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Subject: Adalimumab Products (Humira® and biosimilars)

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Dosage/ Administration	Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions
Related Guidelines	Other	References	Updates		

DESCRIPTION:

Adalimumab (Humira) is one of five commercially available tumor necrosis factor (TNF)-alpha inhibitors, not counting biosimilars as separate products, available in the United States, and was first approved in December 2002. Tumor necrosis factor, a proinflammatory cytokine, initiates the body's defense response to local injury by stimulating the production of inflammatory mediators and signaling immune cells. TNF may augment host defense mechanisms when in low concentration, but large amounts of TNF can lead to excessive inflammation and tissue deterioration. In rheumatoid arthritis, activated T-cells migrate into the synovial lining of the joint where TNF is released and joint destruction begins. The intestinal mucosa from patients with Crohn's disease or ulcerative colitis has been associated with high levels of TNF as compared to healthy individuals; a similar elevation in TNF has been demonstrated in patients with psoriasis.

Humira is approved by the US Food and Drug Administration (FDA) for the treatment of nine indications (the most of any TNF inhibitor): ankylosing spondylitis (2006), Crohn's disease (2007), hidradenitis suppurativa (2015), polyarticular juvenile idiopathic arthritis (2008), plaque psoriasis (2008), psoriatic arthritis (2005), rheumatoid arthritis (2002), ulcerative colitis (2012), and uveitis (2016). In October 2018, the indications for uveitis and hidradenitis suppurativa were expanded to include pediatric patients (2 years of age and older) and adolescent patients (12 years of age and older), respectively. In February 2021, the indication for ulcerative colitis was expanded to include pediatric patients (5 years of age and older). In 2019, AbbVie released a citrate-free formulation of Humira that includes a thinner needle and half the injection volume as compared the original Humira formulation. The changes are intended to reduce the amount of pain immediately following injection. As of January 2021, both formulations are available in the market. In January 2021, AbbVie released an 80 mg/0.8 mL citrate-free pen as an every-other-week alternative dosing option to Humira 40 mg weekly. The only indications FDA-approved for 40 mg weekly dosing (and now 80 mg every-other-week dosing) are hidradenitis suppurativa, pediatric ulcerative colitis (40 kg or greater), and rheumatoid arthritis when used as monotherapy for patients with a suboptimal response to 40 mg every 2 weeks. The National Comprehensive Cancer Network (NCCN) guidelines on the Management of Immune Checkpoint Inhibitor-Related-Toxicities now include all TNF alpha inhibitors as options to be considered for the management of moderate or severe immunotherapy-related inflammatory arthritis if unable to taper corticosteroids after 1 week.

In September 2016 the first biosimilar to adalimumab, adalimumab-atto (Amjevita), was FDA approved. Additional biosimilars have followed: adalimumab-adbm (Cyltezo) approved in August 2017, adalimumab-adaz (Hyrimoz) approved in October 2018, adalimumab-bwwd (Hadlima) approved in July 2019, adalimumab-afzb (Abrilada) approved in November 2019, adalimumab-fkjp (Hulio) approved in July 2020, adalimumab-aqvh (Yusimry) in December 2021, adalimumab-aacf (Idacio) in December 2022, adalimumab-aaty (Yuflyma) in May 2023, and adalimumab-ryvk (Simlandi) in February 2024. In October 2021, Cyltezo was approved by the FDA as the first interchangeable biosimilar product to treat certain inflammatory diseases. Cyltezo is now consider both biosimilar to, and interchangeable with (may be substituted for), its reference product Humira for Cyltezo's approved uses. Simlandi is also interchangeable. Amjevita was the first biosimilar to launch on January 31, 2023. In addition, unbranded adalimumab-aacf, adalimumab-adaz, adalimumab-adbm, and adalimumab-fkjp have also launched as low WAC alternatives to their brand counterparts. The TNF-alpha inhibitors as a class are considered to have similar efficacy and safety for the majority of indications. Similar to other TNF-alpha inhibitors, the package labeling contains a Boxed Warning regarding potential increased risk of serious infections (e.g., tuberculosis) and certain malignancies during therapy.

RHEUMATOID DISORDERS

Ankylosing spondylitis (AS)

Ankylosing spondylitis (AS) is a form of chronic inflammatory arthritis characterized by sacroiliitis, enthesitis, and a marked propensity for sacroiliac joint and spinal fusion. AS is distinguished by universal involvement with sacroiliac joint inflammation or fusion and more prevalent spinal ankylosis. Goals of treatment for AS are to reduce symptoms, maintain spinal flexibility and normal posture, reduce functional limitations, maintain work ability, and decrease disease complications. The mainstays of treatment have been nonsteroidal anti-inflammatory drugs (NSAIDs) and exercise/physical therapy.

NSAIDs are used as first line therapy for patients with active AS, with continuous treatment with NSAIDs being preferred. In patients with stable disease, NSAIDs may be used on-demand to decrease the risk of adverse effects with long term use. No particular NSAID is recommended as a preferred option. Biologics should be used in patients who continue to have persistently high disease activity despite NSAIDs. Failure of standard treatment with NSAIDs can be defined as a lack of response (or intolerance) to at least 2 NSAIDs after at least a 4-week duration of therapy in total.

Tumor necrosis factor (TNF) inhibitors or interleukin (IL)-17 inhibitors are recommended as initial biologic therapy. Other present comorbidities (e.g., inflammatory bowel disease, psoriasis, uveitis) can help guide selection of the initial biologic agent/drug class. Patients who have an inadequate response to a TNF inhibitor or IL-17 inhibitor may switch to a biologic of the other drug class, or switch to a Janus kinase (JAK) inhibitor. Patients with secondary failure to a biologic (presence of antidrug antibodies) may switch to another biologic of the same or different mode of action.

Systemic glucocorticoids should generally not be used in the treatment of AS. Short-term glucocorticoid injections may be used in select patients with peripheral signs and symptoms. Conventional disease-modifying antirheumatic drugs (cDMARDs) (e.g., methotrexate, sulfasalazine, leflunomide) are not recommended as treatment due to their lack of efficacy. However, sulfasalazine may be considered in patients with peripheral arthritis.

Rheumatoid arthritis (RA)

Rheumatoid arthritis (RA) is an inflammatory autoimmune disease that primarily affects the joints but can also damage extra-articular organs. The main goal of therapy is to achieve remission, but additional goals include decreased disease activity, prevention of systemic complications, and improved physical functioning. The choice of therapy depends on several factors, including the severity of disease activity when therapy is initiated and the response of the patient to prior therapeutic interventions. American College of Rheumatology (ACR) guidelines list the following guiding principles in the treatment of RA:

- RA requires early evaluation, diagnosis, and management
- Treatment decisions should follow a shared decision-making process

- Treatment decisions should be reevaluated within a minimum of 3 months based on efficacy and tolerability of the disease-modifying antirheumatic drug(s) (DMARDs) chosen
- Recommendations are limited to DMARDs approved by the US FDA for treatment of RA:
    - Conventional synthetic DMARDs (csDMARDs): hydroxychloroquine, sulfasalazine, methotrexate (MTX), leflunomide
    - Biologic DMARDs (bDMARDs): Tumor necrosis factor (TNF) inhibitors (e.g., etanercept, adalimumab, infliximab, golimumab, certolizumab pegol), T cell costimulatory inhibitor (e.g., abatacept), Interleukin (IL)-6 receptor inhibitors (e.g., tocilizumab, sarilumab), anti-CD20 antibody* (e.g., rituximab)

        *Recommendations referring to bDMARDs exclude rituximab unless patients have had an inadequate response to TNF inhibitors (in order to be consistent with FDA approval) or have a history of lymphoproliferative disorder for which rituximab is an approved therapy
    - Targeted synthetic DMARDs (tsDMARDs): Janus kinase (JAK) inhibitors (e.g., tofacitinib, baricitinib, upadacitinib)
- Triple therapy refers to hydroxychloroquine, sulfasalazine, and either methotrexate or leflunomide
- Biosimilars are considered equivalent to FDA-approved originator bDMARDs
- Treat-to-target refers to a systematic approach involving frequent monitoring of disease activity using validated instruments and modifications of treatment to minimize disease activity with the goal of reaching a predefined target (low disease activity or remission)

ACR guidelines (2021) are broken down by previous treatment and disease activity:

- DMARD-naïve patients with moderate-to-high disease activity initial treatment:
    - MTX monotherapy is strongly recommended over hydroxychloroquine, sulfasalazine, bDMARDs monotherapy, tsDMARD monotherapy, or combination of MTX plus a non-TNF bDMARD or tsDMARD
    - MTX monotherapy is conditionally recommended over leflunomide, dual or triple csDMARD therapy, or combination MTX plus a TNF inhibitor
- DMARD-naïve patients with low disease activity initial treatment
    - Hydroxychloroquine is conditionally recommended over other csDMARDs
    - Sulfasalazine is conditionally recommended over MTX
    - MTX is conditionally recommended over leflunomide
- Initial therapy in csDMARD-treated patients, but MTX naïve, with moderate-to high disease activity:
    - MTX monotherapy is conditionally recommended over combination MTX and a bDMARD or tsDMARD
- Treatment modifications in patients treated with DMARDs who are not at target:
    - Addition of a bDMARD or tsDMARD is conditionally recommended over triple therapy for patients taking maximally tolerated doses of MTX who are not at target
    - Switching to a bDMARD or tsDMARD of a different class is conditionally recommended over switching to a bDMARD or tsDMARD belonging to the same class for patients taking a bDMARD or tsDMARD who are not at target.

The European Alliance of Associations for Rheumatology (EULAR) guidelines for RA (2022 update) also recommend a treat-to-target approach in therapy. MTX is recommended as first line therapy and should be initiated as soon as the diagnosis of RA is made. If MTX is not clinically appropriate, then an alternative csDMARD should be used as part of the (first) treatment strategy. If initial csDMARD therapy does not produce adequate improvement after 3 months, another csDMARD may be added or switched

to as long as poor prognosis factors are absent. In the presence of poor prognosis factors, a bDMARD or JAK inhibitor should be added to csDMARD therapy. If treatment failure occurs with the initial bDMARD or JAK inhibitor, another bDMARD or JAK inhibitor should be considered. If a TNF- or IL-6 receptor inhibitor therapy was initially failed, patients may receive an agent with another mode of action or a second TNF- or IL-6 receptor inhibitor.

Initial dosing of MTX for RA should optimally be 15 mg once weekly, with the dose increased as tolerated and as needed to control signs and symptoms. A fast dose escalation of 5 mg/month to 25-30 mg/week has been associated with higher efficacy, but toxicity with this dosing regimen is a limiting factor. In the presence of sufficient folic acid supplementation, the MTX dose can be rapidly escalated to 25 mg once weekly. The MTX target dose is 25 mg weekly, or the highest tolerable dose.

Polyarticular Juvenile Idiopathic Arthritis (PJIA)

Juvenile idiopathic arthritis (JIA) is arthritis that begins before the 16th birthday and persists for at least 6 weeks with other known conditions excluded. Polyarticular juvenile idiopathic arthritis (PJIA) is a subset of JIA. The ACR defines PJIA as arthritis in more than 4 joints during their disease course and excludes systemic JIA. Treatment goals are aimed at achieving clinically inactive disease and to prevent long-term morbidities, including growth disturbances, joint contractures and destruction, functional limitations, and blindness or visual impairment from chronic uveitis.

The American College of Rheumatology guidelines (2019) (ACR)/Arthritis Foundation recommend the following treatment approach for PJIA:

- Nonsteroidal anti-inflammatory drugs (NSAIDs) are conditionally recommended as adjunct therapy
- Disease modifying antirheumatic drug (DMARD) therapy:
    - Methotrexate (MTX) is conditionally recommended over leflunomide and sulfasalazine
    - Subcutaneous MTX is conditionally recommended over oral MTX
- Intraarticular glucocorticoids are conditionally recommended as adjunct therapy and conditionally recommended for bridging only in patients with moderate to high disease activity
- Strongly recommend against chronic low-dose glucocorticoid use, irrespective of disease activity and/or risk factors
- Strongly recommend combination use of a DMARD and infliximab
- Initial therapy for all patients:
    - DMARD is strongly recommended over NSAID monotherapy
    - MTX monotherapy is conditionally recommended over triple DMARD therapy
    - DMARD is conditionally recommended over a biologic
    - Initial biologic therapy may be considered for patients with risk factors and involvement of high-risk joints (e.g., cervical spine, wrist, hip), high disease activity, and/or those judged by their physician to be at high risk of disabling joint damage
- Subsequent therapy:
    - Low disease activity:
        - Escalating therapy (e.g., intraarticular glucocorticoid injections, optimization of DMARD dose, trial of MTX if not already done, and adding or changing biologic agent)
    - Moderate to high disease activity:
        - Add a biologic to original DMARD over changing to a second DMARD or changing to triple DMARD therapy

        - Switch to a non- tumor necrosis factor (TNF) biologic if currently treated with first TNF-inhibitor ± DMARD over switching to another TNF-inhibitor (unless the patient had good initial response to first TNF-inhibitor)
        - TNF-inhibitor, abatacept, or tocilizumab (depending on prior biologics received) over rituximab after trial of second biologic

Psoriatic Arthritis (PsA)

Psoriatic arthritis (PsA) is a chronic inflammatory musculoskeletal disease associated with psoriasis (PS), most commonly presenting with peripheral arthritis, dactylitis, enthesitis, and spondylitis. Active PsA is defined as symptoms at an unacceptably bothersome level as reported by the patient due to one of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, active skin and/or nail involvement, and/or extraarticular manifestations such as uveitis or inflammatory bowel disease (IBD). Disease severity is based on the assessment of the level of disease activity at a given point in time, and the presence/absence of poor prognostic factors and long-term damage. Severe PsA is defined in the American College of Rheumatology (ACR) and the National Psoriasis Foundation (NPF) guidelines for PsA and includes the presence of one or more of the following:

- Erosive disease
- Elevated markers of inflammation (e.g., erythrocyte sedimentation rate [ESR], C-reactive protein [CRP]) attributable to PsA
- Long-term damage that interferes with function (e.g., joint deformities, vision loss)
- Highly active disease that causes a major impairment in quality of life, such as:
    - Active PsA at many sites including dactylitis and enthesitis
    - Function-limiting PsA at a few sites
- Rapidly progressive disease

Treatment involves the use of a variety of interventions, including many agents used for the treatment of other inflammatory arthritis disorders, particularly spondyloarthritis and rheumatoid arthritis, and other management strategies of the cutaneous manifestations of psoriasis. Symptomatic treatments include nonsteroidal anti-inflammatory drugs (NSAIDs), glucocorticoids, and local glucocorticoid injections. Only patients with very mild peripheral disease may sufficiently benefit from NSAIDs as monotherapy, and instead patients are typically treated with disease-modifying antirheumatic drugs (DMARDs) and/or biologics. Efficacy of DMARD and biologic therapies should be assessed 3 months after initiation, and if adequate improvement is not seen then the treatment regimen should be updated or changed. The ACR-NPF guidelines for PsA recommend a treat-to-target approach in therapy, regardless of disease activity, and treatment recommendations for active disease are as follows:

- Treatment naïve patients:
    - First line options include oral small molecules (OSM), tumor necrosis factor (TNF) inhibitors, interleukin (IL)-17 inhibitors, and IL-12/23 inhibitors
        - OSM (i.e., methotrexate [MTX], sulfasalazine, cyclosporine, leflunomide, apremilast) should be considered if the patient does not have severe PsA, does not have severe PS, prefers oral therapy, has concern over starting a biologic, or has contraindications to TNF inhibitors
        - Biologics (e.g., TNF inhibitor, IL-17 inhibitor, IL-12/23 inhibitor) are recommended as a first line option in patients with severe PsA and/or severe PS
- Previous treatment with OSM and continued active disease:
    - Switch to a biologic (i.e., TNF inhibitor, IL-17 inhibitor, IL-12/23 inhibitor); recommended over switching to a different OSM
        - Biologic monotherapy is conditionally recommended over biologic plus MTX combination therapy

- Switch to a different OSM (except apremilast) OR add on apremilast to current OSM therapy; recommended over adding another OSM
- Add another OSM (except apremilast) to current OSM therapy; may consider for patients that have exhibited partial response to current OSM
- Switch to apremilast monotherapy; may be considered instead of adding apremilast to current OSM therapy if the patient has intolerable side effects with the current OSM

- Previous treatment with a biologic and continued active disease:
  - Switch to another biologic (e.g., TNF inhibitor, IL-17 inhibitor, IL-12/23 inhibitor, abatacept, or tofacitinib) as monotherapy
  - Add MTX to the current biologic; may consider adding MTX in patients with a partial response to current biologic therapy

The European Alliance of Associations for Rheumatology (EULAR) guidelines for PsA (2023 update) also recommend a treat-to-target approach in therapy. MTX (preferred) or another conventional synthetic disease-modifying antirheumatic drug (csDMARD) (e.g., sulfasalazine, leflunomide) should be used for initial therapy. If the treatment target is not achieved with a csDMARD, a biologic should be initiated with preference of product being based on patient specific disease characteristics. Biologics include TNF inhibitors, IL-12/23 inhibitors, IL-17A inhibitors, IL-17A/F inhibitors, IL-23 inhibitors, and cytotoxic T-lymphocyte–associated antigen 4 (CTLA4) analogs. No order of preference of biologics is provided since none have demonstrated superiority for joint involvement, however, CTLA4 analogs are least preferred due to limited efficacy in clinical trials. The use of a Janus kinase (JAK) inhibitor (e.g., tofacitinib, upadacitinib) may be used after failure of a biologic or if biologics are not clinically appropriate for the patient. However, careful consideration should be applied prior to using a JAK inhibitor due to the increased risk of cardiovascular and malignancy events in older patients with RA and cardiovascular risk factors. A phosphodiesterase-4 (PDE4) inhibitor (i.e., apremilast) may be considered in patients with mild disease and an inadequate response to at least one csDMARD, in whom neither a biologic nor a JAK inhibitor is appropriate. Patients with an inadequate response to a biologic or JAK inhibitor may switch to a different drug within the same class or switch to a different mode of action. Adding MTX to a biologic may increase drug survival by limiting the development of antidrug antibodies, especially for TNF inhibitors.

DERMATOLOGICAL DISORDERS

Psoriasis (PS)

Psoriasis (PS) is a chronic inflammatory skin and systemic disorder. It is a complex disease that affects the skin and joints and is associated with numerous comorbidities, including obesity and inflammatory bowel disease. Psoriasis vulgaris, or plaque psoriasis, is a cutaneous form that often presents with pink plaques with silvery scale on the scalp, elbows, knees, or presacral region, but any area of the skin may be involved. Plaque psoriasis is the most common form (affecting 90% of adults with psoriasis), but others include guttate, erythrodermic, pustular, inverse, nail, and psoriatic arthritis (PsA). PS is clinically diagnosed based on the presence of cutaneous and systemic symptoms, and treatment is similar for most forms but is guided by the body surface area (BSA) involved. The American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) categorize psoriasis severity as mild (less than 3% of BSA), moderate (3% to 10% of BSA), or severe (greater than 10% of BSA). The AAD/NPF guidelines also note that psoriasis can be considered severe irrespective of BSA when it causes serious emotional consequences, occurs in select locations (e.g., hands, feet, scalp, face, or genital area), or when it causes intractable pruritus.

Topical therapies are most commonly used to treat mild to moderate PS, but they may be used in combination with phototherapy, systemic, or biologic therapies for the treatment of moderate to severe PS. Topical therapies alone can be sufficient for managing limited disease and also have fewer significant adverse effects compared to systemic treatment options. However, topical therapies may be inadequate to obtain and maintain skin clearance, and systemic therapies may be warranted. Conventional systemic

agents are widely used as monotherapy or in combination with biologics for moderate to severe disease, and they are beneficial for widespread disease and ease of administration. Biologics are routinely used when one or more conventional agents fail to produce an adequate response but are considered first line in patients with severe PS or patients with concomitant severe PsA. The NPF medical board recommends a treat-to-target approach to therapy for psoriasis that includes the following:

- The preferred assessment instrument for determining treatment response is BSA
- The preferred time to perform initial evaluation of treatment response is after 3 months
- Target response after treatment initiation should be BSA less than or equal to 1% after 3 months
- Acceptable response is either a BSA less than or equal to 3% or a BSA improvement greater than or equal to 75% from baseline at 3 months after treatment initiation

Selection of treatment is based on several factors including benefit-risk assessment, clinical presentation, disease severity, and comorbidities. The AAD/NPF psoriasis treatment guidelines support the following treatment options:

- Topical therapies:
    - Topical corticosteroids (TCS)
    - Topical calcineurin inhibitors (TCIs), such as tacrolimus and pimecrolimus
    - Vitamin D analogues (e.g., calcipotriene and calcitriol)
    - Tazarotene (topical retinoid)
    - Coal tar preparations
    - Topical anthralin
- Psoralen plus ultraviolet light (PUVA) phototherapy
- Systemic non-biologic therapies:
    - Methotrexate (MTX)
    - Cyclosporine
    - Acitretin
    - Apremilast
- Biologic therapies:
    - Tumor necrosis factor (TNF)-α inhibitors (e.g., adalimumab, certolizumab, etanercept, infliximab)
    - Interleukin (IL)-17 inhibitors (e.g., brodalumab, ixekizumab, secukinumab)
    - IL-23 inhibitors (e.g., guselkumab, risankizumab, tildrakizumab)
    - IL-12/IL-23 Inhibitors (e.g., ustekinumab)

      *Note: Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics was published in 2019. No specific biologic drug/class is recommended as first-line for all patients with psoriasis, and instead choice of therapy should be individualized based on patient specific factors. Additional biologic drugs have since received FDA approval for psoriasis that are not discussed.

Primary failure for biologics is defined as initial nonresponse to treatment. Primary failure to a tumor necrosis factor (TNF)-α inhibitor does not preclude successful response to a different TNF-α inhibitor, and failure of another biologic therapy does not preclude successful response to ustekinumab. All biologics may lose efficacy in a patient who initially responds favorably to the medication (secondary failure), and loss of efficacy may be attributed to the presence of antidrug antibodies. The concomitant use of MTX with a biologic may increase drug survival by limiting antibody formation.

For the treatment of PS in the pediatric patient population, topical corticosteroids are the mainstay option based on extensive clinical experience that supports efficacy. Topical calcineurin inhibitors are also a treatment option and may be preferred for psoriasis of the face, genitalia, and body folds. Vitamin D analogues are recommended as a treatment option for childhood plaque psoriasis and are considered safe, effective, and generally well tolerated. Other topical therapies that may be used for the treatment of pediatric psoriasis include tazarotene, anthralin, and coal tar. Phototherapy may be efficacious and well tolerated for pediatric patients with generalized psoriasis or localized psoriasis refractory to topical agents. Systemic non-biologic therapies, such as methotrexate, cyclosporine, and acitretin, are options for moderate to severe psoriasis. Biologic therapies (e.g., adalimumab, etanercept, infliximab, ustekinumab) have also shown efficacy in moderate to severe plaque psoriasis in this patient population.

Hidradenitis Suppurativa (HS)

Hidradenitis suppurativa (HS) is a chronic inflammatory disease causing painful, nodules to form in the folds of the skin and often secrete puss and blood. HS can be described as mild (single or few lesions in one area of the skin, Hurley Stage I), moderate (repeated cycles of enlarged lesions that break open and occur in more than one area of the skin, Hurley Stage II), and severe (widespread lesions, scarring, and chronic pain; Hurley Stage III).

Pharmacological treatment for mild HS includes topical clindamycin, oral tetracyclines, hormonal treatment, retinoids, intralesional corticosteroid injections (i.e., triamcinolone), and deroofing. Oral tetracyclines are recommended for mild to moderate HS for at least a 12 weeks course or as long-term maintenance. Combination clindamycin and rifampin is effective second-line therapy for mild to moderate HS, or as first-line or adjunct therapy for severe HS. Combination rifampin, moxifloxacin, and metronidazole are recommended as second or third-line therapy for moderate to severe disease. Dapsone may be effective for a minority of patients with mild to moderate HS as long-term maintenance therapy. Oral retinoids, such as acitretin and isotretinoin, have also been used for mild HS as second or third-line therapy. Hormonal therapy may be considered in female patients for mild to moderate disease as monotherapy, or as adjunct therapy for severe disease. such as hormonal contraceptives, metformin, finasteride, and spironolactone.

Treatment recommendations for moderate to severe and refractory HS include immunosuppressants (e.g., cyclosporine and low dose systemic corticosteroids) and biologic agents. The TNF-inhibitors that are recommended are adalimumab, at doses within FDA labeling, and infliximab, but optimal doses have not been established. Anakinra and ustekinumab may be effective, but require dose ranging studies to determine optimal doses for management.

INFLAMMATORY BOWEL DISEASE

Crohn’s Disease (CD)

Crohn’s disease (CD) is a chronic inflammatory bowel disease with genetic, immunologic, and environmental influences. It can affect any portion of the gastrointestinal tract but involves the small intestine and proximal colon most often. The most common symptom is diarrhea, but abdominal pain, fatigue, fever, weight loss, and vomiting are also prevalent. Symptoms typically occur as a chronic, intermittent course, with only a minority of patients having continuously active symptomatic disease or a prolonged remission. In most cases, CD is a chronic, progressive, destructive disease. Early diagnosis and management of CD can lead to better outcomes and less negative impact on quality of life.

Patients are considered to have moderate to severe disease if they have failed to respond to treatment for mild to moderate disease, or if they present with more prominent symptoms of CD. Inflammation-related biomarkers are more likely to be abnormal, and greater endoscopic disease burden is typical. This includes larger or deeper ulcers, strictures, or extensive areas of disease and/or evidence of stricturing, penetrating, or perianal disease. The International Organization for the Study of Inflammatory Bowel Diseases characterizes patients with severe disease as having at least 10 loose stools per day, daily abdominal pain, presence of anorectal symptoms, systemic corticosteroid use within the prior year, lack of symptomatic improvement despite prior exposure to biologics and/or immunosuppressive agents, or significant impact of the disease on activities of daily living. They are also at a high risk for adverse

disease-related complications, including surgery, hospitalization, and disability, based on a combination of structural damage, inflammatory burden, and impact of quality of life. Patients with severe disease may have large or deep mucosal lesions on endoscopy or imaging, presence of fistula and/or perianal abscess, presence of strictures, prior intestinal resections, presence of a stoma, and/or extensive disease (e.g., involvement of long bowel segments, pancolitis).

The choice of therapy in CD is dependent on the anatomic location of the disease, the severity of disease, and whether the treatment is needed to induce remission or maintain remission. The goal of treatment for induction of remission is to achieve clinical response and control of inflammation within 3 months of treatment initiation. After inducing clinical remission, patients should be transitioned to steroid-sparing maintenance therapy. In the absence of immunomodulator or biologic treatment, corticosteroid dependency and/or resistance occurs in up to half of patients. In general, the drug(s) used for induction of remission should be continued as maintenance therapy, with the exception of corticosteroids.

The American Gastroenterological Association (AGA) 2021 guideline provides the following recommendations and guidance:

- Biologic therapy:
    - The AGA suggest early introduction with a biologic, with or without an immunomodulator, rather than delaying their use until after failure of 5-aminosalicylates and/or corticosteroids (Conditional recommendation, low certainty of evidence)
        - Earlier therapy with a biologic may result in overtreating some patients and potentially exposing them to treatment-related risks and costs with limited benefit. However, step-up therapy comes with a potential risk of harm from disease progression related to inadequate disease therapy.
    - Anti-tumor necrosis factor (TNF) (i.e., infliximab or adalimumab) and ustekinumab are recommended over no treatment for the induction and maintenance of remission
    - Vedolizumab is suggested over no treatment for the induction and maintenance of remission
    - AGA suggests against the use of natalizumab over no treatment for the induction and maintenance of remission
    - Patients naïve to biologic therapy, the AGA recommends infliximab, adalimumab, or ustekinumab over certolizumab pegol and suggests the use of vedolizumab over certolizumab pegol for the induction of remission
    - Patients with primary non-response to anti-TNF, the AGA recommends ustekinumab and suggests vedolizumab for induction of remission
    - Patients with secondary non-response to infliximab, the AGA recommends use of adalimumab or ustekinumab and suggests the use of vedolizumab for the induction of remission (if adalimumab was the first line drug, there is indirect evidence to suggest using infliximab as a second-line agent)
- Corticosteroid therapy:
    - Corticosteroids are suggested over no treatment for the induction of remission, and are recommended against for maintenance of remission
        - In patients with CD involving the distal ileum and/or ascending colon who are more concerned about systemic corticosteroids and less concerned about the lower efficacy, they may reasonably choose budesonide over systematic corticosteroids for inducing remission
- Disease modifying antirheumatic drug (DMARD) therapy:
    - Patients in corticosteroid induced remission or with quiescent moderate to severe CD, the AGA suggests thiopurines for maintenance of remission
    - Subcutaneous or intramuscular methotrexate are suggested over no treatment for the induction and maintenance of remission

    - The AGA recommends against the use of 5-aminosalicylates or sulfasalazine over no treatment for the induction or maintenance of remission
    - The AGA suggests against the use of thiopurines over no treatment for achieving remission and recommends biologic drug monotherapy over thiopurine monotherapy for induction of remission
    - The AGA suggests against the use of oral methotrexate monotherapy over no treatment for the induction and maintenance of remission
- Combination therapy:
    - Patients that are naïve to biologics and immunomodulators, the AGA suggest use of infliximab in combination with thiopurines over infliximab monotherapy for the induction and maintenance of remission (combination infliximab with methotrexate may be more effective over infliximab monotherapy)
    - Patients that are naïve to biologics and immunomodulators, the AGA suggest use of adalimumab in combination with thiopurines over adalimumab monotherapy for the induction and maintenance of remission (combination adalimumab with methotrexate may be more effective over adalimumab monotherapy)
    - No recommendations are being made regarding the use of ustekinumab or vedolizumab in combination with thiopurines or methotrexate over biologic monotherapy for induction or maintenance or remission

The American College of Gastroenterology (ACG) 2025 guideline provides the following recommendations and guidance:

- Biologic therapy:
    - Biologic agents are effective for treating patients with active CD and previous inadequate response to corticosteroids, thiopurines, and/or methotrexate
    - Suggest against requiring failure of conventional therapy before initiation of advanced therapy for the management of CD (conditional recommendation, low level of evidence)
        - The risk of adverse effects and high cost of biologic agents may not be justifiable in a lower risk population
    - Recommend the following drugs for induction and maintenance of remission for moderately to severely active CD:
        - Anti-TNF agents (i.e., infliximab, adalimumab, certolizumab), vedolizumab, ustekinumab, risankizumab, mirikizumab, guselkumab
    - Recommend combination therapy of intravenous infliximab with immunomodulators (thiopurines) as compared with treatment with either immunomodulators alone or intravenous infliximab alone in patients with CD who are naïve to those agents
    - Recommend the use of risankizumab as compared with ustekinumab in patients with moderate to severe CD and prior exposure to anti-TNF therapy
    - Biosimilar infliximab, adalimumab, and ustekinumab are effective treatments for patients with moderate-to-severe CD and can be used for de novo induction and maintenance therapy
    - There are data to support the safety and efficacy of transitioning or switching to biosimilar infliximab or adalimumab for patients with CD in stable disease maintenance
- Janus kinase (JAK) inhibitor therapy:
    - Recommend upadacitinib use for induction and maintenance of remission for patients with moderate-to-severe CD who have previously been exposed to anti-TNF agents
- Corticosteroid therapy:

    - Recommend oral corticosteroids for short-term induction of remission in patients with moderately to severely active CD
        - Recommend controlled ileal release budesonide at a dose of 9 mg daily for induction of symptomatic remission in patients with mildly to moderately active ileocecal CD
    - Corticosteroids should not be used for maintaining remission, and their use should not exceed 3 continuous months without attempting to introduce a steroid-sparing agent (such as an immunomodulator)
- DMARD therapy:
    - Recommend against azathioprine or 6-mercaptopurine for induction of remission in moderately to severely active CD
        - Due to their slow onset of action of 8 to 12 weeks, thiopurines are not effective agents for induction of remission
    - Suggest azathioprine or 6-mercaptopurine for maintenance of remission in patients with moderately to severely active CD who had induction of remission with corticosteroids
    - Suggest methotrexate (up to 25 mg once weekly intramuscular or subcutaneous) for maintenance of remission in patients with moderately to severely active CD who had induction of remission with corticosteroids
    - Azathioprine, 6-mercaptopurine, or methotrexate may be used in the treatment of active CD and as adjunctive therapy for reducing immunogenicity associated with anti-TNF therapy

Ulcerative Colitis (UC)

Ulcerative colitis (UC) is a chronic inflammatory bowel disease affecting the large intestine. It typically starts with inflammation of the rectum, but often extends proximally to involve additional areas of the colon. The most common symptom is bloody diarrhea, but urgency, tenesmus, abdominal pain, malaise, weight loss, and fever can also be associated. UC commonly has a gradual onset and will present with periods of spontaneous remission and subsequent relapses.

Disease severity is based on patient-reported outcomes (e.g., bleeding, bowel habits, bowel urgency), inflammatory burden (e.g., endoscopic assessment, inflammatory markers), disease course, and disease impact. Commonly assessed symptoms include frequency and timing of bowel movements, rectal bleeding, bowel urgency, abdominal pain, bowel cramping, and weight loss. Poor prognostic factors include less than 40 years of age at diagnosis, extensive colitis, severe endoscopic disease, hospitalization for colitis, elevated C-reactive protein (CRP), and low serum albumin. Therapeutic management in UC should be guided by the extent of bowel involvement, assessment of disease activity (i.e., quiescent, mild, moderate, or severe), and disease prognosis. Treatment response should be evaluated 12 weeks after initiation of therapy to confirm efficacy and safety.

The American College of Gastroenterology (ACG) published recommendations and guidance (2025) for the management of moderate-to-severe UC:

<u>General treatment information</u>:

- Patients with mildly to moderately active UC and a number of prognostic factors associated with an increased risk of hospitalization or surgery should be treated with therapies for moderate-to-severe disease
- Patients with mildly to moderately active UC who are not responsive (or are intolerant) to 5-aminosalicylate (5-ASA) therapies (e.g., balsalazide, mesalamine, sulfasalazine) should be treated as patients with moderate-to-severe disease

<u>Corticosteroid therapy</u>:

- In patients with moderately active UC, recommend oral budesonide multi-matrix system (MMX) for induction of remission

- In patients with moderately active UC, consider nonsystemic corticosteroids such as budesonide MMX before the use of systemic therapy

- Recommend oral systemic corticosteroids to induce remission in UC of any extent
  - In patients with severely active UC, consider systemic corticosteroids rather than topical corticosteroids
- Recommend against systemic, budesonide MMX, or topical corticosteroids for maintenance of remission

Disease modifying antirheumatic drug (DMARD) therapy:

- Recommend against monotherapy with thiopurines or methotrexate for induction of remission
- 5-ASA therapy could be used as monotherapy for induction of moderately but not severely active UC
- 5-ASA therapy for maintenance of remission is likely not as effective in prior severely active UC as compared with prior moderately active UC
- Suggest thiopurines for maintenance of remission in patients now in remission due to corticosteroid induction
- Suggest against using methotrexate for maintenance of remission

Biologic/advanced therapy:

- Recommend the following drugs for induction of remission and continuing the same drug for maintenance of remission:
  - Anti-tumor necrosis factor (TNF) agents (e.g., infliximab, adalimumab, golimumab), ustekinumab, guselkumab, mirikizumab, risankizumab, vedolizumab, tofacitinib, upadacitinib, sphingosine-1-phosphate (S1P) receptor modulators (e.g., ozanimod, etrasimod)
  - Most clinical trials and available data demonstrate a benefit of using the steroid-sparing therapy that induces remission to maintain that remission
- When infliximab is used as induction therapy, recommend combination therapy with a thiopurine
  - Data on combination anti-TNF and immunomodulators in moderately to severely active UC only exist for infliximab and thiopurines
- Infliximab is the preferred anti-TNF therapy for patients with moderately to severely active UC
- Recommend vedolizumab as compared to adalimumab for induction and maintenance of remission
- Patients who are primary nonresponders to an anti-TNF (defined as lack of therapeutic benefit after induction and despite sufficient serum drug concentrations) should be evaluated and considered for alternative mechanisms of disease control (e.g., in a different class of therapy) rather than cycling to another drug within the anti-TNF class
- Biosimilars to anti-TNF therapies and to ustekinumab are acceptable substitutes for originator therapies. Delays in switching should not occur and patients and clinicians should be notified about such changes

The American Gastroenterology Association (AGA) published recommendations and guidance (2018) for the management of mild-to-moderate UC:

- In patients with moderate disease activity, suggest using high dose mesalamine (greater than 3 g/day) with rectal mesalamine for induction of remission and maintenance of remission
- Add either oral prednisone or budesonide MMX in patients that are refractory to optimized oral and rectal 5-ASA, regardless of disease extent

- If progression to moderate-to-severe disease activity occurs, or if the patient is at high risk for colectomy despite therapy, consider escalating to treatment for moderate-to-severe disease with immunomodulators and/or biologics

The American Gastroenterology Association (AGA) published recommendations and guidance (2024) for the management of moderate-to-severe UC:

General treatment information:

- Suggest early use of advanced therapy (e.g., biologics, ozanimod, etrasimod), with or without immunomodulator therapy (e.g., thiopurines), rather than treatment with 5-ASA and a gradual step up to biologic/immunomodulator therapy after 5-ASA treatment failure (conditional recommendation, very low certainty of evidence)
    - Patients with less severe disease or those who place a higher value on the safety of 5-ASA therapy over the efficacy of immunosuppressives may reasonably choose gradual step therapy with 5-ASA therapy

DMARD therapy:

- Suggest against using thiopurine monotherapy for inducing remission
- Suggest thiopurine monotherapy may be used for maintaining remission typically induced with corticosteroids
- Suggest against using methotrexate monotherapy for inducing or maintaining remission

Advanced therapy:

- Recommend using one of the following advanced therapies over no treatment:
    - Infliximab, golimumab, vedolizumab, tofacitinib, upadacitinib, ustekinumab, ozanimod, etrasimod, risankizumab, guselkumab
- Suggest using one of the following advanced therapies over no treatment:
    - Adalimumab, filgotinib*, mirikizumab (*not currently approved by the Food and Drug Administration)
- Biosimilars of infliximab, adalimumab, and ustekinumab can be considered equivalent to their originator drug in their efficacy
- Suggest the use of infliximab in combination with an immunomodulator over infliximab or an immunomodulator alone
- Suggest the use of adalimumab or golimumab in combination with an immunomodulator over adalimumab, golimumab or immunomodulator monotherapy

Advanced therapy-naïve patients (first-line therapy):

- Suggest that a higher or intermediate efficacy medication be used rather than a lower efficacy medication
    - Higher efficacy: infliximab, vedolizumab, ozanimod, etrasimod, upadacitinib, risankizumab, guselkumab
    - Intermediate efficacy: golimumab, ustekinumab, tofacitinib, filgotinib, mirikizumab
    - Lower efficacy: adalimumab

Prior exposure to one or more advanced therapies, particularly TNF antagonists:

- Suggest that a higher or intermediate efficacy medication be used rather than a lower efficacy medication
    - Higher efficacy: tofacitinib, upadacitinib, ustekinumab

- Intermediate efficacy: filgotinib, mirikizumab, risankizumab, guselkumab
- Lower efficacy: adalimumab, vedolizumab, ozanimod, etrasimod

OTHER DISORDERS

Uveitis

Uveitis is characterized by inflammation of the portion of the eye known as the uvea, with the anterior portion of uvea including the iris and ciliary body and the posterior portion being the choroid. Uveitis can cause redness, pain, decreased or loss of vision, worsening field changes, and floaters involving the eye. Uveitis is subdivided into four types based on the primary anatomical location of the inflammation: anterior, intermediate, posterior, and panuveitis. Intermediate uveitis is defined by inflammation of the vitreous cavity and pars plana, posterior uveitis involves the retina and choroid, and panuveitis includes all layers. Uveitis can be caused by infections, inflammatory diseases, or trauma, or be idiopathic in nature.

The goal of treatment in uveitis is to suppress ocular inflammation and achieve an inactive disease state or drug-induced remission. Treatment of non-infectious uveitis (NIU) depends on the location of inflammation. Intermediate, posterior, and panuveitis treatment is complex and should be guided by an ophthalmologist or uveitis specialist. NIU should be treated early and aggressively to prevent complications and preserve sight, with corticosteroids being used initially to suppress inflammation. Oral corticosteroids are the mainstay of treatment, but periocular or intravitreal corticosteroid injections may also be used to limit systemic effects. Treatment with conventional systemic agents (i.e., azathioprine, mycophenolate, methotrexate[MTX], cyclosporine, tacrolimus) may be introduced to control persistent or severe inflammation, or to prevent ocular structural complications. They may also be used if there is a need for a corticosteroid-sparing effect in chronic disease or to maintain disease remission. MTX is used most commonly, with mycophenolate being used if MTX was ineffective, not tolerated, or contraindicated. A conventional immunomodulatory agent should be used for at least three months before assuming that it is not effective.

Adalimumab, a tumor necrosis factor (TNF)-inhibitor, is generally considered for treatment in patients whose disease is inadequately controlled by corticosteroids and conventional systemic agents. TNF-inhibitors are effective in most cases, but they may eventually lose their effect and require an escalation in dose. This loss of effect is primarily due to an immune response targeting the drug itself. The concurrent use of an antimetabolite (e.g., MTX or mycophenolate) may prolong the effectiveness of the biologic.

POSITION STATEMENT:

Comparative Effectiveness

The Food and Drug Administration has deemed the drug(s) or biological product(s) in this coverage policy to be appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional). Therefore, coverage (i.e., administration) in a provider-administered setting such as an outpatient hospital, ambulatory surgical suite, physician office, or emergency facility is not considered medically necessary.

NOTE: The list of self-administered products with prerequisites for certain indications can be found at Preferred Agents and Drug List.

Initiation of Adalimumab-aaty, Adalimumab-adaz, Hadlima (adalimumab-bwwd), Humira (adalimumab), or Simlandi (adalimumab-ryvk) [i.e., a preferred adalimumab product] meets the definition of medical necessity when **ALL** of the following are met (“1” to “5”):

1. **ONE** of the following (“a”, “b”, or “c”):
    a. The member has been treated with the requested preferred adalimumab product (starting on samples is not approvable) within the past 90 days

b. The prescriber states the member has been treated with the requested preferred adalimumab product (starting on samples is not approvable) within the past 90 days, **AND** is at risk if therapy is changed

c. **BOTH** of the following ('i" and "ii"):

a. The requested preferred adalimumab product will be used for the treatment of an indication listed in Table 1, and **ALL** of the indication-specific criteria are met

b. **EITHER** of the following if the member has an FDA-approved indication ("I" or "II")

i. The member's age is within FDA labeling for the requested indication for the requested preferred adalimumab product

ii. The prescriber has provided information in support of using the requested preferred adalimumab product for the member's age for the requested indication

2. The prescriber is a specialist in the area of the member's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for HS, PS) or the prescriber has consulted with a specialist in the area of the member's diagnosis

3. Member does **NOT** have any FDA labeled contraindications to the requested preferred adalimumab product

4. Member will **NOT** be using the requested preferred adalimumab product in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Leqselvi (deuruxolitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Olumiant (baricitinib), Rinvoq/Rinvoq LQ (upadacitinib), and Xeljanz/Xeljanz XR (tofacitinib)]; Otezla/Otezla XR (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]

5. **ANY** of the following ("a", "b", "c", or "d"):

a. The dosage does not exceed:

- Loading dose
  - Adult AS, PsA, and RA: no loading dose required
  - PJIA and pediatric uveitis: no loading dose required
  - Adult CD and UC: Initial dose of 160 mg on day 1, 80 mg on day 15, then maintenance dose starting on day 29
    - QL: Humira Crohn's Disease, Ulcerative Colitis, or Hidradenitis Starter kit [40 mg/0.8 mL pen] - 1 kit (6 pens)/180 days
    - QL: Humira Crohn's Disease, Ulcerative Colitis, or Hidradenitis Starter kit [40 mg/0.4 mL pen (citrate-free)] - 1 kit (6 pens)/180 days
    - QL: Humira Crohn's disease, Ulcerative colitis, or Hidradenitis suppurativa Starter kit [80 mg/0.8 mL pen] - 1 kit (3 pens)/180 days
    - QL: Three Humira 80 mg syringes or pens/autoinjectors (28-day supply)
    - QL: Six Hadlima or Humira 40 mg syringes or pens/autoinjectors (28-day supply)
  - Pediatric CD:
    - 17 kg to <40 kg: Initial dose of 80 mg on day 1, 40 mg on day 15, then maintenance dose starting on day 29
      - QL: Humira Pediatric Crohn's Starter Kit [40 mg/0.8mL (3 syringe pack)] - 1 kit (3 syringes)/180 day
      - QL: Humira Pediatric Crohn's Disease Starter kit [40 mg/0.4 mL and 80 mg/0.8 mL syringe (citrate-free)]- 1 kit (2 syringes)/180 days

- QL: Three Hadlima or Humira 40 mg syringes or pens/autoinjectors (28-day supply)

- ≥40 kg: 160 mg on day 1, 80 mg on day 15, then maintenance dose starting on day 29
  - QL: Humira Pediatric Crohn's Starter Kit [40 mg/0.8mL (6 syringe pack)] - 1 kit (6 syringes)/180 days
  - QL: Humira Pediatric Crohn's Disease Starter kit [80 mg/0.8 mL syringe (citrate-free)]- 1 kit (3 syringes)/180 days
  - QL: Three Humira 80 mg syringes or pens/autoinjectors (28-day supply)
  - QL: Six Hadlima or Humira 40 mg syringes or pens/autoinjectors (28-day supply)

- Pediatric UC:
  - 20 kg to <40 kg: Initial dose of 80 mg on day 1, 40 mg on days 8 and 15, and then maintenance dose starting on day 29
    - QL: Humira Psoriasis, Uveitis or Adolescent Hidradenitis Suppurativa Starter kit [80 mg/0.8 mL and 40 mg/0.4 mL pen] - 1 kit (3 pens)/180 days
    - QL: Four Hadlima or Humira 40 mg syringes or pens/autoinjectors (28-day supply)
  - ≥40 kg: Initial dose of 160 mg (single dose or split over two consecutive days) on day 1, 80 mg on days 8 and 15, and then maintenance dose starting on day 29
    - QL: Humira Pediatric Ulcerative Colitis Starter kit [80 mg/0.8 mL pen (citrate-free)] - 1 kit (4 pens)/180 day
    - QL: Four Humira 80 mg syringes or pens/autoinjectors (28-day supply)
    - QL: Eight Hadlima or Humira 40 mg syringes or pens/autoinjectors (28-day supply)
- PS and adult uveitis: Initial dose of 80 mg, then maintenance dose starting one week after the initial dose
  - QL: Humira Psoriasis, Uveitis, or Adolescent Hidradenitis Suppurativa Starter kit [40 mg/0.8 mL pen] - 1 kit (4 pens)/180 days
  - QL: Humira Psoriasis, Uveitis, or Adolescent Hidradenitis Suppurativa Starter kit [40 mg/0.4 mL pen (citrate-free)] - 1 kit (4 pens)/180 days
  - QL: Humira Psoriasis, Uveitis, or Adolescent Hidradenitis Suppurativa Starter kit [80 mg/0.8 mL and 40 mg/0.4 mL pen] - 1 kit (3 pens)/180 days
  - QL: Four Hadlima or Humira 40 mg syringes or pens/autoinjectors (28-day supply)
- Adult HS: Initial dose of 160 mg day 1, 80 mg on day 15, then maintenance dose starting on day 29
  - QL: Humira Crohn's Disease, Ulcerative Colitis, or Hidradenitis Starter kit [40 mg/0.8 mL pen] - 1 kit (6 pens)/180 days
  - QL: Humira Crohn's Disease, Ulcerative Colitis, or Hidradenitis Starter kit [40 mg/0.4 mL pen (citrate-free)] - 1 kit (6 pens)/180 days
  - QL: Humira Crohn's disease, Ulcerative Colitis, or Hidradenitis Suppurativa Starter kit [80 mg/0.8 mL pen (citrate-free)] - 1 kit (3 pens)/180 days
  - QL: Three Humira 80 mg syringes or pens/autoinjectors (28-day supply)
  - QL: Six Hadlima or Humira 40 mg syringes or pens/autoinjectors (28-day supply)

- Adolescent HS:
  - 30 kg to <60 kg: Initial dose of 80 mg on day 1, then maintenance dose starting on day 8
    - QL: Humira Psoriasis, Uveitis or Adolescent Hidradenitis Suppurativa Starter kit [40 mg/0.8 mL pen] - 1 kit (4 pens)/180 days
    - QL: Humira Psoriasis, Uveitis, or Adolescent Hidradenitis Suppurativa Starter kit [40 mg/0.4 mL pen (citrate-free)] - 1 kit (4 pens)/180 days
    - QL: Humira Psoriasis, Uveitis or Adolescent Hidradenitis Suppurativa Starter kit [80 mg/0.8 mL and 40 mg/0.4 mL pen] - 1 kit (3 pens)/180 days
    - QL: Five Hadlima or Humira 40 mg syringes or pens/autoinjectors (28-day supply)
  - ≥60 kg: 160 mg on day 1, 80 mg on day 15, then maintenance dose starting on day 29
    - QL: Humira Crohn's Disease, Ulcerative Colitis, or Hidradenitis Starter kit [40 mg/0.8 mL pen] - 1 kit (6 pens)/180 days
    - QL: Humira Crohn's Disease, Ulcerative Colitis, or Hidradenitis Starter kit [40 mg/0.4 mL pen (citrate-free)] - 1 kit (6 pens)/180 days
    - QL: Humira Crohn's disease, Ulcerative Colitis, or Hidradenitis Suppurativa Starter kit [80 mg/0.8 mL pen (citrate-free)] - 1 kit (3 pens)/180 days
    - QL: Three Humira 80 mg syringes or pens/autoinjectors (28-day supply)
    - QL: Six Hadlima or Humira 40 mg syringes or pens/autoinjectors (28-day supply)
- Maintenance dose - 40 mg every 2 weeks (14 days) [for HS, pediatric UC (greater than 40 kg), and RA monotherapy ONLY - 40 mg once a week (every 7 days) or 80 mg every 2 weeks (14 days)]
  - QL: 10 mg syringe - 2 syringes/28 days
  - QL: 20 mg syringe - 2 syringes/28 days
  - QL: 40 mg syringe - 2 syringes/28 days
  - QL: 40 mg autoinjector/pen - 2 pens/28 days
  - QL: 40 mg vial - 2 vials/28 days
  - QL: 80 mg autoinjector/pen (Humira only) - 2 pens/28 days

b. The member has an FDA labeled indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):

   i. The requested quantity (dose) does **NOT** exceed the maximum FDA labeled dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

   ii. **ALL** of the following ("1", "2", and "3"):

      1. The requested quantity (dose) exceeds the FDA maximum labeled dose for the requested indication
      2. The member has tried and had an inadequate response to at least a 3-month trial of the maximum FDA labeled dose for the requested indication (medical records required)
      3. **EITHER** of the following ("a" or "b"):

a. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does not exceed the program quantity limit

b. The requested quantity (dose) exceeds the maximum FDA labeled dose **AND** the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

c. The member has a compendia supported indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):

i. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does not exceed the program quantity limit

ii. The requested quantity (dose) exceeds the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

d. The member does **NOT** have an FDA labeled indication **NOR** a compendia supported indication for the requested agent, **AND BOTH** of the following ("i" and "ii"):

i. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

ii. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

Approval duration:

- Adult AS, PsA, and RA - 12 months
- PJIA and adolescent uveitis - 12 months
- UC - Loading dose (doses on day 1 and 15 for adults or days 1, 8, and 15 for pediatrics) for 4 weeks, then maintenance dose for 8 additional weeks [12 weeks for total duration of approval]
- CD - Loading dose (doses on day 1 and 15) for 1 month, then maintenance dose for 11 additional months [12 months for total duration of approval]
- PS and adult uveitis - Loading dose (doses on day 1, 8, 22) for 1 month, then maintenance dose for 11 additional months [12 months for total duration of approval]
- Adult HS and pediatric HS (≥60 kg) - Loading dose (doses on day 1 and 15) for 1 month, then maintenance dose for 11 additional months [12 months for total duration of approval]
- Pediatric HS (30 kg to <60 kg) - Loading dose (doses on day 1, 8, 22) for 1 month, then maintenance dose for 11 additional months [12 months for total duration of approval]
- Other indications - 12 months

Table 1

Diagnosis	Criteria

Moderately to severely active rheumatoid arthritis (RA)	**ONE** of the following: 1. The member has tried and had an inadequate response to maximally tolerated methotrexate (e.g., titrated to 25 mg weekly) after at least a 3-month duration of therapy **OR** 2. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA after at least a 3-month duration of therapy **OR** 3. The member has an intolerance or hypersensitivity to **ONE** conventional agent (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR** 4. The member has an FDA labeled contraindication to **ALL** conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR** 5. The member's medication history (excluding samples) indicates use of another biologic immunomodulator agent **OR** a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of RA
Active psoriatic arthritis (PsA)	**ONE** of the following: 1. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA after at least a 3-month duration of therapy **OR** 2. The member has an intolerance or hypersensitivity to **ONE** conventional agent used in the treatment of PsA **OR** 3. The member has an FDA labeled contraindication to **ALL** conventional agents used in the treatment of PsA **OR** 4. The member has severe active PsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities, vision loss], highly active disease that causes major impairment in quality of life, active PsA at many sites [including dactylitis, enthesitis], function-limiting PsA at a few sites, rapidly progressive) **OR** 5. The member has concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e.,

	hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** 6. The member's medication history (excluding samples) indicates use of another biologic immunomodulator agent **OR** a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of PsA
Moderate to severe plaque psoriasis (PS)	**ONE** of the following: 1. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., acitretin, calcipotriene, calcitriol, coal tar, cyclosporine, methotrexate, pimecrolimus, phototherapy [e.g., PUVA, UVB], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS after at least a 3-month duration of therapy **OR** 2. The member has an intolerance or hypersensitivity to **ONE** conventional agent used in the treatment of PS **OR** 3. The member has an FDA labeled contraindication to **ALL** conventional agents used in the treatment of PS **OR** 4. The member has severe active PS (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** 5. The member has concomitant severe psoriatic arthritis (PsA) (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities, vision loss], highly active disease that causes major impairment in quality of life, active PsA at many sites [including dactylitis, enthesitis], function-limiting PsA at a few sites, rapidly progressive) **OR** 6. The member's medication history (excluding samples) indicates use of another biologic immunomodulator agent **OR** a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of PS
Moderately to severely active Crohn's disease (CD)	**ONE** of the following: 1. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD after at least a 3-month duration of therapy **OR**

	2. The member has an intolerance or hypersensitivity to **ONE** conventional agent used in the treatment of CD **OR** 3. The member has an FDA labeled contraindication to **ALL** conventional agents used in the treatment of CD **OR** 4. The member's medication history (excluding samples) indicates use of another biologic immunomodulator agent **OR** a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of CD **OR** 5. The member has severe disease and/or risk factors for disease complications for which initial treatment with adalimumab is deemed clinically necessary - provider must include additional details regarding disease severity and/or risk factors
Moderately to severely active ulcerative colitis (UC)	**ONE** of the following: 1. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC after at least a 3-month duration of therapy **OR** 2. The member has an intolerance or hypersensitivity to **ONE** conventional agent used in the treatment of UC **OR** 3. The member has an FDA labeled contraindication to **ALL** conventional agents used in the treatment of UC **OR** 4. The member's medication history (excluding samples) indicates use of another biologic immunomodulator agent **OR** a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of UC **OR** 5. The member has severe disease and/or risk factors for disease complications for which initial treatment with adalimumab is deemed clinically necessary - provider must include additional details regarding disease severity and/or risk factors
Non-infectious intermediate uveitis, posterior uveitis, or panuveitis	**ONE** of the following: 1. **BOTH** of the following: a. **ONE** of the following: i. The member has tried and had an inadequate response to **ONE** oral corticosteroid used in the treatment of non-infectious

	intermediate uveitis, posterior uveitis, or panuveitis after at least a 2-week duration of therapy **OR** ii. The member has tried and had an inadequate response to **ONE** periocular or intravitreal corticosteroid injection used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** iii. The member has an intolerance or hypersensitivity to **ONE** oral corticosteroids or periocular or intravitreal corticosteroid injections used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** iv. The member has an FDA labeled contraindication to **ALL** oral corticosteroids and periocular/intravitreal corticosteroids used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **AND** b. **ONE** of the following: i. The member has tried and had an inadequate response to **ONE** conventional systemic agent (i.e., azathioprine, mycophenolate, methotrexate, cyclosporine, tacrolimus) used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis after at least a 3-month duration of therapy **OR** ii. The member has an intolerance or hypersensitivity to **ONE** conventional systemic agent used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** iii. The member has an FDA labeled contraindication to **ALL** conventional systemic agents used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** 2. The member's medication history (excluding samples) indicates use of another biologic immunomodulator agent **OR** a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis
Active ankylosing spondylitis (AS)	**ONE** of the following: 1. The member has tried and had an inadequate response to **TWO** different NSAIDs used in the treatment of AS after at least a 4-week TOTAL duration of therapy **OR**

	2. The member has tried and had an inadequate response to **ONE** NSAID used in the treatment of AS after at least a 4-week duration of therapy **AND** an intolerance or hypersensitivity to **ONE** additional NSAID used in the treatment of AS **OR** 3. The member has an intolerance or hypersensitivity to **TWO** different NSAIDs used in the treatment of AS **OR** 4. The member has an FDA labeled contraindication to **ALL** NSAIDs used in the treatment of AS **OR** 5. The member's medication history (excluding samples) indicates use of another biologic immunomodulator agent **OR** a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of AS
Moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA)	**ONE** of the following: 1. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., methotrexate, leflunomide) used in the treatment of PJIA after at least a 3-month duration of therapy **OR** 2. The member has an intolerance or hypersensitivity to **ONE** conventional agent used in the treatment of PJIA **OR** 3. The member has an FDA labeled contraindication to **ALL** of the conventional agents used in the treatment of PJIA **OR** 4. The member's medication history (excluding samples) indicates use of another biologic immunomodulator agent **OR** a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of PJIA
Moderate to severe hidradenitis suppurative (HS)	**ONE** of the following: 1. The member has tried and had an inadequate response to **ONE** systemic antibiotic therapy (i.e., oral tetracycline [doxycycline, minocycline, tetracycline]; clindamycin plus rifampin; clindamycin monotherapy) used in the treatment of HS after at least a 3-month duration of therapy **OR** 2. The member has an intolerance or hypersensitivity to **ONE** systemic antibiotic therapy used in the treatment of HS **OR**

	3. The member has an FDA labeled contraindication to **ALL** systemic antibiotic therapies used in the treatment of HS **OR** 4. The member's medication history (excluding samples) indicates use of another biologic immunomodulator agent **OR** a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of HS
Other indications	The member has another FDA labeled indication or an indication supported in DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a

Continuation of Adalimumab-aaty, Adalimumab-adaz, Hadlima (adalimumab-bwwd), Humira (adalimumab), or Simlandi (adalimumab-ryvk) [i.e., a preferred adalimumab product] **the definition of medical necessity** when **ALL** of the following are met ("1" to "6"):

1. An authorization or reauthorization for the requested preferred adalimumab product has been previously approved by Florida Blue [Note: members not previously approved for the requested agent will require initial evaluation review]
2. Member has had clinical benefit with the requested preferred adalimumab product
3. The prescriber is a specialist in the area of the member's diagnosis (e.g., rheumatologist for PsA, RA; gastroenterologist for CD, UC; dermatologist for HS, PS) or the prescriber has consulted with a specialist in the area of the member's diagnosis
4. Member does **NOT** have any FDA labeled contraindications to the requested preferred adalimumab product
5. Member will **NOT** be using the requested preferred adalimumab product in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Leqselvi (deuruxolitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Olumiant (baricitinib), Rinvoq/Rinvoq LQ (upadacitinib), and Xeljanz/Xeljanz XR (tofacitinib)]; Otezla/Otezla XR (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
6. **ANY** of the following ("a", "b", "c", or "d"):
    a. The dosage does not exceed 40 mg every 2 weeks (14 days) [for HS, pediatric UC (greater than 40 kg), and RA monotherapy **ONLY** - 40 mg once a week (every 7 days) or 80 mg every 2 weeks (14 days)]
        - QL: 10 mg/ syringe - 2 syringes/28 days
        - QL: 20 mg syringe - 2 syringes/28 days
        - QL: 40 mg syringe - 2 syringes/28 days
        - QL: 40 mg autoinjector/pen - 2 pens/28 days
        - QL: 40 mg vial - 2 vials/28 days
        - QL: 80 mg autoinjector/pen (Humira only) - 2 pens/28 days
    b. The member has an FDA labeled indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):
        i. The requested quantity (dose) does **NOT** exceed the maximum FDA labeled dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower

quantity of a higher strength and/or package size that does not exceed the program quantity limit

ii. **ALL** of the following ("1", "2", and "3"):

1. The requested quantity (dose) exceeds the FDA maximum labeled dose for the requested indication
2. The member has tried and had an inadequate response to at least a 3-month trial of the maximum FDA labeled dose for the requested indication (medical records required)
3. **EITHER** of the following ("a" or "b"):

a. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does not exceed the program quantity limit

b. The requested quantity (dose) exceeds the maximum FDA labeled dose **AND** the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

c. The member has a compendia supported indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):

i. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does not exceed the program quantity limit

ii. The requested quantity (dose) exceeds the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

d. The member does **NOT** have an FDA labeled indication **NOR** a compendia supported indication for the requested agent, **AND BOTH** of the following ("i" and "ii"):

i. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

ii. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

Approval duration: 12 months

Initiation of Abrilada (adalimumab-afzb), Adalimumab-aacf, Adalimumab-adbm, Adalimumab-bwwd, Adalimumab-fkjp, Adalimumab-ryvk, Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hulio (adalimumab-fkjp), Hyrimoz (adalimumab-adaz), Idacio (adalimumab-aacf), Yuflyma (adalimumab-aaty), or Yusimry (adalimumab-aqvh) [i.e., a non-preferred adalimumab product] **meets the definition of medical necessity** when **ALL** of the following are met ("1" to "5"):

1. **BOTH** of the following ("a" and "b"):

a. The requested non-preferred adalimumab product will be used for the treatment of an indication listed in Table 2, and **ALL** of the indication-specific criteria are met

b. **EITHER** of the following if the member has an FDA-approved indication ("i" or "ii")

i. The member's age is within FDA labeling for the requested indication for the requested non-preferred adalimumab product

ii. The prescriber has provided information in support of using the requested non-preferred adalimumab product for the member's age for the requested indication

2. The prescriber is a specialist in the area of the member's diagnosis (e.g., rheumatologist for JIA, PsA, RA; gastroenterologist for CD, UC; dermatologist for HS, PS) or the prescriber has consulted with a specialist in the area of the member's diagnosis
3. Member does **NOT** have any FDA labeled contraindications to the requested non-preferred adalimumab product
4. Member will **NOT** be using the requested non-preferred adalimumab product in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Leqselvi (deuruxolitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Olumiant (baricitinib), Rinvoq/Rinvoq LQ (upadacitinib), and Xeljanz/Xeljanz XR (tofacitinib)]; Otezla/Otezla XR (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
5. **ANY** of the following ("a", "b", "c", or "d"):
   a. The dosage does not exceed:
      - Loading dose
        - Adult AS, PsA, and RA: no loading dose required
        - PJIA and pediatric uveitis: no loading dose required
        - Adult CD and UC: Initial dose of 160 mg on day 1, 80 mg on day 15, then maintenance dose starting on day 29
          - QL: Six 40 mg syringes or pens/autoinjectors (28-day supply)
          - QL: Three 80 mg syringes or pens/autoinjectors (28-day supply)
          - QL: Cyltezo Starter Package for Crohn's Disease, Ulcerative Colitis or Hidradenitis Suppurativa [six 40 mg/0.8 mL or 40 mg/0.4 mL pens] - 1 kit/180 days
          - QL: Hyrimoz Starter Pack for Crohn's Disease, Ulcerative Colitis, and Hidradenitis Suppurativa (citrate-free) [three 80 mg/0.8 mL pens] - 1 kit/180 days
          - QL: Idacio Starter Package for Crohn's Disease, Ulcerative Colitis or Hidradenitis Suppurativa (citrate-free) [six 40 mg/0.8 mL pens] - 1 kit/180 days
          - QL: Yuflyma Starter Pack for Crohn's Disease, Ulcerative Colitis, and Hidradenitis Suppurativa (citrate-free) [three 80 mg/0.8 mL pens] – 1 kit/180 days
          - QL: Yuflyma Starter Pack for Crohn's Disease, Ulcerative Colitis, and Hidradenitis Suppurativa (citrate-free) [three 80 mg/0.8 mL pens and one 40 mg/0.4 mL pen] – 1 kit/180 days
        - Pediatric CD:
          - 17 kg to <40 kg: Initial dose of 80 mg on day 1, 40 mg on day 15, then maintenance dose starting on day 29
            - QL: Three 40 mg syringes or pens/autoinjectors (28-day supply)
            - QL: Hyrimoz Starter Pack for Pediatric Crohn's Disease (<40 kg) (citrate-free) [one 80 mg/0.8 mL and one 40 mg/0.4 mL syringe] - 1 kit/180 days
            - QL: Yuflyma Starter Pack for Pediatric Crohn's Disease (<40 kg) (citrate-free) [one 80 mg/0.8 mL and one 40 mg/0.4 mL syringe] – 1 kit/180 days
          - ≥40 kg: 160 mg on day 1, 80 mg on day 15, then maintenance dose starting on day 29
            - QL: Six 40 mg syringes or pens/autoinjectors (28-day supply)

- QL: Three 80 mg syringes or pens/autoinjectors (28-day supply)
- QL: Hyrimoz Starter Pack for Pediatric Crohn's Disease (≥40 kg) (citrate-free) [three 80 mg/0.8 mL syringes] - 1 kit/180 days
- QL: Yuflyma Starter Pack for Pediatric Crohn's Disease (≥40 kg) (citrate-free) [three 80 mg/0.8 mL syringes] – 1 kit/180 days

- Pediatric UC:
  - 20 kg to <40 kg: Initial dose of 80 mg on day 1, 40 mg on days 8 and 15, and then maintenance dose starting on day 29
    - QL: Four 40 mg syringes or pens/autoinjectors (28-day supply)
    - QL: Hyrimoz Starter Pack for Pediatric Crohn's Disease (<40 kg) (citrate-free) [one 80 mg/0.8 mL and one 40 mg/0.4 mL syringe] - 1 kit/180 days
    - QL: Yuflyma Starter Pack for Pediatric Crohn's Disease (<40 kg) (citrate-free) [one 80 mg/0.8 mL and one 40 mg/0.4 mL syringe] – 1 kit/180 days
  - ≥40 kg: Initial dose of 160 mg (single dose or split over two consecutive days) on day 1, 80 mg on days 8 and 15, and then maintenance dose starting on day 29
    - QL: Eight 40 mg syringes or pens/autoinjectors (28-day supply)
    - QL: Four 80 mg syringes or pens/autoinjectors (28-day supply)
    - QL: Hyrimoz Starter Pack for Pediatric Crohn's Disease (≥40 kg) (citrate-free) [three 80 mg/0.8 mL syringes] - 1 kit/180 days
    - QL: Yuflyma Starter Pack for Pediatric Crohn's Disease (≥40 kg) (citrate-free) [three 80 mg/0.8 mL syringes] – 1 kit/180 days
- PS and adult uveitis: Initial dose of 80 mg, then maintenance dose starting one week after the initial dose
  - QL: Four 40 mg/0.8 mL syringes or pens/autoinjectors (28-day supply)
  - QL: Cyltezo Starter Package for Psoriasis or Uveitis (citrate-free) [four 40 mg/0.8 mL or 40 mg/0.4 mL pens] - 1 kit/180 days
  - QL: Hyrimoz Starter Pack for Plaque Psoriasis or Uveitis (citrate-free) [one 80 mg/0.8 mL and two 40 mg/0.4 mL pens] – 1 kit/180 days
  - QL: Idacio Starter Package for Plaque Psoriasis or Uveitis (citrate-free) [four 40 mg/0.8 mL pens] - 1 kit/180 days
  - QL: Yuflyma Starter Pack for Plaque Psoriasis or Uveitis (citrate-free) [one 80 mg/0.8 mL and two 40 mg/0.4 mL pens] - 1 kit/180 days
- Adult HS: Initial dose of 160 mg day 1, 80 mg on day 15, then maintenance dose starting on day 29
  - QL: Six 40 mg syringes or pens/autoinjectors (28-day supply)
  - QL: Three 80 mg syringes or pens/autoinjectors (28-day supply)
  - QL: Cyltezo Starter Package for Crohn's Disease, Ulcerative Colitis or Hidradenitis Suppurativa [six 40 mg/0.8 mL or 40 mg/0.4 mL pens] - 1 kit/180 days
  - Hyrimoz Starter Pack for Crohn's Disease, Ulcerative Colitis, and Hidradenitis Suppurativa (citrate-free) [three 80 mg/0.8 mL pens] – 1 kit/180 days
  - QL: Idacio Starter Package for Crohn's Disease, Ulcerative Colitis or Hidradenitis Suppurativa (citrate-free) [six 40 mg/0.8 mL pens] - 1 kit/180 days

- QL: Yuflyma Starter Pack for Crohn's Disease, Ulcerative Colitis, and Hidradenitis Suppurativa (citrate-free) [three 80 mg/0.8 mL pens] – 1 kit/180 days
- QL: Yuflyma Starter Pack for Crohn's Disease, Ulcerative Colitis, and Hidradenitis Suppurativa (citrate-free) [three 80 mg/0.8 mL pens and one 40 mg/0.4 mL pen] – 1 kit/180 days

- Adolescent HS:
  - 30 kg to <60 kg: Initial dose of 80 mg on day 1, then maintenance dose starting on day 8
    - QL: Five 40 mg syringes or pens/autoinjectors (28-day supply)
  - ≥60 kg: 160 mg on day 1, 80 mg on day 15, then maintenance dose starting on day 29
    - QL: Six 40 mg syringes or pens/autoinjectors (28-day supply)
    - QL: Three 80 mg syringes or pens/autoinjectors (28-day supply)
    - Hyrimoz Starter Pack for Crohn's Disease, Ulcerative Colitis, and Hidradenitis Suppurativa (citrate-free) [three 80 mg/0.8 mL pens] – 1 kit/180 days

- Maintenance dose - 40 mg every 2 weeks (14 days) [for HS, pediatric UC (greater than 40 kg), and RA monotherapy ONLY - 40 mg once a week (every 7 days) or 80 mg every 2 weeks (14 days)]
  - QL: 10 mg syringe - 2 syringes/28 days
  - QL: 20 mg syringe - 2 syringes/28 days
  - QL: 40 mg syringe - 2 syringes/28 days
  - QL: 40 mg pen/autoinjector - 2 pens/28 days
  - QL: 40 mg vial – 2 vials/28 days
  - QL: 80 mg pen/autoinjector - 2 pens/28 days

b. The member has an FDA labeled indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):

i. The requested quantity (dose) does **NOT** exceed the maximum FDA labeled dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

ii. **ALL** of the following ("1", "2", and "3"):

1. The requested quantity (dose) exceeds the FDA maximum labeled dose for the requested indication
2. The member has tried and had an inadequate response to at least a 3-month trial of the maximum FDA labeled dose for the requested indication (medical records required)
3. **EITHER** of the following ("a" or "b"):
   a. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does not exceed the program quantity limit
   b. The requested quantity (dose) exceeds the maximum FDA labeled dose **AND** the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

c. The member has a compendia supported indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):

   i. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does not exceed the program quantity limit

   ii. The requested quantity (dose) exceeds the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

d. The member does **NOT** have an FDA labeled indication NOR a compendia supported indication for the requested agent, **AND BOTH** of the following ("i" and "ii")

   i. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

   ii. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

Approval duration:

- Adult AS, PsA, and RA - 12 months
- PJIA and adolescent uveitis - 12 months
- UC - Loading dose (doses on day 1 and 15 for adults or days 1, 8, and 15 for pediatrics) for 4 weeks, then maintenance dose for 8 additional weeks [12 weeks for total duration of approval]
- CD - Loading dose (doses on day 1 and 15) for 1 month, then maintenance dose for 11 additional months [12 months for total duration of approval]
- PS and adult uveitis - Loading dose (doses on day 1, 8, 22) for 1 month, then maintenance dose for 11 additional months [12 months for total duration of approval]
- Adult HS and pediatric HS (≥60 kg) - Loading dose (doses on day 1 and 15) for 1 month, then maintenance dose for 11 additional months [12 months for total duration of approval]
- Pediatric HS (30 kg to <60 kg) - Loading dose (doses on day 1, 8, 22) for 1 month, then maintenance dose for 11 additional months [12 months for total duration of approval]
- Other indications - 12 months

Table 2

Diagnosis	Criteria
Moderately to severely active rheumatoid arthritis (RA)	**BOTH** of the following ("1" and "2"): 1. **ONE** of the following: a. The member has tried and had an inadequate response to maximally tolerated methotrexate (e.g., titrated to 25 mg weekly) after at least a 3-month duration of therapy **OR** b. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., hydroxychloroquine, leflunomide,

	sulfasalazine) used in the treatment of RA after at least a 3-month duration of therapy **OR** c. The member has an intolerance or hypersensitivity to **ONE** conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR** d. The member has an FDA labeled contraindication to **ALL** conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR** e. The member's medication history (excluding samples) indicates use of another biologic immunomodulator agent **OR** a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of RA **AND** 2. **ANY** of the following (submitted medical records/chart notes are required for confirmation): a. The member has tried and had an inadequate response to at least **THREE** preferred adalimumab products after at least a 3-month trial per agent **OR** b. The member has tried and had an inadequate response to **TWO** preferred adalimumab products after at least a 3-month duration of therapy per product, **AND** an intolerance or hypersensitivity to **ONE** preferred adalimumab product that is not expected to occur with the requested non-preferred adalimumab product **OR** c. The member has tried and had an inadequate response to **ONE** preferred adalimumab product after at least a 3-month duration of therapy, **AND** an intolerance or hypersensitivity to **TWO** preferred adalimumab products that is not expected to occur with the requested non-preferred adalimumab product **OR** d. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to at least **THREE** preferred adalimumab products that is not expected to occur with the requested non-preferred adalimumab product **OR** e. The member has an FDA labeled contraindication to **ALL** preferred adalimumab products that is not expected to occur with the requested non-preferred adalimumab product **The preferred adalimumab products are:**

	• Adalimumab-aaty • Adalimumab-adaz • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Simlandi (adalimumab-ryvk)
Active psoriatic arthritis (PsA)	**BOTH** of the following ("1" and "2"): 1. **ONE** of the following: a. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA after at least a 3-month duration of therapy **OR** b. The member has an intolerance or hypersensitivity to **ONE** conventional agent used in the treatment of PsA **OR** c. The member has an FDA labeled contraindication to **ALL** conventional agents used in the treatment of PsA **OR** d. The member has severe active PsA (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities, vision loss], highly active disease that causes major impairment in quality of life, active PsA at many sites [including dactylitis, enthesitis], function-limiting PsA at a few sites, rapidly progressive) **OR** e. The member has concomitant severe psoriasis (PS) (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands, feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** f. The member's medication history (excluding samples) indicates use of another biologic immunomodulator agent **OR** a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of PsA **AND** 2. **ANY** of the following (submitted medical records/chart notes are required for confirmation): a. The member has tried and had an inadequate response to at least **THREE** preferred adalimumab products after at least a 3-month trial per agent **OR**

	b. The member has tried and had an inadequate response to **TWO** preferred adalimumab products after at least a 3-month duration of therapy per product, **AND** an intolerance or hypersensitivity to **ONE** preferred adalimumab product that is not expected to occur with the requested non-preferred adalimumab product **OR** c. The member has tried and had an inadequate response to **ONE** preferred adalimumab product after at least a 3-month duration of therapy, **AND** an intolerance or hypersensitivity to **TWO** preferred adalimumab products that is not expected to occur with the requested non-preferred adalimumab product **OR** d. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to at least **THREE** preferred adalimumab products that is not expected to occur with the requested non-preferred adalimumab product **OR** c. The member has an FDA labeled contraindication to **ALL** preferred adalimumab products that is not expected to occur with the requested non-preferred adalimumab product **The preferred adalimumab products are:** • Adalimumab-aaty • Adalimumab-adaz • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Simlandi (adalimumab-ryvk)
Moderate to severe plaque psoriasis (PS)	**BOTH** of the following ("1" and "2"): 1. **ONE** of the following: a. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., acitretin, calcipotriene, calcitriol, coal tar, cyclosporine, methotrexate, pimecrolimus, phototherapy [e.g., PUVA, UVB], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS after at least a 3-month duration of therapy **OR** b. The member has an intolerance or hypersensitivity to **ONE** conventional agent used in the treatment of PS **OR** c. The member has an FDA labeled contraindication to **ALL** conventional agents used in the treatment of PS **OR** d. The member has severe active PS (e.g., greater than 10% body surface area involvement, occurring on select locations [i.e., hands,

	feet, scalp, face, or genitals], intractable pruritus, serious emotional consequences) **OR** e. The member has concomitant severe psoriatic arthritis (PsA) (e.g., erosive disease, elevated markers of inflammation [e.g., ESR, CRP] attributable to PsA, long-term damage that interferes with function [i.e., joint deformities, vision loss], highly active disease that causes major impairment in quality of life, active PsA at many sites [including dactylitis, enthesitis], function-limiting PsA at a few sites, rapidly progressive) **OR** f. The member's medication history (excluding samples) indicates use of another biologic immunomodulator agent **OR** a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) XR that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of PS **AND** 2. **ANY** of the following (submitted medical records/chart notes are required for confirmation): a. The member has tried and had an inadequate response to at least **THREE** preferred adalimumab products after at least a 3-month trial per agent: **OR** b. The member has tried and had an inadequate response to **TWO** preferred adalimumab products after at least a 3-month duration of therapy per product, **AND** an intolerance or hypersensitivity to **ONE** preferred adalimumab product that is not expected to occur with the requested non-preferred adalimumab product **OR** c. The member has tried and had an inadequate response to **ONE** preferred adalimumab product after at least a 3-month duration of therapy, **AND** an intolerance or hypersensitivity to **TWO** preferred adalimumab products that is not expected to occur with the requested non-preferred adalimumab product **OR** d. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to at least **THREE** preferred adalimumab products that is not expected to occur with the requested non-preferred adalimumab product: **OR** e. The member has an FDA labeled contraindication to **ALL** preferred adalimumab products that is not expected to occur with the requested non-preferred adalimumab product: **The preferred adalimumab products are:** • Adalimumab-aaty

	• Adalimumab-adaz • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Simlandi (adalimumab-ryvk)
Moderately to severely active Crohn's disease (CD)	**BOTH** of the following ("1" and "2"): 1. **ONE** of the following: a. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) used in the treatment of CD after at least a 3-month duration of therapy **OR** b. The member has an intolerance or hypersensitivity to **ONE** of the conventional agents used in the treatment of CD **OR** c. The member has an FDA labeled contraindication to **ALL** of the conventional agents used in the treatment of CD **OR** d. The member's medication history (excluding samples) indicates use of another biologic immunomodulator agent **OR** a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of CD **OR** e. The member has severe disease and/or risk factors for disease complications for which initial treatment with adalimumab is deemed clinically necessary - provider must include additional details regarding disease severity and/or risk factors **AND** 2. **ANY** of the following (submitted medical records/chart notes are required for confirmation): c. The member has tried and had an inadequate response to at least **THREE** preferred adalimumab products after at least a 3-month trial per agent **OR** d. The member has tried and had an inadequate response to **TWO** preferred adalimumab products after at least a 3-month duration of therapy per product, **AND** an intolerance or hypersensitivity to **ONE** preferred adalimumab product that is not expected to occur with the requested non-preferred adalimumab product **OR** e. The member has tried and had an inadequate response to **ONE** preferred adalimumab product after at least a 3-month duration of therapy, **AND** an intolerance or hypersensitivity to **TWO** preferred

	adalimumab products that is not expected to occur with the requested non-preferred adalimumab product **OR** f. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to at least **THREE** preferred adalimumab products that is not expected to occur with the requested non-preferred adalimumab product: **OR** c. The member has an FDA labeled contraindication to **ALL** preferred adalimumab products that is not expected to occur with the requested non-preferred adalimumab product **The preferred adalimumab products are** • Adalimumab-aaty • Adalimumab-adaz • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Simlandi (adalimumab-ryvk)
Moderately to severely active ulcerative colitis (UC)	**BOTH** of the following ("1" and "2"): 1. **ONE** of the following: a. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC after at least a 3-month duration of therapy **OR** b. The member has an intolerance or hypersensitivity to **ONE** conventional agent used in the treatment of UC **OR** c. The member has an FDA labeled contraindication to **ALL** conventional agents used in the treatment of UC **OR** d. The member's medication history (excluding samples) indicates use of another biologic immunomodulator agent **OR** a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of UC **OR** e. The member has severe disease and/or risk factors for disease complications for which initial treatment with adalimumab is deemed clinically necessary - provider must include additional details regarding disease severity and/or risk factors

	AND 2. **ANY** of the following (submitted medical records/chart notes are required for confirmation): a. The member has tried and had an inadequate response to at least **THREE** preferred adalimumab products after at least a 3-month trial per agent **OR** b. The member has tried and had an inadequate response to **TWO** preferred adalimumab products after at least a 3-month duration of therapy per product, **AND** an intolerance or hypersensitivity to **ONE** preferred adalimumab product that is not expected to occur with the requested non-preferred adalimumab product **OR** c. The member has tried and had an inadequate response to **ONE** preferred adalimumab product after at least a 3-month duration of therapy, **AND** an intolerance or hypersensitivity to **TWO** preferred adalimumab products that is not expected to occur with the requested non-preferred adalimumab product **OR** d. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to at least **THREE** preferred adalimumab products that is not expected to occur with the requested non-preferred adalimumab product: **OR** e. The member has an FDA labeled contraindication to **ALL** preferred adalimumab products that is not expected to occur with the requested non-preferred adalimumab product **The preferred adalimumab products are:** • Adalimumab-aaty • Adalimumab-adaz • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Simlandi (adalimumab-ryvk)
Non-infectious intermediate uveitis, posterior uveitis, or panuveitis	**BOTH** of the following ("1" and "2"): 1. **ONE** of the following: a. **BOTH** of the following: i. **ONE** of the following: • The member has tried and had an inadequate response to **ONE** oral corticosteroids used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis after at least a 2-week duration of therapy

	OR • The member has tried and had an inadequate response to **ONE** periocular or intravitreal corticosteroid injections in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** • The member has an intolerance or hypersensitivity to **ONE** oral corticosteroids or periocular or intravitreal corticosteroid injections used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** • The member has an FDA labeled contraindication to **ALL** oral corticosteroids and periocular/intravitreal corticosteroids used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **AND** ii. **ONE** of the following: • The member has tried and had an inadequate response to **ONE** conventional systemic agent (i.e., azathioprine, mycophenolate, methotrexate, cyclosporine, tacrolimus) used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis after at least a 3-month duration of therapy **OR** • The member has an intolerance or hypersensitivity to **ONE** conventional systemic agent used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** • The member has an FDA labeled contraindication to **ALL** conventional systemic agents used in the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **OR** b. The member's medication history (excluding samples) indicates use of another biologic immunomodulator agent **OR** a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of non-infectious intermediate uveitis, posterior uveitis, or panuveitis **AND** 2. **ANY** of the following (submitted medical records/chart notes are required for confirmation): a. The member has tried and had an inadequate response to at least **THREE** preferred adalimumab products after at least a 3-month trial per agent **OR**

	b. The member has tried and had an inadequate response to **TWO** preferred adalimumab products after at least a 3-month duration of therapy per product, **AND** an intolerance or hypersensitivity to **ONE** preferred adalimumab product that is not expected to occur with the requested non-preferred adalimumab product **OR** c. The member has tried and had an inadequate response to **ONE** preferred adalimumab product after at least a 3-month duration of therapy, **AND** an intolerance or hypersensitivity to **TWO** preferred adalimumab products that is not expected to occur with the requested non-preferred adalimumab product **OR** d. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to at least **THREE** preferred adalimumab products that is not expected to occur with the requested non-preferred adalimumab product **OR** e. The member has an FDA labeled contraindication to **ALL** of the following that is not expected to occur with the requested non-preferred adalimumab product **The preferred adalimumab products are:** • Adalimumab-aaty • Adalimumab-adaz • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Simlandi (adalimumab-ryvk
Active ankylosing spondylitis (AS)	**BOTH** of the following ("1" and "2"): 1. **ONE** of the following: a. The member has tried and had an inadequate response to **TWO** different NSAIDs used in the treatment of AS after at least a 4-week TOTAL duration of therapy **OR** b. The member has tried and had an inadequate response to **ONE** NSAID used in the treatment of AS after at least a 4-week duration of therapy **AND** an intolerance or hypersensitivity to **ONE** additional NSAID used in the treatment of AS OR c. The member has an intolerance or hypersensitivity to **TWO** different NSAIDs used in the treatment of AS **OR** d. The member has an FDA labeled contraindication to **ALL** NSAIDs used in the treatment of AS

	OR e. The member's medication history (excluding samples) indicates use of another biologic immunomodulator agent **OR** a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of AS **AND** 2. **ANY** of the following (submitted medical records/chart notes are required for confirmation): a. The member has tried and had an inadequate response to at least **THREE** preferred adalimumab products for at least a 3-month trial per agent **OR** b. The member has tried and had an inadequate response to **TWO** preferred adalimumab products after at least a 3-month duration of therapy per product, **AND** an intolerance or hypersensitivity to **ONE** preferred adalimumab product that is not expected to occur with the requested non-preferred adalimumab product **OR** c. The member has tried and had an inadequate response to **ONE** preferred adalimumab product after at least a 3-month duration of therapy, **AND** an intolerance or hypersensitivity to **TWO** preferred adalimumab products that is not expected to occur with the requested non-preferred adalimumab product **OR** d. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to at least **THREE** preferred adalimumab products that is not expected to occur with the requested non-preferred adalimumab product: **OR** e. The member has an FDA labeled contraindication to **ALL** preferred adalimumab products that is not expected to occur with the requested non-preferred adalimumab product **The preferred adalimumab products are:** • Adalimumab-aaty • Adalimumab-adaz • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Simlandi (adalimumab-ryvk)
Moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA)	**BOTH** of the following ("1" and "2"): 1. **ONE** of the following:

	a. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., methotrexate, leflunomide) used in the treatment of PJIA after at least a 3-month duration of therapy **OR** b. The member has an intolerance or hypersensitivity to **ONE** conventional agent used in the treatment of PJIA **OR** c. The member has an FDA labeled contraindication to **ALL** of the conventional agents used in the treatment of PJIA **OR** d. The member's medication history (excluding samples) indicates use of another biologic immunomodulator agent **OR** a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of PJIA **AND** 2. **ANY** of the following (submitted medical records/chart notes are required for confirmation): a. The member has tried and had an inadequate response to at least **THREE** preferred adalimumab products for at least a 3-month trial per agent **OR** b. The member has tried and had an inadequate response to **TWO** preferred adalimumab products after at least a 3-month duration of therapy per product, **AND** an intolerance or hypersensitivity to **ONE** preferred adalimumab product that is not expected to occur with the requested non-preferred adalimumab product **OR** c. The member has tried and had an inadequate response to **ONE** preferred adalimumab product after at least a 3-month duration of therapy, **AND** an intolerance or hypersensitivity to **TWO** preferred adalimumab products that is not expected to occur with the requested non-preferred adalimumab product **OR** d. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to at least **THREE** preferred adalimumab products that is not expected to occur with the requested non-preferred adalimumab product **OR** e. The member has an FDA labeled contraindication to **ALL** preferred adalimumab products that is not expected to occur with the requested non-preferred adalimumab product **The preferred adalimumab products are:** • Adalimumab-aaty

	• Adalimumab-adaz • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Simlandi (adalimumab-ryvk)
Moderate to severe hidradenitis suppurative (HS)	**BOTH** of the following ("1" and "2"): 1. **ONE** of the following: a. The member has tried and had an inadequate response to **ONE** systemic antibiotic therapy (i.e., oral tetracycline [doxycycline, minocycline, tetracycline]; clindamycin plus rifampin; clindamycin monotherapy) used in the treatment of HS after at least a 3-month duration of therapy **OR** b. The member has an intolerance or hypersensitivity to **ONE** systemic antibiotic therapy used in the treatment of HS **OR** c. The member has an FDA labeled contraindication to **ALL** systemic antibiotic therapies used in the treatment of HS **OR** d. The member's medication history (excluding samples) indicates use of another biologic immunomodulator agent **OR** a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of HS **AND** 2. **ANY** of the following (submitted medical records/chart notes are required for confirmation): a. The member has tried and had an inadequate response to at least **THREE** preferred adalimumab products for at least a 3-month trial per agent **OR** b. The member has tried and had an inadequate response to **TWO** preferred adalimumab products after at least a 3-month duration of therapy per product, **AND** an intolerance or hypersensitivity to **ONE** preferred adalimumab product that is not expected to occur with the requested non-preferred adalimumab product **OR** c. The member has tried and had an inadequate response to **ONE** preferred adalimumab product after at least a 3-month duration of therapy, **AND** an intolerance or hypersensitivity to **TWO** preferred adalimumab products that is not expected to occur with the requested non-preferred adalimumab product **OR** d. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or

	hypersensitivity to at least **THREE** preferred adalimumab products that is not expected to occur with the requested non-preferred adalimumab product: **OR** e. The member has an FDA labeled contraindication to **ALL** preferred adalimumab products that is not expected to occur with the requested non-preferred adalimumab product **The preferred adalimumab products are:** • Adalimumab-aaty • Adalimumab-adaz • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Simlandi (adalimumab-ryvk)

Continuation of Abrilada (adalimumab-afzb), Adalimumab-aacf, Adalimumab-adbm, Adalimumab-bwwd, Adalimumab-fkjp, Adalimumab-ryvk, Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hulio (adalimumab-fkjp), Hyrimoz (adalimumab-adaz), Idacio (adalimumab-aacf), Yuflyma (adalimumab-aaty), or Yusimry (adalimumab-aqvh) [i.e., a non-preferred adalimumab product] meets the definition of medical necessity when **ALL** of the following are met ("1" to "7"):

1. An authorization or reauthorization for the requested non-preferred adalimumab product has been previously approved by Florida Blue [Note: members not previously approved for the requested agent will require initial evaluation review]
2. Member has had clinical benefit with the requested non-preferred adalimumab product
3. The prescriber is a specialist in the area of the member's diagnosis (e.g., rheumatologist for PsA, RA; gastroenterologist for CD, UC; dermatologist for HS, PS) or the prescriber has consulted with a specialist in the area of the member's diagnosis
4. Member does **NOT** have any FDA labeled contraindications to the requested non-preferred adalimumab product
5. Member will NOT be using the requested non-preferred adalimumab product in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Leqselvi (deuruxolitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Olumiant (baricitinib), Rinvoq/Rinvoq LQ (upadacitinib), and Xeljanz/Xeljanz XR (tofacitinib)]; Otezla/Otezla XR (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
6. The member meets the following prerequisite biologic immunomodulator agent requirements depending on the indication for use:
    a. RA – see bullets 2a to 2c in Table 2 (submitted medical records/chart notes are required for confirmation
    b. PsA - see bullets 2a to 2c in Table 2 (submitted medical records/chart notes are required for confirmation
    c. PS - see bullets 2a to 2c in Table 2 (submitted medical records/chart notes are required for confirmation
    d. CD - see bullets 2a to 2c in Table 2 (submitted medical records/chart notes are required for confirmation

e. UC - see bullets 2a to 2c in Table 2 (submitted medical records/chart notes are required for confirmation

f. Uveitis - see bullets 2a to 2c in Table 2 (submitted medical records/chart notes are required for confirmation

g. AS - see bullets 2a to 2c in Table 2 (submitted medical records/chart notes are required for confirmation

h. PJIA - see bullets 2a to 2c in Table 2 (submitted medical records/chart notes are required for confirmation)

i. HS - see bullets 2a to 2c in Table 2 (submitted medical records/chart notes are required for confirmation)

7. **ANY** of the following ("a", "b", "c", or "d"):

   a. The dosage does not exceed 40 mg every 2 weeks (14 days)

      [for HS, pediatric UC (greater than 40 kg), and RA monotherapy **ONLY** - 40 mg once a week (every 7 days) or 80 mg every 2 weeks (14 days)]

      - QL: 10 mg syringe - 2 syringes/28 days
      - QL: 20 mg syringe - 2 syringes/28 days
      - QL: 40 mg syringe - 2 syringes/28 days
      - QL: 40 mg pen/autoinjector - 2 pens/28 days
      - QL: 40 mg vial - 2 vials/28 days
      - QL: 80 mg pen/autoinjector - 2 pens/28 days

   b. The member has an FDA labeled indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):

      i. The requested quantity (dose) does **NOT** exceed the maximum FDA labeled dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

      ii. **ALL** of the following ("1", "2", and "3"):

         1. The requested quantity (dose) exceeds the FDA maximum labeled dose for the requested indication

         2. The member has tried and had an inadequate response to at least a 3-month trial of the maximum FDA labeled dose for the requested indication (medical records required)

         3. **EITHER** of the following ("a" or "b"):

            a. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does not exceed the program quantity limit

            b. The requested quantity (dose) exceeds the maximum FDA labeled dose **AND** the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

   c. The member has a compendia supported indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):

      i. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a

lower quantity of a higher strength/and or package size that does not exceed the program quantity limit

ii. The requested quantity (dose) exceeds the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

d. The member does **NOT** have an FDA labeled indication NOR a compendia supported indication for the requested agent, **AND BOTH** of the following ("i" and "ii"):

i. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

ii. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

Approval duration: 12 months

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

Table 3

FDA-approved indications and recommended dosing	
Indication	**Dosage†**
Ankylosing Spondylitis	• 40 mg every other week
Crohn's Disease (CD) [for adults and pediatric patients 6 years of age and older]	Weight 17 kg to less than 40 kg: • Initial: 80 mg at week 0, and 40 mg at week 2 (day 15) • Maintenance: 20 mg every other week beginning at week 4 Weight 40 kg or greater: • Initial: 160 mg at week 0, and 80 mg at week 2 (day 15) • Maintenance: 40 mg every other week beginning at week 4
Hidradenitis Suppurativa [for adolescents, 12 years of age and older, and adults; except Abrilada, Hadlima, Hulio, Idacio, and Yusimry - for adults only]	≥60 kg (132 lbs.): • Initial: 160 mg at week 0, followed by 80 mg at week 2 (day 15) • Maintenance: 40 mg every week or 80 mg every other week beginning at week 4 (day 29) 30 kg (66 lbs.) to <60 kg (132 lbs.): • Initial: 80 mg at week 0, followed by 40 mg at week 1 (day 8)

	• Maintenance: 40 mg every 2 weeks beginning at week 3 (day 22)
Juvenile Idiopathic Arthritis (JIA) [20 mg dosing applies to Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, and Humira only] [10 mg dosing applies to Abrilada, Hadlima, Humira, and Hyrimoz only]	Dose is based on weight: • 10 to ≤15 kg (22 to 33 lbs): 10 mg every other week • 15 kg to ≤30 kg (33-66 lbs): 20 mg every other week • 30 kg or more: 40 mg every other week
Plaque Psoriasis	• Initial: 80 mg at week 0 • Maintenance: 40 mg every other week beginning at week 1
Psoriatic Arthritis (PsA)	• 40 mg every other week
Rheumatoid Arthritis (RA)	• Concomitant DMARD: 40 mg every other week • Monotherapy: 40 mg weekly or 80 mg every other week

Ulcerative Colitis (UC)
 	
[pediatric UC, 5 years of age and older, for Humira only]
	Adult (≥18 years old):
	• Initial: 160 mg at week 0, followed by 80 mg at week 2 (day 15)
	• Maintenance: 40 mg every other week beginning at week 4 (day 29)
	Pediatric:
	• 20 kg (44 lbs.) to <40 kg (88 lbs.):
	  ○ Initial: 80 mg on week 0 (day 1), followed by 40 mg on weeks 1 and 2 (days 8 and 15)
	  ○ Maintenance: 40 mg every other week or 20 mg weekly beginning at week 4 (day 29)
	• 40 kg (88 lbs.) or more:
	  ○ Initial: 160 mg (single dose or split over two consecutive days) on week 0 (day 1), followed by 80 mg on weeks 1 and 2 (days 8 and 15)
	  ○ Maintenance: 80 mg every other week or 40 mg weekly beginning at week 4 (day 29)

Uveitis (non-infectious intermediate, posterior and panuveitis) [for pediatric uveitis, 2 years of age and older, and adults, except for Abrilada, Hadlima, Hulio, Idacio, and Yusimry - for adults only]	Adult (≥18 years old): • Initial: 80 mg at week 0 • Maintenance: 40 mg every other week beginning at week 1 Pediatric • ≥30 kg (66 lbs.): 40 mg every other week • 15 kg (33 lbs.) to <30 kg (66 lbs.): 20 mg every other week • 10 kg (22 lbs.) to <15 kg (33 lbs.): 10 mg every other week
†Administered as a subcutaneous injection	

- **Dose Adjustments:** dosage adjustments are not required for members with hepatic or renal impairment.

- **Drug Availability:**

  <u>Humira</u>

  - **Autoinjector/Pen**
    - 80 mg/0.8 mL single-use pen (citrate-free) - carton of two pens
    - 40 mg/0.4 mL single-use pen (citrate-free) - carton of two pens
  - **Prefilled Syringe**
    - 40 mg/0.4 mL single-use syringe (citrate-free) - carton of two syringes
    - 20 mg/0.2 mL single-use syringe (citrate-free) - carton of two syringes
    - 10 mg/0.1 mL single-use syringe (citrate-free) - carton of two syringes

  <u>Amjevita</u>

  - **Autoinjector/Pen**
    - 80 mg/0.8 mL single-use pen (citrate-free) - carton of one or two pens
    - 40 mg/0.8 mL single-use pen (citrate-free) - carton of one or two pens
    - 40 mg/0.4 mL single-use pen (citrate-free) - carton of one or two pens
  - **Prefilled Syringe**
    - 80 mg/0.8 mL single-use syringe (citrate-free) - carton of one or two syringes
    - 40 mg/0.8 mL single-use syringe (citrate-free) - carton of one or two syringes
    - 40 mg/0.4 mL single-use syringe (citrate-free) - carton of one or two syringes
    - 20 mg/0.4 mL single-use syringe (citrate-free) - carton of one syringe
    - 20 mg/0.2 mL single-use syringe (citrate-free) - carton of one syringe
    - 20 mg/0.2 mL single-use syringe (citrate-free) - carton of one syringe

  <u>Hadlima</u>

  - **PushTouch Autoinjector/Pen**
    - 40 mg/0.8 mL single-use autoinjector - carton of two autoinjectors
    - 40 mg/0.4 mL single-use autoinjector (citrate-free) - carton of two autoinjectors
  - **Prefilled Syringe**
    - 40 mg/0.8 mL single-use syringe - carton of two syringes
    - 40 mg/0.4 mL single-use syringe (citrate-free) - carton of two syringes
  - **Single-Use Institutional Use Vial**
    - 40 mg/0.8 mL single-use vial – carton of one vial

Abrilada

- **Autoinjector/Pen**
  - 40 mg/0.8 mL single-use pen (citrate-free) - carton of one or two pens
- **Prefilled Syringe**
  - 40 mg/0.8 mL single-use syringe (citrate-free) - carton of one or two syringes
  - 20 mg/0.4 mL single-use syringe (citrate-free) - carton of two syringes
  - 10 mg/0.2 mL single-use syringe (citrate-free) - carton of two syringes
- **Single-Use Institutional Use Vial**
  - 40 mg/0.8 mL single-use vial (citrate-free) – carton of one vial

Cyltezo

- **Starter Packs**
  - Starter Package for Psoriasis or Uveitis (citrate-free) [four 40 mg/0.8 mL pens or four 40 mg/0.4 mL pens]
  - Starter Package for Crohn's Disease, Ulcerative Colitis or Hidradenitis Suppurativa [six 40 mg/0.8 mL pens or six 40 mg/0.4 mL pens]
- **Autoinjector/Pen**
  - 40 mg/0.8 mL single-use pen (citrate-free) - carton of two pens
  - 40 mg/0.4 mL single-use pen (citrate-free) - carton of two pens
- **Prefilled Syringe**
  - 40 mg/0.8 mL single-use syringe (citrate-free) - carton of two syringes
  - 40 mg/0.4 mL single-use syringe (citrate-free) - carton of two syringes
  - 20 mg/0.4 mL single-use syringe (citrate-free) - carton of two syringes
  - 10 mg/0.4 mL single-use syringe (citrate-free) - carton of two syringes

Hulio

- **Autoinjector/Pen**
  - 40 mg/0.8 mL single-use pen (citrate-free) - carton of two pens
- **Prefilled Syringe**
  - 40 mg/0.8 mL single-use syringe (citrate-free) - carton of two syringes
  - 20 mg/0.4 mL single-use syringe (citrate-free) - carton of two syringes

Hyrimoz

- **Starter Packs**
  - Starter Pack for Plaque Psoriasis or Uveitis (citrate-free) [one 80 mg/0.8 mL and two 40 mg/0.4 mL pens]

- Starter Pack for Crohn's Disease, Ulcerative Colitis, and Hidradenitis Suppurativa (citrate-free) [three 80 mg/0.8 mL pens]
- Starter Pack for Crohn's Disease, Ulcerative Colitis, and Hidradenitis Suppurativa (citrate-free) [three 80 mg/0.8 mL pens and one 40 mg/0.4 mL pen]
- Starter Pack for Pediatric Crohn's Disease (≥40 kg) (citrate-free) [three 80 mg/0.8 mL syringes]
- Starter Pack for Pediatric Crohn's Disease (<40 kg) (citrate-free) [one 80 mg/0.8 mL and one 40 mg/0.4 mL syringe]

- **Autoinjector/SensoreadyPen**
  - 80 mg/0.8 mL single-use pen (citrate-free) – carton of 2 pens
  - 40 mg/0.8 mL single-use pen - carton of two pens
  - 40 mg/0.4 mL single-use pen (citrate-free) - carton of two or four pens

- **Prefilled Syringe**
  - 80 mg/0.8 mL single-use syringe (citrate-free) – carton of two syringes
  - 40 mg/0.8 mL single-use syringe - carton of two syringes
  - 40 mg/0.4 mL single-use syringe (citrate-free) - carton of two syringes
  - 20 mg/0.4 mL single-use syringe - carton of two syringes
  - 20 mg/0.2 mL single-use syringe (citrate-free) - carton of two syringes
  - 10 mg/0.2 mL single-use syringe - carton of one syringe
  - 10 mg/0.1 mL single-use syringe (citrate-free) - carton of two syringes

Idacio

- **Starter Packs**
  - Starter Package for Crohn's Disease, Ulcerative Colitis or Hidradenitis Suppurativa (citrate-free) [six 40 mg/0.8 mL pens]
  - Starter Package for Plaque Psoriasis or Uveitis (citrate-free) [four 40 mg/0.8 mL pens]

- **Autoinjector/Pen**
  - 40 mg/0.8 mL single-use pen (citrate-free) - carton of two pens

- **Prefilled Syringe**
  - 40 mg/0.8 mL single-use syringe (citrate-free) - carton of two syringes

Simlandi

- **Autoinjector/Pen**
  - 40 mg/0.4 mL single-use pen (citrate-free) – carton of one or two pens

Yuflyma

- **Starter Packs**

- Starter Pack for Plaque Psoriasis or Uveitis (citrate-free) [one 80 mg/0.8 mL and two 40 mg/0.4 mL pens]
- Starter Pack for Crohn's Disease, Ulcerative Colitis, and Hidradenitis Suppurativa (citrate-free) [three 80 mg/0.8 mL pens]
- Starter Pack for Crohn's Disease, Ulcerative Colitis, and Hidradenitis Suppurativa (citrate-free) [three 80 mg/0.8 mL pens and one 40 mg/0.4 mL pen]
- Starter Pack for Pediatric Crohn's Disease (≥40 kg) (citrate-free) [three 80 mg/0.8 mL syringes]
- Starter Pack for Pediatric Crohn's Disease (<40 kg) (citrate-free) [one 80 mg/0.8 mL and one 40 mg/0.4 mL syringe]

- **Autoinjector/Pen**
  - 80 mg/0.8 mL single-use autoinjector (citrate-free) - carton of one and two autoinjectors
  - 40 mg/0.4 mL single-use autoinjector (citrate-free) - carton of one, two, four, and six autoinjectors

- **Prefilled Syringe**
  - 80 mg/0.8 mL single-use syringe (citrate-free) - carton of one and syringes (with or without a safety guard)
  - 40 mg/0.4 mL single-use syringe (citrate-free) - cartons of one, two, four, and six syringes (with or without a safety guard)
  - 20 mg/0.2 mL single-use syringe (citrate-free) - cartons of two syringes without a safety guard)

Yusimry

- **Autoinjector/Pen**
  - 40 mg/0.8 mL single-use pen (citrate-free) - carton of two pens

- **Prefilled Syringe**
  - 40 mg/0.8 mL single-use syringe (citrate-free) - carton of two syringes

PRECAUTIONS:

Boxed Warning

- **Infections:** tuberculosis (TB), invasive fungal, and other opportunistic infections, some fatal, have occurred. Perform test for latent TB; if positive, start treatment for TB prior to starting therapy. Monitor all patients for active TB, even if initial tuberculin skin test is negative.
- **Malignancy:** lymphoma and other malignancies, some fatal have been reported in children and adolescent individuals treated with TNF blockers including adalimumab. Post-marketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have occurred in adolescents and young adults with inflammatory bowel disease.

Contraindications

- None

Warnings/Precautions

Serious Infections: adalimumab products should not be initiated in members during an active infection. If an infection develops, monitor carefully, and discontinue adalimumab if infection becomes serious.

- **Invasive fungal infections:** If a member develops a systemic infection while on an adalimumab product, consider empiric antifungal therapy for those who reside or travel to regions where mycoses are endemic
- **Anaphylaxis:** anaphylaxis or serious allergic reactions may occur.
- **Hepatitis B virus reactivation:** members who are HBV caries should be monitored during and several months after therapy. If reactivation occurs during therapy, discontinue the adalimumab product and initiate anti-viral therapy.
- **Demyelinating disease:** exacerbation of new onset may occur
- **Cytopenia, pancytopenia:** advise members to seek immediate medical attention if symptoms develop and consider discontinuing the adalimumab product.
- **Heart failure:** worsening or new onset heart failure may occur.
- **Lupus-like syndrome:** discontinue the adalimumab product if syndrome develops.
- **Drug Interactions:** avoid concomitant use with abatacept (Orencia) and anakinra (Kineret), due to increased risk of serious infection.
- **Live vaccines:** Avoid administration of live vaccines (e.g., varicella and MMR) in members taking an adalimumab product.
- **Pregnancy and Lactation**
- Available studies with use of adalimumab during pregnancy do not reliably establish an association between adalimumab and major birth defects.
    - Because many immunoglobulins are secreted in milk and the potential for serious adverse reactions exists, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

BILLING/CODING INFORMATION:

HCPCS Coding:

J0139	Injection, adalimumab, 1 mg
J3590	Unclassified biologics [for adalimumab products other than Abrilada, Humira and Idacio]
Q5140	Injection, adalimumab-fkjp, biosimilar, 1 mg
Q5141	Injection, adalimumab-aaty, biosimilar, 1 mg
Q5142	Injection, adalimumab-ryvk biosimilar, 1 mg
Q5143	Injection, adalimumab-adbm, biosimilar, 1 mg
Q5144	Injection, adalimumab-aacf (idacio), biosimilar, 1 mg
Q5145	Injection, adalimumab-afzb (abrilada), biosimilar, 1 mg

ICD-10 Diagnosis Codes That Support Medical Necessity:

H20.00 – H20.9	Iridocyclitis
H44.111 – H44.119	Panuveitis
H44.131 - H44.139	Sympathetic uveitis
K50.00 – K50.919	Crohn’s disease [regional enteritis]
K51.00 – K51.919	Ulcerative colitis
K52.3	Indeterminate colitis

L40.0	Psoriasis vulgaris
L40.50 – L40.59	Arthropathic psoriasis
L73.2	Hidradenitis suppurativa
M05.00 – M05.09	Felty's syndrome
M05.10 – M05.19	Rheumatoid lung disease with rheumatoid arthritis
M05.20 – M05.29	Rheumatoid vasculitis with rheumatoid arthritis
M05.30 – M05.39	Rheumatoid heart disease with rheumatoid arthritis
M05.40 – M05.49	Rheumatoid myopathy with rheumatoid arthritis
M05.50 – M05.59	Rheumatoid polyneuropathy with rheumatoid arthritis
M05.60 – M05.69	Rheumatoid arthritis with involvement of other organs and systems
M05.70 – M05.7A	Rheumatoid arthritis with rheumatoid factor without organ or systems involvement
M05.80 – M05.8A	Other rheumatoid arthritis with rheumatoid factor
M05.9	Rheumatoid arthritis with rheumatoid factor, unspecified
M05.A	Abnormal rheumatoid factor and anti-citrullinated protein antibody with rheumatoid arthritis
M06.00 – M06.0A	Rheumatoid arthritis without rheumatoid factor
M06.20 – M06.29	Rheumatoid bursitis
M06.30 – M06.39	Rheumatoid nodule
M06.4	Inflammatory polyarthropathy [for immunotherapy-related inflammatory arthritis ONLY]
M06.80 – M06.8A	Other specified rheumatoid arthritis
M06.9	Rheumatoid Arthritis, unspecified
M08.09	Unspecified Juvenile rheumatoid arthritis, multiple sites
M08.1	Juvenile ankylosing spondylitis
M08.3	Juvenile Rheumatoid polyarthritis (seronegative)
M08.89	Other juvenile arthritis, multiple sites
M35.2	Behçet's disease
M45.0 – M45.9	Ankylosing spondylitis
M46.81 – M46.89	Other specified inflammatory spondylopathies

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage Products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

Crohn's disease: A chronic granulomatous inflammatory disease of unknown etiology, involving any part of the gastrointestinal tract from mouth to anus, but commonly involving the terminal ileum with scarring and thickening of the bowel wall.

DMARDs: An acronym for disease-modifying antirheumatic drugs. These are drugs that modify the rheumatic disease processes, and slow or inhibit structural damage to cartilage and bone. These drugs are unlike symptomatic treatments such as NSAIDs that do not alter disease progression. DMARDs can be further subcategorized. With the release of biologic agents (e.g., anti-TNF drugs), DMARDs were divided into either: (1) conventional, traditional, synthetic, or non-biological DMARDs; or as (2) biological DMARDs. However, with the release of newer targeted non-biologic drugs and biosimilars, DMARDs are now best categorized as: (1) conventional synthetic DMARDs (csDMARD) (e.g., MTX, sulfasalazine), (2) targeted synthetic DMARDs (tsDMARD) (e.g., baricitinib, tofacitinib, apremilast), and (3) biological DMARDs (bDMARD), which can be either a biosimilar DMARD (bsDMARD) or biological originator DMARD (boDMARD).

Hidradenitis suppurativa (HS) (a.k.a., acne inversa): a chronic, inflammatory, recurrent, debilitating skin disease of the hair follicle that usually presents after puberty with painful, deep-seated, inflamed lesions in the apocrine gland-bearing areas of the body, most commonly the axillae, inguinal and anogenital regions. HS may have a large impact on quality of life, often causing depression, impaired sexual health, and embarrassment. Squamous cell carcinoma may arise from chronic (10-30 years of evolution) lesions. The main goals of treatment are to prevent the formation of new lesion, treat new lesions, and eliminate existing nodules and sinus tract to limit or prevent scar formation.

Moderate to Severe Crohn's Disease: Moderate to severe disease applies to patients who have failed to respond to treatment for mild to moderate disease or those with more prominent symptoms of fevers, significant weight loss, abdominal pain or tenderness, intermittent nausea or vomiting (without obstructive findings), or significant anemia.

Plaque psoriasis: It is the most common form of psoriasis. It affects 80 to 90% of people with psoriasis. Plaque psoriasis typically appears as raised areas of inflamed skin covered with silvery white scaly skin. These areas are called plaques.

Psoriatic arthritis (PsA): joint inflammation that occurs in about 5% to 10% of people with psoriasis (a common skin disorder). It is a severe form of arthritis accompanied by inflammation, psoriasis of the skin or nails, and a negative test for rheumatoid factor. Enthesitis refers to inflammation of entheses, the site where ligaments or tendons insert into the bones. It is a distinctive feature of PsA and does not occur with other forms of arthritis. Common locations for enthesitis include the bottoms of the feet, the Achilles' tendons, and the places where ligaments attach to the ribs, spine, and pelvis.

Rheumatoid arthritis: An inflammatory disease of the synovium, or lining of the joint which results in pain, stiffness, and swelling of multiple joints. The inflammation may extend to other joints and cause bone and cartilage erosion, joint deformities, movement problems, and activity limitations.

RELATED GUIDELINES:

Abatacept (Orencia), 09-J0000-67
Anakinra (Kineret), 09-J0000-45
Apremilast (Otezla) Tablet, 09-J2000-19
Baricitinib (Olumiant), 09-J3000-10
Bimekizumab (Bimzelx), 09-J4000-70
Brodalumab (Siliq) Injection, 09-J2000-74
Certolizumab Pegol (Cimzia), 09-J0000-77
Deucravacitinib (Sotyktu), 09-J4000-37
Etanercept (Enbrel), 09-J0000-38
Etrasimod (Velsipity), 09-J4000-72
Golimumab (Simponi, Simponi Aria), 09-J1000-11
Guselkumab (Tremfya), 09-J2000-87

Infliximab Products, 09-J0000-39
Ixekizumab (Taltz), 09-J2000-62
Mirikizumab (Omvoh), 09-J4000-71
Rituximab Products, 09-J0000-59
Risankizumab (Skyrizi), 09-J3000-45
Sarilumab (Kevzara), 09-J2000-87
Secukinumab (Cosentyx), 09-J2000-30
Tildrakizumab-asmn (Ilumya), 09-J3000-04
Tocilizumab Products (Actemra, Tofidence, Tyenne), 09-J1000-21
Tofacitinib (Xeljanz, Xeljanz XR) Tablets, 09-J1000-86
Upadacitinib (Rinvoq), 09-J3000-51
Ustekinumab (Stelara), 09-J1000-16
Vedolizumab (Entyvio), 09-J2000-18

OTHER:

NOTE: The list of biologic immunomodulator agents not permitted as concomitant therapy can be found at Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.

Table 4: Conventional Synthetic DMARDs

Generic Name	Brand Name
Auranofin (oral gold)	Ridaura
Azathioprine	Imuran
Cyclosporine	Neoral, Sandimmune
Hydroxychloroquine	Plaquenil
Leflunomide	Arava
Methotrexate	Rheumatrex, Trexall
Sulfasalazine	Azulfidine, Azulfidine EN-Tabs

Table 5: Grading of Severity of Rheumatoid Arthritis

Severity	Criteria
Mild	Joint pain Inflammation of at least 3 joints No inflammation in tissues other than the joints Usually, a negative result on a rheumatoid factor test An elevated erythrocyte sedimentation rate (ESR) or C reactive protein (CRP) level No evidence of bone or cartilage damage on x-rays
Moderate	Between 6 and 20 inflamed joints Usually no inflammation in tissues other than the joints An elevated ESR or CRP levels A positive rheumatoid factor test or anti-cyclic citrullinated peptide (anti-CCP) antibodies Evidence of inflammation but no evidence of bone damage on x-rays
Severe	More than 20 persistently inflamed joints or a rapid loss of functional abilities Elevated ESR or CRP levels Anemia related to chronic illness Low blood albumin level A positive rheumatoid factor test, often with a high level Evidence of bone and cartilage damage on x-ray Inflammation in tissues other than joints

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 03/11/26.

GUIDELINE UPDATE INFORMATION:

01/01/05	New Medical Coverage Guideline.
08/15/05	Revised and Updated: Updated description, dosage/administration. Deleted precautions, updated when services are not covered, billing/coding information, and definitions, table 1, references.
11/15/05	Updated when services are covered for psoriatic arthritis, updated ICD-9 codes, definitions, and references.
11/15/06	Scheduled review: added indication of ankylosing spondylitis, added ICD-9 code, corrected CPT-4 coding and updated references.
01/01/07	MCG revised to include Medicare Part D as program exception.
04/15/07	Revision; consisting of adding Crohn's disease indication and ICD-9 code, related guidelines and definitions.
06/15/07	Review and revision; consisting of reformatting, updating related guidelines and references.
03/15/08	Revision; consisting of adding plaque psoriasis and juvenile idiopathic arthritis (JIA) as covered indications, rewording coverage criteria for Crohn's disease, updated dosage and administration section, added ICD-9 codes and updated references.
05/15/08	Review and revision; consisting of reformatting, adding a black box warning under "PRECAUTIONS", adding related guideline and updating references.
09/15/08	Revision of guideline; consisting of adding 3 ICD-9 codes.
01/01/09	Annual HCPCS coding update: deleted code 90772; added code 96372.
09/15/09	Review and revision; consisting of updating references, boxed warning and ICD-9 coding.
04/15/10	Revision; consisting of adding specific continuation criteria.

08/15/10	Review and revision; consisting of adding age criteria to all indications, updated precautions and references.
01/15/11	Revision; consisting of adding ICD-10 codes.
04/01/11	Revision; consisting of adding dosage limitations.
08/15/11	Review and revision to guideline; consisting of updating the precautions section, coding and references.
08/15/12	Review and revision to guideline; consisting of reformatting position statement, updating precautions and references.
09/15/12	Revision to guideline consisting of modifying plaque psoriasis criteria and continuation criteria.
11/15/12	Revision to guideline consisting of adding new indication of ulcerative colitis.
01/15/13	Revision to guideline; consisting of revising/reformatting/updating position statement, description, dosage/administration sections; reformatting precautions section; updating references.
04/15/13	Revision to guideline; consisting of revising position statement to include Orphan Drug indications and duration of approval
09/15/13	Review and revision to guideline; consisting of reformatting position statement, updating program exceptions section and references.
01/01/14	Revision to guideline; consisting of updating position statement.
04/15/14	Revision to guideline; consisting of reformatting and revising position statement to include clarifying language.
09/15/14	Review and revision to guideline; consisting of updating position statement, references, coding and related guidelines.
12/15/14	Revision to guideline; consisting of position statement, dosage/administration, references
09/15/15	Review and revision to guideline; consisting of consisting of updating description section, position statement, billing/coding, related guidelines, and references.
11/01/15	Revision: ICD-9 Codes deleted.
11/15/15	Revision to guideline; consisting of updating description section, position statement, dosage/administration, and references based on a new FDA-approved indication.
02/15/16	Revision to guideline consisting of updating maximum dosages for pediatric patients in the position statement.
09/15/16	Review and revision to guideline consisting of consisting of updating description section, position statement, billing/coding, definitions, related guidelines, and references.
10/01/16	Revision: ICD-10 code updates
10/15/17	Review and revision to guideline consisting of updating description, position statement, definitions, related guidelines, and references
01/01/18	Revision to guideline consisting of updating the preferred self-administered biologic products according to indication for use.
07/01/18	Revision to guideline consisting of updating the position statement.
10/15/18	Review and revision to guideline consisting of updating the position statement, related guidelines, and references.
12/15/18	Revision to guideline consisting of updating the description, position statement, dosage/administration, and references based on new pediatric/adolescent indications.
10/15/19	Review and revision to guideline consisting of updating the description, position statement, billing/coding, related guidelines, and references.
01/01/20	Revision to guideline consisting of updating the position statement “Note” due to changes in preferred products.
03/15/20	Revision to guideline consisting of updating the description section.
07/01/20	Review and revision to guideline consisting of consisting of updating the description section, position statement, definitions, billing/coding, and other.
01/01/21	Review and revision to guideline consisting of updating the description, position statement and references.
02/15/21	Revision to guideline consisting of updating the description, position statement, dosage/administration, and references.

05/15/21	Revision to guideline consisting of updating the description, position statement, dosage/administration, other section, and references.
09/15/21	Update to Table 1 in Position Statement.
11/15/21	Revision to guideline consisting of updating the position statement.
01/01/22	Review and revision to guideline consisting of updating the description, position statement and references.
02/15/22	Revision to guideline consisting of updating the description and position statement.
03/15/22	Revision to guideline consisting of updating the position statement and other sections.
05/15/22	Update to Table 1 in Position Statement.
07/15/22	Update to Table 1 in Position Statement.
09/15/22	Update to Table 1 in Position Statement.
01/01/23	Review and revision to guideline consisting of updating the description section (biosimilar information), position statement, other section, and references. New drugs were added to the list of drugs that are not permitted for use in combination. For UC, added allowance for Humira to be used first-line for members with severe disease and/or risk factors for disease complications.
04/01/23	Revision to guideline consisting of updating the title, description section, position statement, dosage/administration, billing/coding, other section, and references. MCG renamed Adalimumab Products (Humira and biosimilars). Amjevita added to the policy as a Step 3c agent with Humira always a required prerequisite.
04/15/23	Revision to guideline consisting of updating the position statement and other section.
07/01/23	Revision to guideline consisting of updating the description section, position statement, dosage/administration, billing/coding, other section, and references. Amjevita and Hadlima added to the policy as Step 1a agents (co-preferred with Humira). Abrilada, Cyltezo, Hulio, Hyrimoz, Idacio, Yuflyma, and Yusimry added to the policy as Step 3c agents with Amjevita, Hadlima, and Humira as required prerequisites. Added HCPCS code Q5131.
01/01/24	Review and revision to guideline consisting of updating the description (biosimilar updates and NCCN info), position statement, dosage/administration, billing/coding, other section, and references. Product availability/package sizes updated. “High concentration” Amjevita [i.e., 20 mg/0.2 mL, 40 mg/0.4 mL, and 80 mg/0.8 mL concentrations] added as a non-preferred product. New HCPCS code for Abrilada. Update to Table 1 in Position Statement. New drugs were added to the list of drugs that are not permitted for use in combination.
07/01/24	Revision to guideline consisting of updating the description section, position statement, dosage/administration, billing/coding, related guidelines, other section, and references. Amjevita low-concentration moved from a Step 1 agent to a non-preferred Step 3c agent. Simlandi added to the policy as a Step 3c agent with Hadlima and Humira as required prerequisites. Rinvoq is a new Step 1b agent for PJIA. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
10/01/24	Simlandi changed from a non-preferred Step 3c adalimumab product to a preferred Step 1a adalimumab product.
11/15/24	Revision to guideline consisting of updating the position statement and other section. Tremfya added as Step 1a agent for UC.
01/01/25	Review and revision to guideline consisting of updating the position statement, other section, and references. Adalimumab-aaty and Adalimumab-adaz added among the preferred adalimumab products. Update to original Table 1 which is now a link out from the Position Statement. Table titles updated. Revised wording regarding maximum dosage exceptions. New drugs were added to the list of drugs that are not permitted for use in combination. New HCPCS codes.
10/01/25	Revision: Added ICD-10 code M05.A. Updated ICD-10 code ranges for RA.
01/01/26	Review and revision to guideline consisting of updating the description, position statement, and references.

04/01/26	Revision to guideline consisting of updating the position statement and references. Adalimumab-bwwd (an unbranded version of Hadlima from Cordavis) added as a non-preferred biosimilar.
07/01/26	Revision: Modified the prerequisite requirement that bypasses the conventional agent step to exclude sample use and include systemic targeted synthetic small molecule drugs as an option. Updated the HS prerequisites to only systemic antibiotic therapy. Added additional wording to the definition of severe active PsA.