, sulfasalazine, cyclosporine), or all non-biologic DMARDs are contraindicated.
  - **ii.** The member requires initial biologic therapy due to involvement of high-risk joints (for example, cervical spine, wrist, or hip), high disease activity, and/or those judged by their physician to be at high risk of disabling joint damage.

4. Psoriatic Arthritis (PsA) (ICD-10: L40.5)

a. Spinal or axial PsA

When a benefit, coverage of Enbrel may be approved when all of the following criteria are met **(i. through iv.)**:

- **i.** The member is 2 years of age or older.
- **ii.** The member has a diagnosis of spinal or axial PsA.
- **iii.** The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
- **iv.** The member has experienced therapeutic failure or intolerance to at least one (1) nonsteroidal anti-inflammatory drug (NSAID), or all NSAIDs are contraindicated.

b. PsA without spinal or axial disease

When a benefit, coverage of Enbrel may be approved when all of the following criteria are met **(i. through iv.)**:

- **i.** The member is 2 years of age or older.
- **ii.** The member has a diagnosis of PsA without spinal disease.
- **iii.** The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
- **iv.** The member has experienced therapeutic failure or intolerance to at least one (1) non-biologic DMARD (for example, methotrexate, leflunomide, sulfasalazine, cyclosporine), or all non-biologic DMARDs are contraindicated.

c. Enthesitis and/or dactylitis associated PsA
When a benefit, coverage of Enbrel may be approved when all of the following criteria are met **(i. through iv.)**:
- **i.** The member is 2 years of age or older.
- **ii.** The member has a diagnosis of enthesitis and/or dactylitis associated with PsA.
- **iii.** The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
- **iv.** The member has experienced therapeutic failure or intolerance to at least one (1) NSAID or a local glucocorticoid injection, or all NSAIDs and all local glucocorticoid injections are contraindicated.

5. Plaque Psoriasis (PsO) (ICD-10: L40, excluding L40.5)
When a benefit, coverage of Enbrel may be approved when all of the following criteria are met **(a. through d.)**:
- **a.** The member is 4 years of age or older.
- **b.** The member has a diagnosis of moderate to severe PsO.
- **c.** The medication is prescribed by or in consultation with a dermatologist or rheumatologist.
- **d.** The member meets one (1) of the following criteria **(i., ii, or iii.)**:
  - **i.** The member has experienced therapeutic failure or intolerance to phototherapy (for example, PUVA, UVB).
  - **ii.** The member has experienced therapeutic failure or intolerance to at least one (1) systemic therapy (for example, methotrexate).
  - **iii.** The member is contraindicated to both phototherapy and systemic therapy.

B. Reauthorization
When a benefit, reauthorization of Enbrel may be approved when the following criterion is met **(1.)**:
1. The member has demonstrated disease stability or a beneficial response to therapy.

C. Quantity Limitations
When prior authorization is approved, Enbrel may be authorized in quantities as follows:

Diagnosis	Induction Therapy	Maintenance Therapy
AS, PJIA, pediatric PsO, PsA, RA	N/A	Four (4) 50 mg prefilled syringes/ autoinjectors every four (4) weeks -OR- Eight (8) 25 mg prefilled syringes every four (4) weeks
PsO, adults	Twenty-four (24) 50 mg syringes/ autoinjectors within the first twelve (12) weeks of therapy -OR- Forty-eight (48) 25 mg syringes/ autoinjectors within the first twelve (12) weeks of therapy	Four (4) 50 mg prefilled syringes/ autoinjectors every four (4) weeks -OR- Eight (8) 25 mg prefilled syringes/ autoinjectors every four (4) weeks

N/A=not applicable

VI. Entyvio (vedolizumab) SC

A. Initial Authorization

1. Ulcerative Colitis (ICD-10: K51)
When a benefit, coverage of Entyvio SC may be approved when all of the following criteria are met **(a. through d.)**
- **a.** The member is 18 years of age or older.

b. The member has a diagnosis of ulcerative colitis classified as moderately to severely active.
c. The medication is prescribed by or in consultation with a gastroenterologist.
d. The member meets one (1) of the following **(i. or ii.):**
i. The member has already received at least two doses of Entyvio IV at least 6 weeks before initiating therapy with Entyvio SC, or is currently undergoing induction therapy with Entyvio IV.
ii. The member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for the treatment of UC **(see Table 1).** Note: A trial of an infliximab product (for example, Remicade, biosimilars; Zymfentra), Omvoh intravenous, Tremfya intravenous or preferred ustekinumab IV product also counts.

2. Crohn's Disease (ICD-10: K50)
When a benefit, coverage of Entyvio SC may be approved when all of the following criteria are met **(a. through d.)**
a. The member is 18 years of age or older.
b. The member has a diagnosis of Crohn's disease classified as moderately to severely active.
c. The medication is prescribed by or in consultation with a gastroenterologist.
d. The member meets one (1) of the following **(i. or ii.):**
i. The member has already received at least two doses of Entyvio IV at least 6 weeks before initiating therapy with Entyvio SC, or is currently undergoing induction therapy with Entyvio IV.
ii. The member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for the treatment of CD **(see Table 1).**

B. Reauthorization
When a benefit, reauthorization of Entyvio SC may be approved when the following criterion is met **(1.)**:
1. The member has demonstrated disease stability or a beneficial response to therapy.

C. Quantity Limitations
When prior authorization is approved, Entyvio SC may be authorized in quantities as follows:

Diagnosis	Induction Therapy	Maintenance Therapy
UC, CD	N/A	Two (2) prefilled syringes/pens every four (4) weeks

VII. Ilumya (tildrakizumab-asmn)

A. Initial Authorization
1. Plaque Psoriasis (PsO) (ICD-10: L40, excluding L40.5)
When a benefit, coverage of Ilumya may be approved when all of the following criteria are met **(a. through e.)**:
a. The member is 18 years of age or older.
b. The member has a diagnosis of moderate to severe PsO.
c. The medication is prescribed by or in consultation with a dermatologist or rheumatologist.
d. The member meets one (1) of the following criteria **(i., ii., or iii.)**:

i. The member has experienced therapeutic failure or intolerance to phototherapy (for example, PUVA, UVB).
ii. The member has experienced therapeutic failure or intolerance to at least one (1) systemic therapy (for example, methotrexate).
iii. The member is contraindicated to both phototherapy and systemic therapy.

e. The member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for the treatment of PsO (see **Table 1**).

B. Reauthorization

When a benefit, reauthorization of Ilumya may be approved when the following criterion is met **(1.)**:

1. The member has demonstrated disease stability or a beneficial response to therapy.

C. Quantity Limitations

When prior authorization is approved, Ilumya may be authorized in quantities as follows:

Diagnosis	Induction Therapy	Maintenance Therapy
PsO	Two (2) prefilled syringes within the first four (4) weeks of therapy	One (1) prefilled syringe every twelve (12) weeks

- Ilumya is coded as MSI to reject for prior authorization if select groups do not take global exclusion benefit.

VIII. Kevzara (sarilumab)

A. Initial Authorization

1. Rheumatoid Arthritis (RA) (ICD-10: M05, M06)

When a benefit, coverage of Kevzara may be approved when all of the following criteria are met **(a. through e.)**:

a. The member is 18 years of age or older.
b. The member has a diagnosis of moderate to severe RA.
c. The medication is prescribed by or in consultation with a rheumatologist.
d. The member has experienced therapeutic failure or intolerance to at least one (1) non-biologic DMARD (for example, methotrexate, leflunomide, sulfasalazine, cyclosporine), or all non-biologic DMARDs are contraindicated.
e. The member meets one (1) of the following **(i. or ii.)**:
i. The member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for the treatment of RA (see **Table 1**). Note: A trial of Actemra intravenous, Cimzia, an infliximab product (for example, Remicade, biosimilars), Orencia (intravenous or subcutaneous), or Simponi (Aria or subcutaneous) also counts.
ii. The member has heart failure or a previously treated lymphoproliferative disorder.

2. Polymyalgia Rheumatica (PMR) (ICD-10: M35.3)

When a benefit, coverage of Kevzara may be approved when all of the following criteria are met **(a. through d.)**:

a. The member is 18 years of age or older.
b. The member has a diagnosis of PMR.
c. The medication is prescribed by or in consultation with a rheumatologist.
d. The member meets one (1) of the following **(i., ii., or iii.)**:

i. The member will be using Kevzara in combination with a tapering course of corticosteroids.
ii. The member has experienced an inadequate response to corticosteroids.
iii. The member has experienced an intolerance to corticosteroid taper.

3. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (ICD-10: M08.4)
When a benefit, coverage of Kevzara may be approved when all of the following criteria are met **(a. through e.)**:
a. The member weighs greater than or equal to 63 kg.
b. The member has a diagnosis of PJIA.
c. The medication is prescribed by or in consultation with a rheumatologist.
d. The member meets one (1) of the following criteria **(i. or ii.)**:
i. The member has experienced therapeutic failure or intolerance to at least one (1) non-biologic DMARD (for example, methotrexate, leflunomide, sulfasalazine, cyclosporine), or all non-biologic DMARDs are contraindicated.
ii. The member requires initial biologic therapy due to involvement of high-risk joints (for example, cervical spine, wrist, or hip), high disease activity, and/or those judged by their physician to be at high risk of disabling joint damage.
e. The member meets one (1) of the following **(i. or ii.)**:
i. The member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a agents for the treatment of JIA (see **Table 1**). Note: A trial of Actemra intravenous, Orencia intravenous, an infliximab product (for example, Remicade, biosimilars), or Simponi Aria also counts.
ii. The member has heart failure or a previously treated lymphoproliferative disorder.

B. Reauthorization
When a benefit, reauthorization of Kevzara may be approved when the following criterion is met **(1.)**:
1. The member has demonstrated disease stability or a beneficial response to therapy.

C. Quantity Limitations
When prior authorization is approved, Kevzara may be authorized in quantities as follows:

Diagnosis	Induction Therapy	Maintenance Therapy
RA	N/A	Two (2) prefilled pens/syringes (150 mg/1.14 mL or 200 mg/1.14 mL) every four (4) weeks
PMR	N/A	Two (2) prefilled pens/syringes (200 mg/1.14 mL) every four (4) weeks
PJIA	N/A	Two (2) prefilled syringes (200 mg/1.14 mL) every four (4) weeks

N/A=not applicable

IX. Kineret (anakinra)

A. Initial Authorization
1. Rheumatoid Arthritis (RA) (ICD-10: M05, M06)
When a benefit, coverage of Kineret may be approved when all of the following criteria are met **(a. through e.)**:
a. The member is 18 years of age or older.

b. The member has a diagnosis of RA.
c. The medication is prescribed by or in consultation with a rheumatologist.
d. The member has experienced therapeutic failure or intolerance to at least one (1) non-biologic DMARD (for example, methotrexate, leflunomide, sulfasalazine, cyclosporine), or all non-biologic DMARDs are contraindicated.
e. The member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for the treatment of RA (see **Table 1**). Note: A trial of Actemra intravenous, Cimzia, Orencia (subcutaneous or intravenous), an infliximab product (for example, Remicade, biosimilars), Kevzara, or Simponi (Aria or subcutaneous) also counts.

2. Neonatal-Onset Multisystem Inflammatory Disease (NOMID) (ICD-10: M04.2)
When a benefit, coverage of Kineret may be approved when all of the following criteria are met **(a. and b.)**:
a. The member has a diagnosis of NOMID.
b. The medication is prescribed by or in consultation with a rheumatologist, geneticist, or a dermatologist.

3. Deficiency of Interleukin-1 Receptor Antagonist (DIRA) (ICD-10: M04.8)
When a benefit, coverage of Kineret may be approved when all of the following criteria are met **(a., b., and c.)**:
a. The member has a diagnosis of DIRA.
b. The medication is prescribed by or in consultation with a rheumatologist, geneticist, dermatologist, or a physician specializing in the treatment of autoinflammatory disorders.
c. Genetic testing has confirmed a mutation in the *IL1RN* gene.

B. Reauthorization
When a benefit, reauthorization of Kineret may be approved when the following criterion is met **(1.)**:
1. The member has demonstrated disease stability or a beneficial response to therapy.

Dosing
In addition to the initial authorization and reauthorization criteria outlined above, documentation that member weight and prescribed Kineret dose is consistent with dosing below:
***NOMID and DIRA**: The recommended starting dose is 1-2 mg/kg daily. The dose can be individually adjusted to a maximum of 8 mg/kg daily. Kineret may be divided into twice daily dosing. A new syringe must be used for each dose and any unused portion after each dose should be discarded.

C. Quantity Limitations
When prior authorization is approved, Kineret may be authorized in quantities as follows:

Diagnosis	Induction Therapy	Maintenance Therapy
RA, NOMID*, DIRA*	One (1) prefilled syringe once daily	One (1) prefilled syringe once daily

X. Leqselvi (deuroxolitinib)

A. Initial Authorization
1. Alopecia Areata (AA) (ICD-10: L63)
When a benefit, coverage of Leqselvi may be approved when all of the following criteria are met **(a. through e.):**
a. The member is 18 years of age or older.

b. The member has a diagnosis of severe AA defined as ≥ 50% scalp hair loss.
c. The medication is prescribed by or in consultation with a dermatologist.
d. The member has a current episode of AA lasting for ≥ 6 months without spontaneous re-growth.
e. The member has experienced therapeutic failure or intolerance to one (1) of the following, or contraindication to all **(i. or ii.):**
  i. Systemic therapy (e.g., corticosteroid, methotrexate, cyclosporine)
  ii. High potency topical corticosteroid (e.g., clobetasol propionate, betamethasone dipropionate)

B. Reauthorization
When a benefit, reauthorization of Leqselvi may be approved when the following criterion is met **(1.)**:
1. The prescriber attests that the member has demonstrated disease stability or a beneficial response to therapy.

XI. Litfulo (ritlecitinib)

A. Initial Authorization
1. Alopecia Areata (AA) (ICD-10: L63)
When a benefit, coverage of Litfulo may be approved when all of the following criteria are met **(a. through e.):**
a. The member is 12 years of age or older.
b. The member has a diagnosis of severe AA defined as ≥ 50% scalp hair loss.
c. The medication is prescribed by or in consultation with a dermatologist.
d. The member has a current episode of AA lasting for ≥ 6 months without spontaneous re-growth.
e. The member has experienced therapeutic failure or intolerance to one (1) of the following, or contraindication to all **(i. or ii.):**
  i. Systemic therapy (for example, corticosteroid, methotrexate, cyclosporine)
  ii. High potency topical corticosteroid (for example, clobetasol propionate, betamethasone dipropionate)

B. Reauthorization
When a benefit, reauthorization of Litfulo may be approved when the following criterion is met **(1.)**:
1. The member has demonstrated disease stability or a beneficial response to therapy.

XII. Olumiant (baricitinib)

A. Initial Authorization
1. Rheumatoid Arthritis (RA) (ICD-10: M05, M06)
When a benefit, coverage of Olumiant 1 mg or 2 mg may be approved when all of the following criteria are met **(a. through e.)**:
a. The member is 18 years of age or older.
b. The member has a diagnosis of moderate to severely active RA.
c. The medication is prescribed by or in consultation with a rheumatologist.
d. The member has experienced therapeutic failure or intolerance to at least one (1) tumor necrosis factor (TNF) antagonist therapy, including adalimumab, Enbrel, Simponi, or Cimzia.
e. The member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for the treatment of RA (see **Table 1**). Note: A trial of Actemra intravenous, Cimzia, an infliximab product (for example, Remicade, biosimilars), Kevzara, Orencia (intravenous or subcutaneous), or Simponi (Aria or subcutaneous) also counts.

i. If the member has tried and failed adalimumab and Enbrel, the member will not need to try and fail any additional preferred biologic products. If the member has tried and failed either adalimumab or Enbrel, the member will need to try and fail one (1) additional preferred biologic product.

2. Alopecia Areata (AA) (ICD-10: L63)

When a benefit, coverage of Olumiant may be approved when all of the following criteria are met **(a. through f.)**:

- **a.** The member is 18 years of age or older.
- **b.** The member has a diagnosis of severe AA defined as ≥ 50% scalp hair loss.
- **c.** The medication is prescribed by or in consultation with a dermatologist.
- **d.** The member has a current episode of AA lasting for ≥ 6 months without spontaneous re-growth.
- **e.** The member has experienced therapeutic failure or intolerance to one (1) of the following, or contraindication to all **(i. or ii.)**:
  - **i.** Systemic therapy (for example, corticosteroid, methotrexate, cyclosporine)
  - **ii.** High potency topical corticosteroid (for example, clobetasol propionate, betamethasone dipropionate)
- **f.** If the request is for Olumiant 4 mg, the member meets one (1) of the following **(i. or ii.)**:
  - **i.** The member has experienced an inadequate response to Olumiant 2 mg.
  - **ii.** The member has nearly complete or complete scalp hair loss, with or without substantial eyelash or eyebrow hair loss.

B. Reauthorization

When a benefit, reauthorization of Olumiant may be approved when all of the following criteria are met **(1. and 2.)**:

1. The member has demonstrated disease stability or a beneficial response to therapy.
2. If the request is for Olumiant 4 mg, the member meets all of the following criteria **(a. and b.)**:
   - **a.** The member has a diagnosis of alopecia areata.
   - **b.** The member meets one (1) of the following **(i. or ii.)**:
     - **i.** The member continues to have nearly complete or complete scalp hair loss, with or without substantial eyelash or eyebrow hair loss and requires additional therapy.
     - **ii.** Dose reducing to Olumiant 2 mg would not be clinically appropriate at this time.

XIII. Omvoh (mirikizumab-mrkz) SC

A. Initial Authorization

1. Ulcerative Colitis (ICD-10: K51)

When a benefit, coverage of Omvoh SC may be approved when all of the following criteria are met **(a. through d.)**

- **a.** The member is 18 years of age or older.
- **b.** The member has a diagnosis of ulcerative colitis classified as moderately to severely active.
- **c.** The medication is prescribed by or in consultation with a gastroenterologist.
- **d.** The member has already received three (3) induction doses of Omvoh IV within 3 months of initiating therapy with Omvoh SC or is currently undergoing induction therapy with Omvoh IV.

2. Crohn's Disease (ICD-10: K50)

When a benefit, coverage of Omvoh SC may be approved when all of the following criteria are met **(a. through d.)**

- **a.** The member is 18 years of age or older.

b. The member has a diagnosis of Crohn's disease classified as moderately to severely active.
c. The medication is prescribed by or in consultation with a gastroenterologist.
d. The member has already received three (3) induction doses of Omvoh IV within 3 months of initiating therapy with Omvoh SC or is currently undergoing induction therapy with Omvoh IV.

B. Reauthorization

When a benefit, reauthorization of Omvoh SC may be approved when the following criterion is met **(1.)**:

1. The member has demonstrated disease stability or a beneficial response to therapy.

C. Quantity Limitations

When prior authorization is approved, Omvoh SC may be authorized in quantities as follows:

Diagnosis	Induction Therapy	Maintenance Therapy
UC, CD	N/A	Two (2) prefilled pens/syringes every four (4) weeks

XIV. Orencia (abatacept) SC

A. Initial Authorization

1. Rheumatoid Arthritis (RA) (ICD-10: M05, M06)

When a benefit, coverage of Orencia SC may be approved when all of the following criteria are met **(a. through e.)**:

a. The member is 18 years of age or older.
b. The member has a diagnosis of moderate to severe RA.
c. The medication is prescribed by or in consultation with a rheumatologist.
d. The member has experienced therapeutic failure or intolerance to at least one (1) non-biologic DMARD (for example, methotrexate, leflunomide, sulfasalazine, cyclosporine), or all non-biologic DMARDs are contraindicated.
e. The member meets one (1) of the following **(i. or ii.)**:
  i. The member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for the treatment of RA (see **Table 1**). Note: A trial of Actemra intravenous, Cimzia, an infliximab product (for example, Remicade, biosimilars), Kevzara, or Simponi (Aria or subcutaneous) also counts.
  ii. The member has heart failure, a previously treated lymphoproliferative disorder, a previous serious infection, or a demyelinating disorder.

2. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (ICD-10: M08.4)

When a benefit, coverage of Orencia SC may be approved when all of the following criteria are met **(a. through e.)**:

a. The member is 2 years of age or older.
b. The member has a diagnosis of moderate to severe PJIA.
c. The medication is prescribed by or in consultation with a rheumatologist.
d. The member meets one (1) of the following criteria **(i. or ii.)**:
  i. The member has experienced therapeutic failure or intolerance to at least one (1) non-biologic DMARD (for example, methotrexate, leflunomide, sulfasalazine, cyclosporine), or all non-biologic DMARDs are contraindicated.
  ii. The member requires initial biologic therapy due to involvement of high-risk joints (for example, cervical spine, wrist, or hip), high disease activity, and/or those judged by their physician to be at high risk of disabling joint damage.

e. The member meets one (1) of the following **(i. or ii.)**:
- **i.** The member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for the treatment of PJIA (see **Table 1**). Note: A trial of Actemra intravenous, Orencia intravenous, an infliximab product (for example, Remicade, biosimilars), or Simponi Aria also counts.
- **ii.** The member has heart failure, a previously treated lymphoproliferative disorder, a previous serious infection, or a demyelinating disorder.

3. Psoriatic Arthritis (PsA) (ICD-10: L40.5)

a. Spinal or axial PsA

When a benefit, coverage of Orencia SC may be approved when all of the following criteria are met **(i. through v.)**:
- **i.** The member is 2 years of age or older.
- **ii.** The member has a diagnosis of spinal or axial PsA.
- **iii.** The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
- **iv.** The member has experienced therapeutic failure or intolerance to at least one (1) nonsteroidal anti-inflammatory drug (NSAID), or all NSAIDs are contraindicated.
- **v.** The member meets one (1) of the following criteria **(A), B), or C))**:
  - **A)** If the member is 18 years of age or older, the member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for PsA (see **Table 1**). Note: A trial of Cimzia, an infliximab product (for example, Remicade, biosimilars), or Simponi (subcutaneous or Aria) also counts toward a trial of a TNFi.
  - **B)** If the member is less than 18 years of age, the member has experienced therapeutic failure or intolerance to **one (1)** of the following preferred agents **(1) or 2))**. Note: A trial of another TNFi counts towards a trial of Enbrel.
    - **1)** Enbrel
    - **2)** preferred ustekinumab SC product
  - **C)** The member has heart failure, a previously treated lymphoproliferative disorder, a previous serious infection, or a demyelinating disorder.

b. PsA without spinal or axial disease

When a benefit, coverage of Orencia SC may be approved when all of the following criteria are met **(i. through v.)**:
- **i.** The member is 2 years of age or older.
- **ii.** The member has a diagnosis of PsA without spinal disease.
- **iii.** The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
- **iv.** The member has experienced therapeutic failure or intolerance to at least one (1) non-biologic DMARD (for example, methotrexate, leflunomide, sulfasalazine, cyclosporine), or all non-biologic DMARDs are contraindicated.
- **v.** The member meets one (1) of the following criteria **(A), B), or C))**:
  - **A)** If the member is 18 years of age or older, the member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for PsA (see **Table 1**). Note: A trial of Cimzia, an infliximab product (for example, Remicade, biosimilars), or Simponi (subcutaneous or Aria) also counts toward a trial of a TNFi.
  - **B)** If the member is less than 18 years of age, the member has experienced therapeutic failure or intolerance to **one (1)** of the following preferred agents **(1) or 2))**. Note: A trial of another TNFi counts towards a trial of Enbrel.
    - **1)** Enbrel
    - **2)** preferred ustekinumab SC product
  - **C)** The member has heart failure, a previously treated lymphoproliferative disorder, a previous serious infection, or a demyelinating disorder.

c. Enthesitis and/or dactylitis associated PsA

When a benefit, coverage of Orencia SC may be approved when all of the following criteria are met **(i. through v.)**:

i. The member is 2 years of age or older.

ii. The member has a diagnosis of enthesitis and/or dactylitis associated with PsA.

iii. The medication is prescribed by or in consultation with a rheumatologist or dermatologist.

iv. The member has experienced therapeutic failure or intolerance to at least one (1) NSAID or a local glucocorticoid injection, or all NSAIDs and all local glucocorticoid injections are contraindicated.

v. The member meets one (1) of the following criteria **(A), B), or C))**:

A) If the member is 18 years of age or older, the member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for PsA (see **Table 1**). Note: A trial of Cimzia, an infliximab product (for example, Remicade, biosimilars), or Simponi (subcutaneous or Aria) also counts toward a trial of a TNFi.

B) If the member is less than 18 years of age, the member has experienced therapeutic failure or intolerance to **one (1)** of the following preferred agents **(1) or 2))**. Note: A trial of another TNFi counts towards a trial of Enbrel.

1) Enbrel

2) preferred ustekinumab SC product

C) The member has heart failure, a previously treated lymphoproliferative disorder, a previous serious infection, or a demyelinating disorder.

B. Reauthorization

When a benefit, reauthorization of Orencia SC may be approved when the following criterion is met **(1.)**:

1. The member has demonstrated disease stability or a beneficial response to therapy.

C. Quantity Limitations

When prior authorization is approved, Orencia SC may be authorized in quantities as follows:

Diagnosis	Induction Therapy	Maintenance Therapy
RA, PJIA, PsA	N/A	Four (4) prefilled syringes every four (4) weeks

XV. Otezla (apremilast)

A. Initial Authorization

1. Psoriatic Arthritis (PsA) (ICD-10: L40.5)

a. Spinal or axial PsA

When a benefit, coverage of Otezla may be approved when all of the following criteria are met **(i. through iv.)**:

i. The member meets one (1) of the following criteria **(A) or B))**:

A) The member is 18 years of age or older.

B) The member meets both of the following criteria **(1) and 2))**:

1) The member is 6 years of age to less than 18 years of age.

2) The member weighs greater than or equal to 20 kg.

ii. The member has a diagnosis of spinal or axial PsA.

iii. The medication is prescribed by or in consultation with a rheumatologist or dermatologist.

iv. The member has experienced therapeutic failure or intolerance to at least one (1) nonsteroidal anti-inflammatory drug (NSAID), or all NSAIDs are contraindicated.

b. PsA without spinal or axial disease

When a benefit, coverage of Otezla may be approved when all of the following criteria are met **(i. through iv.)**:

i. The member meets one (1) of the following criteria **(A) or B))**:

A) The member is 18 years of age or older.

B) The member meets both of the following criteria **(1) and 2))**:

1) The member is 6 years of age to less than 18 years of age.

2) The member weighs greater than or equal to 20 kg.

ii. The member has a diagnosis of PsA without spinal disease.

iii. The medication is prescribed by or in consultation with a rheumatologist or dermatologist.

iv. The member has experienced therapeutic failure or intolerance to at least one (1) non-biologic DMARD (for example, methotrexate, leflunomide, sulfasalazine, cyclosporine), or all non-biologic DMARDs are contraindicated.

c. Enthesitis and/or dactylitis associated PsA

When a benefit, coverage of Otezla may be approved when all of the following criteria are met **(i. through iv.)**:

i. The member meets one (1) of the following criteria **(A) or B))**:

A) The member is 18 years of age or older.

B) The member meets both of the following criteria **(1) and 2))**:

1) The member is 6 years of age to less than 18 years of age.

2) The member weighs greater than or equal to 20 kg.

ii. The member has a diagnosis of enthesitis and/or dactylitis associated with PsA.

iii. The medication is prescribed by or in consultation with a rheumatologist or dermatologist.

iv. The member has experienced therapeutic failure or intolerance to at least one (1) NSAID or a local glucocorticoid injection, or all NSAIDs and all local glucocorticoid injections are contraindicated.

2. Adult Plaque Psoriasis (PsO) (ICD-10: L40, excluding L40.5)

When a benefit, coverage of Otezla may be approved when all of the following criteria are met **(a. through d.)**:

a. The member is 18 years of age or older.

b. The member has a diagnosis of PsO.

c. The medication is prescribed by or in consultation with a dermatologist or rheumatologist.

d. The member meets one (1) of the following criteria **(i., ii., or iii.)**:

i. The member has experienced therapeutic failure or intolerance to phototherapy (for example, PUVA, UVB).

ii. The member has experienced therapeutic failure or intolerance to at least one (1) systemic therapy (for example, methotrexate).

iii. The member is contraindicated to both phototherapy and systemic therapy.

3. Pediatric Plaque Psoriasis (PsO) (ICD-10: L40, excluding L40.5)

When a benefit, coverage of Otezla may be approved when all of the following criteria are met **(a. through e.)**:

a. The member is 6 years of age to less than 18 years of age.

b. The member weighs greater than or equal to 20 kg.

c. The member has a diagnosis of PsO, classified as moderate-to-severe disease.

d. The medication is prescribed by or in consultation with a dermatologist or rheumatologist.

e. The member meets one (1) of the following criteria **(i., ii., or iii.)**:

i. The member has experienced therapeutic failure or intolerance to phototherapy (for example, PUVA, UVB).

ii. The member has experienced therapeutic failure or intolerance to at least one (1) systemic therapy (for example, methotrexate).

iii. The member is contraindicated to both phototherapy and systemic therapy.

4. Oral Ulcers associated with Behçet's Disease (ICD-10: M35.2)
When a benefit, coverage of Otezla may be approved when all of the following criteria are met **(a. through e.)**:
- **a.** The member is 18 years of age or older.
- **b.** The member has a diagnosis of oral ulcers associated with Behçet's Disease.
- **c.** The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
- **d.** The member has experienced therapeutic failure or intolerance to at least one (1) topical triamcinolone product for acute flare-up of oral ulcers.
- **e.** The member has experienced therapeutic failure or intolerance to colchicine for prevention of recurrent oral ulcers.

B. Reauthorization
When a benefit, reauthorization of Otezla may be approved when the following criterion is met **(1.)**:
1. The member has demonstrated disease stability or a beneficial response to therapy.

XVI. Rinvoq (upadacitinib)

A. Initial Authorization

1. Rheumatoid Arthritis (RA) (ICD-10: M05, M06)
When a benefit, coverage of Rinvoq ER tablet may be approved when all of the following criteria are met **(a. through d.)**:
- **a.** The member is 18 years of age or older.
- **b.** The member has a diagnosis of moderate to severe RA.
- **c.** The medication is prescribed by or in consultation with a rheumatologist.
- **d.** The member has experienced therapeutic failure or intolerance to a preferred **adalimumab product** or **Enbrel** for the treatment of RA (see **Table 1**). Note: A trial of Cimzia, an infliximab product (for example, Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.

2. Psoriatic Arthritis (PsA) (ICD-10: L40.5)
When a benefit, coverage of Rinvoq ER tablet or Rinvoq LQ may be approved when all of the following criteria are met **(a. through d.)**:
- **a.** The member meets one (1) of the following **(i. or ii.)**:
  - **i.** If the request is for Rinvoq ER tablets, the member is 2 years of age or older.
  - **ii.** If the request is for Rinvoq LQ, the member is 2 to less than 18 years of age.
- **b.** The member has a diagnosis of PsA.
- **c.** The medication is prescribed by or in consultation with a rheumatologist or a dermatologist.
- **d.** The member has experienced therapeutic failure or intolerance to a preferred **adalimumab product** or **Enbrel** for the treatment of PsA (see **Table 1**). Note: A trial of Cimzia, an infliximab product (for example, Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.

3. Atopic Dermatitis (ICD-10: L20)
When a benefit, coverage of Rinvoq ER tablet may be approved when all of the following criteria are met **(a. through e.)**:
- **a.** The member is 12 years of age or older.
- **b.** The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist.
- **c.** The member has a diagnosis of atopic dermatitis, classified as all of the following **(i. and ii.)**:

i. Moderate-to-severe
ii. Refractory

d. The member meets one (1) of the following criteria **(i. or ii.)**:
  i. The member has experienced therapeutic failure or intolerance to one (1) of the following **(A) or B))**:
    A) One (1) generic topical corticosteroid
    B) One (1) generic topical calcineurin inhibitor (specifically, tacrolimus, pimecrolimus)
  ii. The prescriber submits documentation that the member has severe atopic dermatitis and topical therapy would not be advisable for maintenance therapy as evidenced by one (1) of the following **(A) or B))**:
    A) The member is incapable of applying topical therapies due to the extent of body surface area (BSA) involvement.
    B) Topical therapies are contraindicated due to severely damaged skin.

e. The member has experienced therapeutic failure or intolerance to one (1) systemic therapy for atopic dermatitis, or all systemic therapies are contraindicated.

4. Ulcerative Colitis (UC) (ICD-10: K51)

When a benefit, coverage of Rinvoq ER tablet may be approved when all of the following criteria are met **(a. through d.)**:

a. The member is 18 years of age or older.
b. The member has a diagnosis of moderate or severe UC.
c. The medication is prescribed by or in consultation with a gastroenterologist.
d. The member has experienced therapeutic failure or intolerance to a preferred **adalimumab product** for the treatment of UC (**see Table 1**). Note: A trial of an infliximab product (for example, Remicade, biosimilars) or Simponi subcutaneous also counts.

5. Ankylosing Spondylitis (AS) (ICD-10: M45, excluding M45.A)

When a benefit, coverage of Rinvoq ER tablet may be approved when all of the following criteria are met **(a. through d.)**:

a. The member is 18 years of age or older.
b. The member has a diagnosis of AS.
c. The medication is prescribed by or in consultation with a rheumatologist.
d. The member has experienced therapeutic failure or intolerance to a preferred **adalimumab product** or **Enbrel** for the treatment of AS (see **Table 1**). Note: A trial of Cimzia, an infliximab product (for example, Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.

6. Non-radiographic Axial Spondyloarthritis (nr-axSpA) (ICD-10: M45.A)

When a benefit, coverage of Rinvoq ER tablet may be approved when all of the following criteria are met **(a. through d.)**:

a. The member is 18 years of age or older.
b. The member has a diagnosis of nr-axSpA.
c. The medication is prescribed by or in consultation with a rheumatologist.
d. The member has experienced therapeutic failure or intolerance to preferred **Cimzia** for the treatment of nr-axSpA (see **Table 1**). Note: A trial of Enbrel, adalimumab, an infliximab Product (for example, Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.

7. Crohn's Disease (CD) (ICD-10: K50)

When a benefit, coverage of Rinvoq ER tablet may be approved when all of the following criteria are met **(a. through d.)**:

a. The member is 18 years of age or older.
b. The member has a diagnosis of moderate or severe CD.
c. The medication is prescribed by or in consultation with a gastroenterologist.

d. The member has experienced therapeutic failure or intolerance to a preferred **adalimumab product** for the treatment of CD (**see Table 1**). Note: A trial of an infliximab product (for example, Remicade, biosimilars) or Cimzia also counts.

8. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (ICD-10: M08.4)
When a benefit, coverage of Rinvoq ER tablet or Rinvoq LQ may be approved when all of the following criteria are met **(a. through e.)**:
- **a.** The member is 2 years of age or older.
- **b.** The member has a diagnosis of PJIA.
- **c.** The medication is prescribed by or in consultation with a rheumatologist.
- **d.** The member meets one (1) of the following criteria **(i. or ii.)**:
  - **i.** The member has experienced therapeutic failure or intolerance to at least one (1) non-biologic DMARD (for example, methotrexate, leflunomide, sulfasalazine, cyclosporine), or all non-biologic DMARDs are contraindicated.
  - **ii.** The member requires initial biologic therapy due to involvement of high-risk joints (for example, cervical spine, wrist, or hip), high disease activity, and/or those judged by their physician to be at high risk of disabling joint damage.
- **e.** The member has experienced therapeutic failure or intolerance to a preferred **adalimumab product** or **Enbrel** for the treatment of PJIA (see **Table 1**). Note: A trial of an infliximab product (for example, Remicade, biosimilars) or Simponi Aria also counts.

9. Giant Cell Arteritis (GCA) (M31.5, M31.6)
When a benefit, coverage of Rinvoq ER tablets may be approved when all of the following criteria are met **(a. through d.)**:
- **a.** The member is 18 years of age or older.
- **b.** The member has a diagnosis of GCA.
- **c.** The medication is prescribed by or in consultation with a rheumatologist.
- **d.** The member has experienced therapeutic failure or intolerance to at least one (1) systemic corticosteroid (for example, prednisone), or all corticosteroids are contraindicated.

B. Reauthorization
When a benefit, reauthorization of Rinvoq ER tablet or Rinvoq LQ may be approved when the following criterion is met **(1.)**:
1. The member has demonstrated disease stability or a beneficial response to therapy.

XVII. Siliq (brodalumab)

A. Initial Authorization

1. Plaque Psoriasis (PsO) (ICD-10: L40, excluding L40.5)
When a benefit, coverage of Siliq may be approved when all of the following criteria are met **(a. through e.)**:
- **a.** The member is 18 years of age or older.
- **b.** The member has a diagnosis of moderate to severe PsO.
- **c.** The medication is prescribed by or in consultation with a dermatologist or rheumatologist.
- **d.** The member meets one (1) of the following criteria **(i., ii., or iii.)**:
  - **i.** The member has experienced therapeutic failure or intolerance to phototherapy (for example, PUVA, UVB).
  - **ii.** The member has experienced therapeutic failure or intolerance to at least one (1) systemic therapy (for example, methotrexate).
  - **iii.** The member is contraindicated to both phototherapy and systemic therapy.
- **e.** The member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for the treatment of PsO (see **Table 1**).

B. Reauthorization

When a benefit, reauthorization of Siliq may be approved when the following criterion is met **(1.)**:

1. The member has demonstrated disease stability or a beneficial response to therapy.

C. Quantity Limitations

When prior authorization is approved, Siliq may be authorized in quantities as follows:

Diagnosis	Induction Therapy	Maintenance Therapy
PsO	Three (3) prefilled syringes within the first two (2) weeks of therapy	Two (2) prefilled syringes every four (4) weeks

XVIII. Simponi (golimumab) SC

A. Initial Authorization

1. Rheumatoid Arthritis (RA) (ICD-10: M05, M06)

When a benefit, coverage of Simponi SC may be approved when all of the following criteria are met **(a. through e.)**:

- **a.** The member is 18 years of age or older.
- **b.** The member has a diagnosis of moderate to severe RA.
- **c.** The medication is prescribed by or in consultation with a rheumatologist.
- **d.** The member has experienced therapeutic failure or intolerance to at least one (1) non-biologic DMARD (for example, methotrexate, leflunomide, sulfasalazine, cyclosporine), or all nonbiologic DMARDs are contraindicated.
- **e.** The member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for the treatment of RA (see **Table 1**).

2. Ankylosing Spondylitis (AS) (ICD-10: M45, excluding M45.A)

When a benefit, coverage of Simponi SC may be approved when all of the following criteria are met **(a. through d.)**:

- **a.** The member is 18 years of age or older.
- **b.** The member has a diagnosis of AS.
- **c.** The medication is prescribed by or in consultation with a rheumatologist.
- **d.** The member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for the treatment of AS (see **Table 1**).

3. Psoriatic Arthritis (PsA) (ICD-10: L40.5)

a. Spinal or axial PsA

When a benefit, coverage of Simponi SC may be approved when all of the following criteria are met **(i. through v.)**:

- **i.** The member is 18 years of age or older.
- **ii.** The member has a diagnosis of spinal or axial PsA.
- **iii.** The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
- **iv.** The member has experienced therapeutic failure or intolerance to at least one (1) nonsteroidal anti-inflammatory drug (NSAID), or all NSAIDs are contraindicated.
- **v.** The member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for the treatment of PsA (see **Table 1**).

b. PsA without spinal or axial disease

When a benefit, coverage of Simponi SC may be approved when all of the following criteria are met **(i. through v.)**:

- **i.** The member is 18 years of age or older.
- **ii.** The member has a diagnosis of PsA without spinal disease.

iii. The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
iv. The member has experienced therapeutic failure or intolerance to at least one (1) non-biologic DMARD (for example, methotrexate, leflunomide, sulfasalazine, cyclosporine), or all non-biologic DMARDs are contraindicated.
v. The member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for the treatment of PsA (see **Table 1**).

c. Enthesitis and/or dactylitis associated PsA
When a benefit, coverage of Simponi SC may be approved when all of the following criteria are met **(i. through v.)**:
i. The member is 18 years of age or older.
ii. The member has a diagnosis of enthesitis and/or dactylitis associated with PsA.
iii. The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
iv. The member has experienced therapeutic failure or intolerance to at least one (1) NSAID or a local glucocorticoid injection, or all NSAIDs and all local glucocorticoid injections are contraindicated.
v. The member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 or 2a preferred agents for the treatment of PsA (see **Table 1**).

4. Ulcerative Colitis (UC) (ICD-10: K51)
When a benefit, coverage of Simponi SC may be approved when all of the following criteria are met **(a. through d.)**:
a. The member is 18 years of age or older.
b. The member has a diagnosis of moderate or severe UC.
c. The medication is prescribed by or in consultation with a gastroenterologist.
d. The member has experienced therapeutic failure or intolerance to a preferred **adalimumab product** for the treatment of UC (see **Table 1**).

B. Reauthorization
When a benefit, reauthorization of Simponi SC may be approved when the following criterion is met **(1.)**:
1. The member has demonstrated disease stability or a beneficial response to therapy.

C. Quantity Limitations
When prior authorization is approved, Simponi SC may be authorized in quantities as follows:

Diagnosis	Induction Therapy	Maintenance Therapy
RA, AS, PsA	One (1) 50 mg syringe/ autoinjector within the first four (4) weeks of therapy	One (1) 50 mg syringe/ autoinjector every four (4) weeks
UC	Three (3) 100 mg syringes/ autoinjector within the first four (4) weeks of therapy	One (1) 100 mg syringe/ autoinjector every four (4) weeks

XIX. Skyrizi SC (risankizumab)

A. Initial Authorization
1. Plaque Psoriasis (PsO) (ICD-10: L40, excluding L40.5)
When a benefit, coverage of Skyrizi SC pen/syringe may be approved when all of the following criteria are met **(a. through d.)**:
a. The member is 18 years of age or older.
b. The member has a diagnosis of moderate to severe PsO.

c. The medication is prescribed by or in consultation with a dermatologist or rheumatologist.
d. The member meets one (1) of the following criteria **(i., ii., or iii.)**:
  i. The member has experienced therapeutic failure or intolerance to phototherapy (for example, PUVA, UVB).
  ii. The member has experienced therapeutic failure or intolerance to at least one (1) systemic therapy (for example, methotrexate).
  iii. The member is contraindicated to both phototherapy and systemic therapy.

2. Psoriatic Arthritis (PsA) (ICD-10: L40.5)

a. Spinal or axial PsA

When a benefit, coverage of Skyrizi SC pen/syringe may be approved when all of the following criteria are met **(i. through iv.):**
  i. The member is 18 years of age or older.
  ii. The member has a diagnosis of spinal or axial PsA.
  iii. The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
  iv. The member has experienced therapeutic failure or intolerance to at least one (1) nonsteroidal anti-inflammatory drug (NSAID), or all NSAIDs are contraindicated.

b. PsA without spinal or axial disease

When a benefit, coverage of Skyrizi SC pen/syringe may be approved when all of the following criteria are met **(i. through iv.):**
  i. The member is 18 years of age or older.
  ii. The member has a diagnosis of PsA without spinal disease.
  iii. The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
  iv. The member has experienced therapeutic failure or intolerance to at least one (1) non-biologic DMARD (for example, methotrexate, leflunomide, sulfasalazine, cyclosporine), or all non-biologic DMARDs are contraindicated.

c. Enthesitis and/or dactylitis associated PsA

When a benefit, coverage of Skyrizi SC pen/syringe may be approved when all of the following criteria are met **(i. through iv.):**
  i. The member is 18 years of age or older.
  ii. The member has a diagnosis of enthesitis and/or dactylitis associated with PsA.
  iii. The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
  iv. The member has experienced therapeutic failure or intolerance to at least one (1) NSAID or a local glucocorticoid injection, or all NSAIDs and all local glucocorticoid injections are contraindicated.

3. Crohn's Disease (CD) (ICD-10: K50)

When a benefit, coverage of Skyrizi SC cartridge with on-body injector may be approved when all of the following criteria are met **(a. through d.)**:
a. The member is 18 years of age or older.
b. The member has a diagnosis of moderate to severe CD.
c. The medication is prescribed by or in consultation with a gastroenterologist.
d. The member has already received three (3) induction doses of Skyrizi IV within 3 months of initiating therapy with Skyrizi SC cartridge with on-body injector or is currently undergoing induction therapy with Skyrizi IV.

4. Ulcerative Colitis (UC) (ICD-10: K51)

When a benefit, coverage of Skyrizi SC cartridge with on-body injector may be approved when all of the following criteria are met **(a. through d.)**:
a. The member is 18 years of age or older.
b. The member has a diagnosis of moderate to severe UC.
c. The medication is prescribed by or in consultation with a gastroenterologist.

d. The member has already received three (3) induction doses of Skyrizi IV within 3 months of initiating therapy with Skyrizi SC cartridge with on-body injector or is currently undergoing induction therapy with Skyrizi IV.

B. Reauthorization

When a benefit, reauthorization of Skyrizi SC may be approved when the following criterion is met **(1.)**:

1. The member has demonstrated disease stability or a beneficial response to therapy.

C. Quantity Limitations

When prior authorization is approved, Skyrizi SC may be authorized in quantities as follows:

Diagnosis	Induction Therapy	Maintenance Therapy
PsO, PsA	Two (2) prefilled syringes/pens (150 mg/mL) within the first four (4) weeks of therapy	One (1) prefilled syringe/pen (150 mg/mL) every twelve (12) weeks
CD, UC	N/A	One (1) prefilled cartridge with on-body injector every eight (8) weeks

N/A=Not Applicable

XX. Sotyktu (deucravacitinib)

A. Initial Authorization

1. Plaque Psoriasis (PsO) (ICD-10: L40, excluding L40.5)

When a benefit, coverage of Sotyktu may be approved when all of the following criteria are met **(a. through d.)**:

a. The member is 18 years of age or older.

b. The member has a diagnosis of moderate to severe PsO.

c. The medication is prescribed by or in consultation with a dermatologist or rheumatologist.

d. The member meets one (1) of the following criteria **(i., ii., or iii.)**:

i. The member has experienced therapeutic failure or intolerance to phototherapy (for example, PUVA, UVB).

ii. The member has experienced therapeutic failure or intolerance to at least one (1) systemic therapy (for example, methotrexate).

iii. The member is contraindicated to both phototherapy and systemic therapy.

B. Reauthorization

When a benefit, reauthorization of Sotyktu may be approved when the following criterion is met **(1.)**:

1. The member has demonstrated disease stability or a beneficial response to therapy.

XXI. Taltz (ixekizumab)

A. Initial Authorization

1. Psoriatic Arthritis (PsA) (ICD-10: L40.5)

a. Spinal or axial PsA

When a benefit, coverage of Taltz may be approved when all of the following criteria are met **(i. through iv.):**

i. The member is 18 years of age or older.

ii. The member has a diagnosis of spinal or axial PsA.

iii. The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
iv. The member has experienced therapeutic failure or intolerance to at least one (1) nonsteroidal anti-inflammatory drug (NSAID), or all NSAIDs are contraindicated.

b. PsA without spinal or axial disease
When a benefit, coverage of Taltz may be approved when all of the following criteria are met **(i. through iv.):**
i. The member is 18 years of age or older.
ii. The member has a diagnosis of PsA without spinal disease.
iii. The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
iv. The member has experienced therapeutic failure or intolerance to at least one (1) non-biologic DMARD (for example, methotrexate, leflunomide, sulfasalazine, cyclosporine), or all non-biologic DMARDs are contraindicated.

c. Enthesitis and/or dactylitis associated PsA
When a benefit, coverage of Taltz may be approved when all of the following criteria are met **(i. through iv.):**
i. The member is 18 years of age or older.
ii. The member has a diagnosis of enthesitis and/or dactylitis associated with PsA.
iii. The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
iv. The member has experienced therapeutic failure or intolerance to at least one (1) NSAID or a local glucocorticoid injection, or all NSAIDs and all local glucocorticoid injections are contraindicated.

2. Plaque Psoriasis (PsO) (ICD-10: L40, excluding L40.5)
When a benefit, coverage of Taltz may be approved when all of the following criteria are met **(a. through d.)**:
a. The member is 6 years of age or older.
b. The member has a diagnosis of moderate to severe PsO.
c. The medication is prescribed by or in consultation with a dermatologist or rheumatologist.
d. The member meets one (1) of the following criteria **(i., ii., or iii.)**:
i. The member has experienced therapeutic failure or intolerance to phototherapy (for example, PUVA, UVB).
ii. The member has experienced therapeutic failure or intolerance to at least one (1) systemic therapy (for example, methotrexate).
iii. The member is contraindicated to both phototherapy and systemic therapy.

3. Ankylosing Spondylitis (AS) (ICD-10: M45, excluding M45.A)
When a benefit, coverage of Taltz may be approved when all of the following criteria are met **(a., b., and c.)**:
a. The member is 18 years of age or older.
b. The member has a diagnosis of AS.
c. The medication is prescribed by or in consultation with a rheumatologist.

4. Non-radiographic Axial Spondyloarthritis (nr-axSpA) (ICD-10: M45.A)
When a benefit, coverage of Taltz may be approved when all of the following criteria are met **(a., b., and c.)**:
a. The member is 18 years of age or older.
b. The member has a diagnosis of nr-axSpA.
c. The medication is prescribed by or in consultation with a rheumatologist.

B. Reauthorization
When a benefit, reauthorization of Taltz may be approved when the following criterion is met **(1.)**:

1. The member has demonstrated disease stability or a beneficial response to therapy.

C. Quantity Limitations

When prior authorization is approved, Taltz may be authorized in quantities as follows:

Diagnosis	Induction Therapy	Maintenance Therapy
Adult PsO with or without PsA	Eight (8) autoinjector/prefilled syringes (80 mg/mL) within the first twelve (12) weeks of therapy	One (1) autoinjector/prefilled syringe (80 mg/mL) every four (4) weeks
Pediatric PsO greater than 50 kg	Two (2) autoinjector/prefilled syringe (80 mg/mL) within the first 4 weeks of therapy	One (1) autoinjector/prefilled syringe (80 mg/mL) every four (4) weeks
Pediatric PsO 25- 50 kg	One (1) autoinjector/prefilled syringe (80 mg/mL) within the first 4 weeks of therapy	One (1) prefilled syringe (40 mg/0.5 mL) every four (4) weeks
Pediatric PsO less than 25 kg	One (1) prefilled syringe (40 mg/0.5 mL) within the first 4 weeks of therapy	One (1) prefilled syringe (20 mg/ 0.25 mL) every four (4) weeks
PsA, AS	Two (2) autoinjector/prefilled syringes (80 mg/mL) within the first four (4) weeks of therapy	One (1) autoinjector/prefilled syringe (80 mg/mL) every four (4) weeks
nr-axSpA	N/A	One (1) autoinjector/prefilled syringe every four (4) weeks

N/A=Not Applicable

XXII. Tocilizumab SC (See Table 2 for Preferred Products)

A. Initial Authorization

1. **Rheumatoid Arthritis (RA)** (ICD-10: M05, M06)
   When a benefit, coverage of a preferred tocilizumab SC may be approved when all of the following criteria are met **(a. through e.)**:
   - **a.** The member is 18 years of age or older.
   - **b.** The member has a diagnosis of moderate to severe RA.
   - **c.** The medication is prescribed by or in consultation with a rheumatologist.
   - **d.** The member has experienced therapeutic failure or intolerance to at least one (1) non-biologic DMARD (for example, methotrexate, leflunomide, sulfasalazine, cyclosporine), or all non-biologic DMARDs are contraindicated.
   - **e.** The member meets one (1) of the following **(i. or ii.):**
     - **i.** The member has experienced therapeutic failure or intolerance to a preferred **adalimumab product** for the treatment of RA (see **Table 1**). Note: A trial of Cimzia, Enbrel, an infliximab product (for example, Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.
     - **ii.** The member has heart failure or a previously treated lymphoproliferative disorder.

2. **Giant Cell Arteritis (GCA)** (ICD-10: M31.5, M31.6)

When a benefit, coverage of a preferred tocilizumab SC may be approved when all of the following criteria are met **(a. through d.)**:

- **a.** The member is 18 years of age or older.
- **b.** The member has a diagnosis of GCA.
- **c.** The medication is prescribed by or in consultation with a rheumatologist.
- **d.** The member has experienced therapeutic failure or intolerance to at least one (1) systemic corticosteroid (for example, prednisone), or all corticosteroids are contraindicated.

3. **Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)** (ICD-10: M34.81)
When a benefit, coverage of Actemra SC may be approved when all of the following criteria are met **(a. through e.)**:
   - **a.** The member is 18 years of age or older.
   - **b.** The member has a diagnosis of SSc-ILD confirmed by high-resolution computed tomography.
   - **c.** The medication is prescribed by or in consultation with a pulmonologist or a rheumatologist.
   - **d.** The member has elevated acute phase reactants, defined as at least one (1) of the following criteria **(i., ii., or iii.)**:
     - **i.** C-reactive protein (CRP) ≥ 6 mg/mL
     - **ii.** Erythrocyte sedimentation rate (ESR) ≥ 28 mm/h
     - **iii.** Platelet count ≥ 330 x 10^9/L
   - **e.** The member's forced vital capacity (FVC) is > 55% of the predicted value.

4. **Polyarticular Juvenile Idiopathic Arthritis (PJIA)** (ICD-10: M08.4)
When a benefit, coverage of preferred tocilizumab SC may be approved when all of the following criteria are met **(a. through e.)**:
   - **a.** The member is 2 years of age or older.
   - **b.** The member has a diagnosis of PJIA.
   - **c.** The medication is prescribed by or in consultation with a rheumatologist.
   - **d.** The member meets one (1) of the following criteria **(i. or ii.)**:
     - **i.** The member has experienced therapeutic failure or intolerance to at least one (1) non-biologic DMARD (for example, methotrexate, leflunomide, sulfasalazine, cyclosporine), or all non-biologic DMARDs are contraindicated.
     - **ii.** The member requires initial biologic therapy due to involvement of high-risk joints (for example, cervical spine, wrist, or hip), high disease activity, and/or those judged by their physician to be at high risk of disabling joint damage.
   - **e.** The member meets one (1) of the following **(i. or ii.)**:
     - **i.** The member has experienced therapeutic failure or intolerance to a preferred **adalimumab product** for the treatment of PJIA (see **Table 1**). Note: A trial of Enbrel, an infliximab product (for example, Remicade, biosimilars), or Simponi Aria also counts.
     - **ii.** The member has heart failure or a previously treated lymphoproliferative disorder.

5. **Systemic Juvenile Idiopathic Arthritis (SJIA)** (ICD-10: M08)
When a benefit, coverage of preferred tocilizumab SC may be approved when all of the following criteria are met **(a., b., and c.)**:
   - **a.** The member is 2 years of age or older.
   - **b.** The member has a diagnosis of SJIA.
   - **c.** The medication is prescribed by or in consultation with a rheumatologist.

6. **Polymyalgia Rheumatica (PMR) (ICD-10: M35.3)**
   When a benefit, coverage of Actemra SC may be approved when all of the following criteria are met **(a. through d.)**:
   - **a.** The member is 18 years of age or older.
   - **b.** The member has a diagnosis of PMR.
   - **c.** The medication is prescribed by or in consultation with a rheumatologist.
   - **d.** The member meets one (1) of the following **(i., ii., or iii.)**:
     - **i.** The member will be using Actemra in combination with a tapering course of corticosteroids.
     - **ii.** The member has experienced an inadequate response to corticosteroids.
     - **iii.** The member has experienced an intolerance to corticosteroid taper.

B. Reauthorization

When a benefit, reauthorization of tocilizumab SC may be approved when the following criterion is met **(1.)**:

1. The member has demonstrated disease stability or a beneficial response to therapy.

C. Quantity Limitations

When prior authorization is approved, tocilizumab SC may be authorized in quantities as follows:

Diagnosis	Induction Therapy	Maintenance Therapy
RA, GCA, PMR	Four (4) prefilled syringes within the first four (4) weeks of therapy	Two (2) prefilled syringes every four (4) weeks -OR- Four (4) prefilled syringes every four (4) weeks
SSc-ILD	N/A	Four (4) prefilled syringes every four (4) weeks
PJIA	N/A	One (1) prefilled syringe every two (2) or three (3) weeks
SJIA	N/A	One (1) prefilled syringe every week or two (2) weeks

N/A=not applicable

XXIII. Tremfya (guselkumab) SC

A. Initial Authorization

1. **Psoriatic Arthritis (PsA) (ICD-10: L40.5)**
   - **a. Spinal or axial PsA**
     When a benefit, coverage of Tremfya SC may be approved when all of the following criteria are met **(i. through iv.):**
     - **i.** The member is 18 years of age or older.
     - **ii.** The member has a diagnosis of spinal or axial PsA.
     - **iii.** The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
     - **iv.** The member has experienced therapeutic failure or intolerance to at least one (1) nonsteroidal anti-inflammatory drug (NSAID), or all NSAIDs are contraindicated.
   - **b. PsA without spinal or axial disease**

When a benefit, coverage of Tremfya SC may be approved when all of the following criteria are met **(i. through iv.):**

i. The member is 18 years of age or older.
ii. The member has a diagnosis of PsA without spinal disease.
iii. The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
iv. The member has experienced therapeutic failure or intolerance to at least one (1) non-biologic DMARD (for example, methotrexate, leflunomide, sulfasalazine, cyclosporine), or all non-biologic DMARDs are contraindicated.

c. Enthesitis and/or dactylitis associated PsA
When a benefit, coverage of Tremfya SC may be approved when all of the following criteria are met **(i. through iv.):**

i. The member is 18 years of age or older.
ii. The member has a diagnosis of enthesitis and/or dactylitis associated with PsA.
iii. The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
iv. The member has experienced therapeutic failure or intolerance to at least one (1) NSAID or a local glucocorticoid injection, or all NSAIDs and all local glucocorticoid injections are contraindicated.

2. Plaque Psoriasis (PsO) (ICD-10: L40, excluding L40.5)
When a benefit, coverage of Tremfya SC may be approved when all of the following criteria are met **(a. through d.)**:

a. The member is 18 years of age or older.
b. The member has a diagnosis of moderate to severe PsO.
c. The medication is prescribed by or in consultation with a dermatologist or rheumatologist.
d. The member meets one (1) of the following criteria **(i., ii., or iii.)**:
i. The member has experienced therapeutic failure or intolerance to phototherapy (for example, PUVA, UVB).
ii. The member has experienced therapeutic failure or intolerance to at least one (1) systemic therapy (for example, methotrexate).
iii. The member is contraindicated to both phototherapy and systemic therapy.

3. Ulcerative Colitis (UC) (ICD-10: K51)
When a benefit, coverage of Tremfya SC may be approved when all of the following criteria are met **(a. through d.)**:

a. The member is 18 years of age or older.
b. The member has a diagnosis of ulcerative colitis classified as moderately to severely active.
c. The medication is prescribed by or in consultation with a gastroenterologist.
d. The member has already received three (3) induction doses of Tremfya IV within 3 to 4 months of initiating therapy with Tremfya SC or is currently undergoing induction therapy with Tremfya IV**.**

4. Crohn's Disease (CD) (ICD-10: K50)
When a benefit, coverage of Tremfya SC may be approved when all of the following criteria are met **(a. through d.)**:

a. The member is 18 years of age or older.
b. The member has a diagnosis of Crohn's disease classified as moderately to severely active.
c. The medication is prescribed by or in consultation with a gastroenterologist.
d. The member meets one (1) of the following criteria **(i. or ii.)**:
i. The member has already received three (3) induction doses of Tremfya IV within 3 to 4 months of initiating therapy with Tremfya SC for maintenance or is currently undergoing induction therapy with Tremfya IV.

ii. The member will be using Tremfya SC for induction dosing.

B. Reauthorization

When a benefit, reauthorization of Tremfya SC may be approved when the following criterion is met **(1.)**:

1. The member has demonstrated disease stability or a beneficial response to therapy.

C. Quantity Limitations

When prior authorization is approved, Tremfya SC may be authorized in quantities as follows:

Diagnosis	Induction Therapy	Maintenance Therapy
PsA, PsO	Two (2) prefilled syringes/injectors (100 mg/mL) within the first four (4) weeks of therapy	One (1) prefilled syringe/injector (100 mg/mL) every eight (8) weeks
UC	N/A	One (1) prefilled syringe/injector (100 mg/mL) every eight (8) weeks -OR- One (1) prefilled syringe/pen (200 mg/2 mL) every four (4) weeks
CD	Six (6) prefilled syringes/injectors (200 mg/2 mL) within the first eight (8) weeks of therapy -OR- Three (3) starter package kits	One (1) prefilled syringe/injector (100 mg/mL) every eight (8) weeks -OR- One (1) prefilled syringe/pen (200 mg/2 mL) every four (4) weeks

- To note, starter package kits are coded for quantity level limitations of three (3) kits per 365 days.

XXIV. Ustekinumab SC (See Table 2 for Preferred Products)

A. Initial Authorization

1. Psoriatic Arthritis (PsA) (ICD-10: L40.5)

a. Spinal or axial PsA

When a benefit, coverage of ustekinumab SC may be approved when all of the following criteria are met **(i. through iv.):**

i. The member is 6 years of age or older.

ii. The member has a diagnosis of spinal or axial PsA.

iii. The medication is prescribed by or in consultation with a rheumatologist or dermatologist.

iv. The member has experienced therapeutic failure or intolerance to at least one (1) nonsteroidal anti-inflammatory drug (NSAID), or all NSAIDs are contraindicated.

b. PsA without spinal or axial disease

When a benefit, coverage of ustekinumab SC may be approved when all of the following criteria are met **(i. through iv.):**

i. The member is 6 years of age or older.

ii. The member has a diagnosis of PsA without spinal disease.

iii. The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
iv. The member has experienced therapeutic failure or intolerance to at least one (1) non-biologic DMARD (for example, methotrexate, leflunomide, sulfasalazine, cyclosporine), or all non-biologic DMARDs are contraindicated.

c. Enthesitis and/or dactylitis associated PsA
When a benefit, coverage of ustekinumab SC may be approved when all of the following criteria are met **(i. through iv.):**
i. The member is 6 years of age or older.
ii. The member has a diagnosis of enthesitis and/or dactylitis associated with PsA.
iii. The medication is prescribed by or in consultation with a rheumatologist or dermatologist.
iv. The member has experienced therapeutic failure or intolerance to at least one (1) NSAID or a local glucocorticoid injection, or all NSAIDs and all local glucocorticoid injections are contraindicated.

2. Plaque Psoriasis (PsO) (ICD-10: L40, excluding L40.5)
When a benefit, coverage of ustekinumab SC may be approved when all of the following criteria are met **(a. through d.)**:
a. The member is 6 years of age or older.
b. The member has a diagnosis of moderate to severe PsO.
c. The medication is prescribed by or in consultation with a dermatologist or rheumatologist.
d. The member meets one (1) of the following criteria **(i., ii., or iii.)**:
i. The member has experienced therapeutic failure or intolerance to phototherapy (for example, PUVA, UVB).
ii. The member has experienced therapeutic failure or intolerance to at least one (1) systemic therapy (for example, methotrexate).
iii. The member is contraindicated to both phototherapy and systemic therapy.

3. Crohn's Disease (CD) (ICD-10: K50)
When a benefit, coverage of ustekinumab SC may be approved when all of the following criteria are met **(a. through d.)**:
a. The member is 18 years of age or older.
b. The member has a diagnosis of moderate to severe CD.
c. The medication is prescribed by or in consultation with a gastroenterologist.
d. The member has already received a single induction dose of ustekinumab IV within 2 months of initiating therapy with ustekinumab SC or is currently undergoing induction therapy with ustekinumab IV.

4. Ulcerative Colitis (UC) (ICD-10: K51)
When a benefit, coverage of ustekinumab SC may be approved when all of the following criteria are met **(a. through d.)**:
a. The member is 18 years of age or older.
b. The member has a diagnosis of moderate or severe UC.
c. The medication is prescribed by or in consultation with a gastroenterologist.
d. The member has already received a single induction dose of ustekinumab IV within 2 months of initiating therapy with ustekinumab SC or is currently undergoing induction therapy with ustekinumab IV.

B. Reauthorization
When a benefit, reauthorization of ustekinumab SC may be approved when the following criterion is met **(1.)**:
1. The member has demonstrated disease stability or a beneficial response to therapy.

Dosing

In addition to the initial authorization and reauthorization criteria outlined above, documentation that member weight and prescribed ustekinumab a dose is consistent with dosing below:

- **Psoriasis (18 years of age or older)**
  - **a.** ≤ 100 kg (220 lbs): 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks.
  - **b.** > 100 kg (220 lbs): 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks.
- **Psoriasis (6 to 17 years of age)**
  - **a.** < 60 kg (132 lbs): 0.75 mg/kg initially and 4 weeks later, followed by 0.75 mg/kg every 12 weeks.
  - **b.** 60 to 100 kg (220 lbs): 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks.
  - **c.** > 100 kg (220 lbs): 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks.
- **Psoriatic Arthritis (18 years of age or older)**
  - **a.** 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks
  - **b.** For patients with co-existent moderate-to-severe plaque psoriasis weighing > 100 kg (220 lbs): 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks.
- **Psoriatic Arthritis (6 to 17 years of age)**
  - **a.** < 60 kg (132 lbs): 0.75 mg/kg initially and 4 weeks later, followed by 0.75 mg/kg every 12 weeks.
  - **b.** 60 kg or more: 45 mg initially and 4 weeks later, followed by 45 mg every 12 weeks.
  - **c.** For patients with co-existent moderate-to-severe plaque psoriasis weighing > 100 kg (220 lbs): 90 mg initially and 4 weeks later, followed by 90 mg every 12 weeks.
- **Crohn's Disease**
  - **a.** Following a weight-based intravenous dose, the recommended dose is 90 mg 8 weeks following the intravenous dose, then every 8 weeks thereafter.
- **Ulcerative Colitis**
  - **a.** Following a weight-based intravenous dose, the recommended dose is 90 mg 8 weeks following the intravenous dose, then every 8 weeks thereafter.

C. Quantity Limitations

When prior authorization is approved, ustekinumab SC may be authorized in quantities as follows:

Diagnosis	Induction Therapy	Maintenance Therapy
PsA, PsO	Two (2) prefilled syringes within the first four (4) weeks of therapy	One (1) syringe every twelve (12) weeks
CD[*,†]	N/A	One (1) syringe every eight (8) weeks -OR- One (1) syringe every four (4) weeks
UC[*]	N/A	One (1) syringe every eight (8) weeks

N/A=Not Applicable

- *Patients diagnosed with Crohn's disease or ulcerative colitis may receive every 8-week dosing of ustekinumab. Patient Level Authorization (PLA) input - One (1) prefilled syringe per 42 days.
- †One (1) prefilled syringe every four (4) weeks may be approved for Crohn's Disease if clinical documentation is provided that the member is a non-responder or partial responder to treatment

with one (1) prefilled syringe every eight (8) weeks. PLA input – One (1) prefilled syringe per 21 days.

XXV. Velsipity (etrasimod)

A. Initial Authorization

1. Ulcerative Colitis (ICD-10: K51)

When a benefit, coverage of Velsipity may be approved when all of the following criteria are met **(a., b., and c.)**

- **a.** The member is 18 years of age or older.
- **b.** The member has a diagnosis of ulcerative colitis classified as moderately to severely active.
- **c.** The medication is prescribed by or in consultation with a gastroenterologist.

B. Reauthorization

When a benefit, reauthorization of Velsipity may be approved when the following criterion is met **(1.)**:

1. The member has demonstrated disease stability or a beneficial response to therapy.

XXVI. Xeljanz (tofacitinib)

A. Initial Authorization

1. Rheumatoid Arthritis (RA) (ICD-10: M05, M06)

When a benefit, coverage of Xeljanz or Xeljanz XR may be approved when all of the following criteria are met **(a. through d.)**:

- **a.** The member is 18 years of age or older.
- **b.** The member has a diagnosis of moderate to severely active RA.
- **c.** The medication is prescribed by or in consultation with a rheumatologist.
- **d.** The member has experienced therapeutic failure or intolerance to a preferred **adalimumab product** or **Enbrel** for the treatment of RA (see **Table 1**). Note: A trial of Cimzia, an infliximab product (for example, Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.

2. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (ICD-10: M08.4)

When a benefit, coverage of Xeljanz tablet or Xeljanz oral solution may be approved when all of the following criteria are met **(a. through e.)**:

- **a.** The member is 2 years of age or older.
- **b.** The member has a diagnosis of PJIA.
- **c.** The medication is prescribed by or in consultation with a rheumatologist.
- **d.** The member meets one (1) of the following criteria **(i. or ii.)**:
  - **i.** The member has experienced therapeutic failure or intolerance to at least one (1) non-biologic DMARD (for example, methotrexate, leflunomide, sulfasalazine, cyclosporine), or all non-biologic DMARDs are contraindicated.
  - **ii.** The member requires initial biologic therapy due to involvement of high-risk joints (for example, cervical spine, wrist, or hip), high disease activity, and/or those judged by their physician to be at high risk of disabling joint damage.
- **e.** The member has experienced therapeutic failure or intolerance to a preferred **adalimumab product** or **Enbrel** for the treatment of PJIA (see **Table 1**). Note: A trial of an infliximab product (for example, Remicade, biosimilars) or Simponi Aria also counts.

3. Psoriatic Arthritis (PsA) (ICD-10: L40.5)

When a benefit, coverage of Xeljanz or Xeljanz XR may be approved when all of the following criteria are met **(a. through d.)**:

a. The member is 18 years of age or older.
b. The member has a diagnosis of PsA.
c. The medication is prescribed by or in consultation with a rheumatologist or a dermatologist.
d. The member has experienced therapeutic failure or intolerance to a preferred **adalimumab product** or **Enbrel** for the treatment of PsA (see **Table 1**). Note: A trial of Cimzia, an infliximab product (for example, Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.

4. Ulcerative Colitis (UC) (ICD-10: K51)
When a benefit, coverage of Xeljanz or Xeljanz XR may be approved when all of the following criteria are met **(a. through d.)**:
a. The member is 18 years of age or older.
b. The member has a diagnosis of moderate or severe UC.
c. The medication is prescribed by or in consultation with a gastroenterologist.
d. The member has experienced therapeutic failure or intolerance to a preferred **adalimumab product** for the treatment of UC (**see Table 1**). Note: A trial of an infliximab product (for example, Remicade, biosimilars) or Simponi subcutaneous also counts.

5. Ankylosing Spondylitis (AS) (ICD-10: M45, excluding M45.A)
When a benefit, coverage of Xeljanz or Xeljanz XR may be approved when all of the following criteria are met **(a. through d.)**:
a. The member is 18 years of age or older.
b. The member has a diagnosis of AS.
c. The medication is prescribed by or in consultation with a rheumatologist.
d. The member has experienced therapeutic failure or intolerance to a preferred **adalimumab product** or **Enbrel** for the treatment of AS (see **Table 1**). Note: A trial of Cimzia, an infliximab product (for example, Remicade, biosimilars), or Simponi (Aria or subcutaneous) also counts.

B. Reauthorization
When a benefit, reauthorization of Xeljanz or Xeljanz XR may be approved when the following criterion is met **(1.)**:
1. The member has demonstrated disease stability or a beneficial response to therapy.

XXVII. Zeposia (ozanimod)

A. Multiple Sclerosis (ICD-10: G35)

1. Initial Authorization
When a benefit, coverage of Zeposia may be approved when all of the following criteria are met **(a. and b.)**:
a. The member is 18 years of age or older.
b. The member has a diagnosis of multiple sclerosis, classified as one (1) of the following relapsing forms **(i., ii., or iii.):**
i. Clinically isolated syndrome
ii. Relapsing-remitting disease
iii. Active secondary progressive disease

2. Reauthorization
When a benefit, reauthorization of Zeposia may be approved when the following criterion is met **(a.)**:
a. The member has experienced a therapeutic response defined as one (1) of the following **(i., ii., or iii.)**:
i. Disease stability
ii. Disease improvement

iii. Delayed disease progression

B. Ulcerative Colitis (ICD-10: K51)

1. Initial Authorization

When a benefit, coverage of Zeposia may be approved when all of the following criteria are met **(a. through d.)**

- **a.** The member is 18 years of age or older.
- **b.** The member has a diagnosis of ulcerative colitis classified as moderately to severely active.
- **c.** The medication is prescribed by or in consultation with a gastroenterologist.
- **d.** The member has experienced therapeutic failure or intolerance to at least **two (2)** step 1 preferred agents for the treatment of UC **(see Table 1).** Note: A trial of an infliximab product (for example, Remicade, biosimilars) or Simponi subcutaneous also counts towards a trial of adalimumab. A trial of Entyvio (vedolizumab intravenous) or preferred ustekinumab IV product also counts towards a trial of preferred ustekinumab SC product.

2. Reauthorization

When a benefit, reauthorization of Zeposia may be approved when the following criterion is met **(a.)**:

- **a.** The member has demonstrated disease stability or a beneficial response to therapy.

XXVIII. Zymfentra (infliximab-dyyb) SC

A. Initial Authorization

1. Ulcerative Colitis (ICD-10: K51)

When a benefit, coverage of Zymfentra may be approved when all of the following criteria are met **(a., b., and c.)**

- **a.** The member is 18 years of age or older.
- **b.** The member has a diagnosis of ulcerative colitis classified as moderately to severely active.
- **c.** The member has already received at least three doses of infliximab IV at least 6 weeks before initiating therapy with Zymfentra or is currently undergoing induction therapy with infliximab IV.

2. Crohn's Disease (ICD-10: K50)

When a benefit, coverage of Zymfentra may be approved when all of the following criteria are met **(a., b., and c.)**

- **a.** The member is 18 years of age or older.
- **b.** The member has a diagnosis of Crohn's disease classified as moderately to severely active.
- **c.** The member received at least three doses of infliximab IV at least 6 weeks before initiating therapy with Zymfentra or is currently undergoing induction therapy with infliximab IV.

B. Reauthorization

When a benefit, reauthorization of Zymfentra may be approved when the following criterion is met **(1.)**:

1. The member has demonstrated disease stability or a beneficial response to therapy.

C. Quantity Limitations

When prior authorization is approved, Zymfentra may be authorized in quantities as follows:

Diagnosis	Induction Therapy	Maintenance Therapy

UC, CD	N/A	Two (2) prefilled syringes/pens every four (4) weeks

XXIX. If the patient has already had a trial of at least one biologic agent, the patient is not required to "step back" and try a non-biologic agent.

XXX. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Olumiant for treatment of COVID-19 in hospitalized patients will not be approved under the pharmacy benefit.

II. Combination use of disease modifying MS agents with Zeposia (for example, Aubagio, Gilenya, interferons, Copaxone, Tysabri, etc.) will not be authorized.

III. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

IV. For Commercial NSF members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial NSF Plans:
  - **Multiple Sclerosis Only (Zeposia):** If approved, up to a 24 month authorization may be granted.
  - **All Other Indications:** If approved, up to a 12 month authorization may be granted.
    - Note: For induction therapy authorization duration, refer to the Quantity Limitations tables for the respective drug and diagnosis.

For previous versions of the Commercial and Healthcare Reform policy, please see policy J-0266 and J-0558.

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