Medical Drug Clinical Criteria

Subject:	Tumor Necrosis Factor Antagonists		
Document #:	CC-0062	**Publish Date:**	05/06/2024
Status:	Revised	**Last Review Date:**	03/11/2024

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Overview

This document addresses the use of tumor necrosis factor inhibitors (TNFi) which target specific pathways of the immune system and either enhance or inhibit the immune response. Indications are drug-specific but TNFi are approved for the treatment of rheumatoid arthritis, psoriasis, psoriatic arthritis, Crohn's disease, ulcerative colitis, ankylosing spondylitis, juvenile idiopathic arthritis, hidradenitis suppurativa, non-infectious uveitis, and other conditions as applicable. Agents addressed in this document include:

- Adalimumab agents (Humira, Adalimumab, Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Idacio, Simlandi, Yuflyma, Yusimry)
- Certolizumab pegol (Cimzia)
- Etanercept agents (Enbrel, Erelzi, Eticovo)
- Golimumab (Simponi, Simponi Aria)
- Intravenous Infliximab agents (Remicade, Infliximab, Avsola, Inflectra, Ixifi, Renflexis)
- Subcutaneous Infliximab-dyyb (Zymfentra)

Rheumatoid Arthritis: The American College of Rheumatology (ACR) guidelines recommend disease-modifying antirheumatic drug (DMARD) monotherapy as first-line treatment in individuals with RA with moderate to high disease activity. Methotrexate (MTX) monotherapy, titrated to a dose of at least 15 mg, is recommended over hydroxychloroquine, sulfasalazine, and leflunomide. Methotrexate monotherapy is also recommended over monotherapy with biologics (TNFi, IL-6 inhibitors, abatacept) or JAK inhibitors. For individuals taking maximally tolerated doses MTX who are not at target, the addition of a biologic or JAK inhibitor is recommended. Non-TNFi biologics or JAK inhibitors are conditionally recommended over TNFi in individuals with heart failure.

Plaque Psoriasis (otherwise known as psoriasis vulgaris): The American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) published joint guidelines on the management and treatment of psoriasis with biologics. The guidelines do not include a treatment algorithm or compare biologics to each other or conventional therapy. The guideline notes that patients with mild-moderate disease may be adequately controlled with topical therapy and/or phototherapy while moderate to severe disease may necessitate treatment with a biologic. Moderate to severe disease is defined as involvement in > 3% of body surface area (BSA) or involvement in sensitive areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia). TNFi biologics, ustekinumab, IL17 inhibitors, and IL23 inhibitors are all recommended as monotherapy treatment options for adult patients with moderate to severe plaque psoriasis. Combination use of TNFi biologics (etanercept, infliximab, adalimumab) and ustekinumab with apremilast is poorly studied and the AAD has given this practice a grade C recommendation based on limited-quality evidence.

Psoriatic Arthritis: The American College of Rheumatology (ACR) guidelines recommend that initial treatment of patients with active severe PsA or concomitant psoriasis should include a TNFi biologic over an oral small molecule (OSM; including methotrexate, sulfasalazine, cyclosporine, leflunomide, and apremilast). For initial therapy, OSMs are preferred over IL-17 and ustekinumab; and may be considered over TNFi biologics in mild to moderate disease without comorbid conditions or in those who prefer oral therapy. Recommendations involving biologics over OSMs as first line therapy are conditional and based on low quality evidence. Evidence cited includes indirect comparisons of placebo-controlled trials, studies with open-label design, and extrapolation from studies in plaque psoriasis. Furthermore, most pivotal trials for TNFi biologics included a study population that were DMARD experienced. Overall, there is a lack of definitive evidence for the safety and efficacy of biologic drugs over conventional therapy for the initial treatment of most patients with psoriatic arthritis. The ACR guidelines also include recommendations for

patients whose disease remains active despite treatment with an OSM. Here, TNFi biologics are recommended over other therapies including IL-17 inhibitors, ustekinumab, tofacitinib, and abatacept. When TNFi biologics are not used, IL-17 inhibitors are preferred over ustekinumab; both of which are preferred over tofacitinib and abatacept. For disease that remains active despite TNFi monotherapy, switching to a different TNFi is recommended over other therapies.

Crohn's Disease: According to the American Gastrointestinal Association clinical practice guidelines, evidence supports the use of methotrexate, corticosteroids, TNFi +/- immunomodulator, ustekinumab, or vedolizumab for induction of remission. Among the biologics, infliximab, adalimumab, ustekinumab, or vedolizumab are recommended or suggested over certolizumab for induction of remission. Evidence supports biologic agents, thiopurines, and methotrexate for maintenance of remission. Ustekinumab and vedolizumab are options for individuals with primary nonresponse to initial treatment with TNFi. Adalimumab, ustekinumab, or vedolizumab may be used in cases where an individual previously responded to infliximab and then lost response (secondary nonresponse).

Ulcerative Colitis: For those with moderately to severely active disease, the American College of Gastroenterology (ACG) guidelines strongly recommend induction of remission using oral budesonide MMX, oral systemic corticosteroids, TNFi, tofacitinib or vedolizumab (moderate to high quality evidence). The American Gastroenterological Association (AGA) guidelines define moderate to severe UC as those who are dependent on or refractory to corticosteroids, have severe endoscopic disease activity, or are at high risk of colectomy. AGA strongly recommends biologics (TNFi, vedolizumab, or ustekinumab) or tofacitinib over no treatment in induction and maintenance of remission (moderate quality of evidence). For biologic-naïve individuals, Infliximab or vedolizumab are conditionally recommended over adalimumab for induction of remission (moderate quality evidence).

Axial Spondyloarthritis: Sponyloarthritis with predominantly axial involvement includes both ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA), based upon the presence or absence, respectively, of abnormalities of the sacroiliac joints on plain radiography. The American College of Rheumatology (ACR) and Spondylitis Association of America guidance recommend NSAIDs as initial treatment for AS and nr-axSpA. In adults with active AS despite treatment with NSAIDS, DMARDs [including sulfasalazine or MTX], TNF inhibitors, and IL-17 inhibitors [secukinumab or ixekizumab] are recommended. TNFi treatment is recommended over IL-17 inhibitors. IL-17 inhibitors are recommended over a different TNFi in patients with primary nonresponse to TNFi (no initial response). An alternative TNFi is recommended in patients with secondary nonresponse to the first TNFi used (relapse after initial response). Recommendations for nr-axSpA are largely extrapolated from evidence in AS; only certolizumab has been approved for this indication.

Juvenile Idiopathic Arthritis: The American College of Rheumatology (ACR) guidelines provide recommendations for juvenile idiopathic arthritis, including systemic disease (SJIA) and JIA with polyarthritis (PJIA). SJIA is an autoinflammatory condition marked by intermittent fever, rash, and arthritis. PJIA is marked by the presence of more than four affected joints in the first six months of illness. For SJIA, NSAIDs or glucocorticoids are conditionally recommended as initial monotherapy, depending on whether macrophage activation syndrome (MAS) is present or not. IL-1 inhibitors (anakinra or canakinumab), or tocilizumab are also conditionally recommended as initial therapy or to achieve inactive disease, with no preferred agent. For SJIA without MAS, IL-1 inhibitors (anakinra or canakinumab) and tocilizumab are strongly recommended for inadequate response to or intolerance of NSAIDs and/or glucocorticoids (ACR 2021). For children with active polyarthritis, biologic therapy including TNFi, abatacept, or tocilizumab +/- DMARD is recommended following initial DMARD therapy (preferably methotrexate) (ACR 2019).

Hidradenitis Suppurativa (HS): Hidradenitis Suppurativa is a chronic inflammatory skin condition that causes painful nodules and abscesses primarily occurring in intertriginous areas. HS is typically classified according to severity based on the number of abscesses and extent of skin involvement. General management includes antiseptic washes, intralesional therapies (steroids or antibiotics), and non-steroidal anti-inflammatories for pain. According to the United States and Canadian HS clinical guidelines, medical management may include oral antibiotics such as tetracyclines (level C recommendation) or rifampin and clindamycin (level B recommendation) for all stages of disease. Moderate to severe disease management includes biologics such as anti-TNF agents (Level A recommendation for adalimumab). Adalimumab and secukinumab are the only biologics approved for HS.

Biosimilar and Interchangeable Agents: Biosimilar products must be highly similar to the reference product and there must be no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product. Biosimilars must utilize the same mechanism of action (MOA), route of administration, dosage form and strength as the reference product; and the indications proposed must have been previously approved for the reference product. The potential exists for a biosimilar product to be approved for one or more indications for which the reference product is licensed based on extrapolation of data intended to demonstrate biosimilarity in one indication. Sufficient scientific justification for extrapolating data is necessary for FDA approval. Factors and issues that should be considered for extrapolation include the MOA for each indication, the

pharmacokinetics, bio-distribution, and immunogenicity of the product in different patient populations, and differences in expected toxicities in each indication and patient population. As biosimilar agents must demonstrate similarity to the reference product in FDA indications, it is reasonable that biosimilarity can be extrapolated to off-label indications as well. In contrast to biosimilar status, an interchangeable biologic must meet the biosimilar standards, but also must be expected to product the same clinical result as the reference product in any given patient; and if administered more than once to a patient, the risk in terms of safety or diminished efficacy from altering or switching between use of the reference or interchangeable product is not greater than that from use of the reference product without such alteration or switch.

There are currently four FDA approved infliximab biosimilar agents, Inflectra (infliximab-dyyb), Ixifi (infliximab-qbtx), Renflexis (infliximab-abda), and Avsola (infliximab-axxq). There is also one FDA approved unbranded product called Infliximab. Infliximab is the same product as Remicade and has the same label, but was approved as an unbranded biologic, not a generic or biosimilar. All four biosimilar products share the same FDA approved indications as Remicade and, as biosimilars, are dosed and administered the same way. The approval of each agent was based on pharmacokinetic data, clinical comparative efficacy data, and extrapolation to selected indications of the reference product. In a randomized, double-blind, non-inferiority trial, adults with RA, ankylosing spondyloarthritis, psoriatic arthritis, Crohn's disease, ulcerative colitis, and psoriasis on stable treatment with reference products were randomized to continue reference product or switch to Inflectra at the same dose for 52 weeks. The primary endpoint, disease worsening, occurred in 26.2% and 29.6% of patients in the reference and biosimilar groups, respectively, demonstrating non-inferiority within the pre-specified margin of 15%. The frequency of adverse events was similar between groups (Jorgensen 2017). In a phase 3, double-blind, active-controlled study, individuals with RA randomized to Ixifi or reference product were re-randomized to continue on reference or switch to the biosimilar at week 30. Authors concluded that at week 54, the efficacy, safety, and immunogenicity were similar between groups and not affected by treatment switching (Alten 2019). Another randomized, double-blind, non-inferiority trial in adults with RA randomized individuals to continue reference product or switch to Renflexis at the same dosing schedule for 24 weeks. Response rate by ACR20 was 68.8% and 63.5% in reference and biosimilar groups, respectively, after transition period. Authors concluded that no clinically meaningful difference in terms of efficacy, safety, and immunogenicity was observed in the switch group compared to the reference group (Smolen 2018). A randomized, double-blind, active-controlled, comparative clinical study supports a single switch from Remicade to Avsola in 556 patients with Rheumatoid Arthritis (RA). Avsola was non-inferior to Remicade (given at the same dose and schedule) when both were given for 52 weeks as measured by ACR20. The authors concluded that this study demonstrated the safety and immunogenicity of Avsola were similar to those of the reference product and that the efficacy and safety were not impacted by a single switch from infliximab reference to Avsola (Genovese 2020).

There are ten FDA approved adalimumab biosimilar products: Abrilada (adalimumab-afzb); Amjevita (adalimumab-atto); Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz); Hadlima (adalimumab-bwwd), Hulio (adalimumab-fkjp), Idacio (adalimumab-aacf), Simlandi (adalimumab-ryvk), Yuflyma (adalimumab-aaty) and Yusimry (adalimumab-aqvh). There is also one FDA approved unbranded product called Adalimumab. Adalimumab unbranded is the same product as Humira and has the same label, but was approved as an unbranded biologic, not a generic or biosimilar. The biosimilar products share most of the same FDA approved indications as Humira, with some exceptions including certain pediatric approvals. As biosimilars, these products are dosed and administered the same way, though equivalent dosage strengths are not available for all products currently. The approval of each agent was based on pharmacokinetic data, clinical comparative efficacy data, and extrapolation to selected indications of the reference product. There is also evidence supporting at least a single switch between reference product and biosimilar in select indications. These studies indicate that a single switch does not result in considerable alterations in efficacy, safety, and immunogenicity of the product (Cohen 2019, Fleischmann 2021, Blauvelt 2021, Wiland 2021, Weinblatt 2018, Genovese 2020, Papp 2017, Hercogová 2020, Hanaur 2021, Menter 2020, Cohen 2018). There are three biosimilars that the FDA has designated as interchangeable with Humira: Cyltezo (adalimumab-adbm), Abrilada (adalimumab-afzb), and Simlandi (adalimumab-ryvk). Supportive literature for interchangeability includes multi-switch randomized phase 3 studies in Rheumatoid arthritis for Abrilada (Fleischmann 2022) and Plaque Psoriasis for Cyltezo and Simlandi (Menter 2022; Feldman 2021). Interchangeability of Cyltezo, Abrilada and Simlandi have been demonstrated for the conditions of use, strengths, dosage forms, and route of administration described in its prescribing information. As interchangeable products, Abrilada, Cyltezo, and Simlandi can be expected to produce the same clinical result as the reference product in any given patient; and if administered more than one to a patient, the risk in terms of safety or diminished efficacy from alternating or switching between the use of the reference product or interchangeable is not greater than that from the reference product without such alternation or switch.

Tumor necrosis factor inhibitors have black box warnings for serious infections and malignancy. Individuals treated with TNFi are at increased risk for developing serious infections that may lead to hospitalization or death. Most individuals who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. TNFi should be discontinued if an individual develops a serious infection or sepsis. Individuals should be tested for latent tuberculosis (TB) before TNFi use and during therapy. Treatment for latent TB should be initiated

prior to TNFi use. Risks and benefits of TNFi should be carefully considered prior to initiation of therapy in individuals with chronic or recurrent infection. Lymphoma and other malignancies have been reported in children and adolescents treated with TNFi. Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL) have been reported in individuals treated with TNFi. Almost all cases had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNFi at or prior to diagnosis. It is uncertain whether HSTCL is related to the use of a TNFi or a TNFi in combination with these other immunosuppressants.

Use of TNFi has been associated with rare cases of new onset or exacerbation of demyelinating disease including multiple sclerosis and Guillain-Barre syndrome. Exercise caution if considering the use of TNFi in individuals with preexisting or recent-onset central or peripheral nervous system demyelinating disorders and discontinuation should be considered if any of these disorders develop.

Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNFi. TNFi should be used with caution in CHF and individuals should be monitored closely. The clinician should consider the status of an individual with moderate or severe heart failure (New York Heart Association (NYHA) Functional Class III-IV) before initiating treatment with infliximab at doses greater than 5mg/kg.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Cimzia (certolizumab pegol)

Initial requests for Cimzia (certolizumab pegol) may be approved for the following:

I. Crohn's disease (CD) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe CD; **AND**
   B. Individual has had an inadequate response to or is intolerant of conventional therapy (such as systemic corticosteroids or immunosuppressants [such as thiopurines or methotrexate]); **OR**
   C. Individual has a contraindication to systemic corticosteroids or thiopurines or methotrexate;

OR

II. Rheumatoid arthritis (RA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe RA; **AND**
   B. Documentation is provided that individual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021); **OR**
   C. Documentation is provided that if methotrexate is not tolerated, individual has had an inadequate response to or is intolerant o other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine); **OR**
   D. Documentation is provided that individual has a contraindication to methotrexate, sulfasalazine, leflunomide, and hydroxychloroquine;

OR

III. Ankylosing spondylitis (AS) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe AS; **AND**
   B. Individual has had an inadequate response to or is intolerant of conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)]; **OR**
   C. Individual has a contraindication to NSAIDs or sulfasalazine;

OR

IV. Non-radiographic axial spondyloarthritis (nr-axSpA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe nr-axSpA; **AND**
   B. Individual has had an inadequate response to or is intolerant of conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)] (ACR 2019); **OR**
   C. Individual has a contraindication to NSAIDs or sulfasalazine;

OR

V. Psoriatic arthritis (PsA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe PsA; **AND**
   B. Individual has had an inadequate response to or is intolerant of conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, cyclosporine, or leflunomide)]; **OR**
   C. Individual has a contraindication to methotrexate, sulfasalazine, cyclosporine, and leflunomide;

OR

VI. Plaque psoriasis (Ps) when each of the following criteria are met:

A. Individual is 18 years of age or older with chronic moderate to severe (that is, extensive or disabling) plaque Ps with either of the following (AAD 2019):
    1. Plaque Ps involving greater than three percent (3%) body surface area (BSA); **OR**
    2. Plaque Ps involving less than or equal to three percent (3%) BSA involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia); **AND**
B. Individual has had an inadequate response to or is intolerant of phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate); **OR**
C. Individual has a contraindication to phototherapy, acitretin, cyclosporine, and methotrexate;

OR

VII. Immune checkpoint inhibitor therapy-related toxicities in an individual with any of the following conditions (NCCN 2A):
    A. Moderate to Severe inflammatory arthritis unresponsive to corticosteroids or nonbiologic DMARDs.

Continuation requests for Cimzia (certolizumab pegol) may be approved if the following criteria is met:

I. Individual has been receiving and is maintained on a stable dose of Cimzia; **AND**
II. There is clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

Requests for Cimzia (certolizumab pegol) may not be approved for the following:

I. In combination with oral or topical JAK inhibitors, ozanimod, apremilast, etrasimod, deucravacitinib, or any of the following biologic immunomodulators: Other TNF antagonists, IL-23 inhibitors, IL-17 inhibitors, IL-6 inhibitors, IL-1 inhibitors, vedolizumab, ustekinumab, abatacept, rituximab, or natalizumab; **OR**
II. Tuberculosis (TB), other active serious infections, or a history of recurrent infections [repeat TB testing not required for ongoing authorization]; **OR**
III. If initiating therapy, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
IV. When the above criteria are not met and for all other indications.

Etanercept Agents [Enbrel (etanercept); Erelzi (etanercept-szzs); Eticovo (etanercept-ykro)]

Initial requests for Enbrel (etanercept), Erelzi (etanercept-szzs), or Eticovo (etanercept-ykro) may be approved for the following:

I. Rheumatoid arthritis (RA) when each the following criteria are met:
    A. Individual is 18 years of age or older with moderate to severe RA; **AND**
    B. Documentation is provided that individual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021); **OR**
    C. Documentation is provided that if methotrexate is not tolerated, individual has had an inadequate response to or is intolerant of other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine); **OR**
    D. Documentation is provided that individual has a contraindication to methotrexate, sulfasalazine, leflunomide, and hydroxychloroquine;

OR

II. Ankylosing spondylitis (AS) when each of the following criteria are met:
    A. Individual is 18 years of age or older with moderate to severe AS; **AND**
    B. Individual has had an inadequate response to or is intolerant of conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)] (ACR 2019); **OR**
    C. Individual has a contraindication to NSAIDs or sulfasalazine;

OR

III. Polyarticular juvenile idiopathic arthritis (PJIA) when each of the following criteria are met:
    A. Individual is 2 years of age or older with moderate to severe PJIA; **AND**
    B. Individual has had an inadequate response to or is intolerant of conventional therapy [nonbiologic DMARDs (such as methotrexate)] (ACR 2019); **OR**
    C. Individual has a contraindication to methotrexate;

OR

IV. Psoriatic arthritis (PsA) when each of the following criteria are met:
    A. Individual is 2 years of age or older with moderate to severe PsA; **AND**
    B. Individual has had an inadequate response to or is intolerant of conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, cyclosporine, or leflunomide)]; **OR**
    C. Individual has a contraindication to methotrexate, sulfasalazine, cyclosporine, and leflunomide;

OR

V. Plaque psoriasis (Ps) when each of the following criteria are met:

A. Individual is 4 years of age or older with chronic moderate to severe (that is, extensive or disabling) plaque Ps with either of the following (AAD 2019):
    1. Plaque Ps involving greater than three percent (3%) body surface area (BSA); **OR**
    2. Plaque Ps involving less than or equal to three percent (3%) BSA involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia); **AND**
B. Individual has had an inadequate response to or is intolerant of, phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate); **OR**
C. Individual has a contraindication to phototherapy, acitretin, cyclosporine, and methotrexate;

OR

VI. Immune checkpoint inhibitor therapy-related toxicities in an individual with any of the following conditions (NCCN 2A):
    A. Moderate to Severe inflammatory arthritis unresponsive to corticosteroids or nonbiologic DMARDs; **OR**
    B. Stevens-Johnson syndrome or toxic epidermal necrolysis;

OR

VII. Graft-versus-host disease (GVHD) when each of the following criteria are met (NCCN 2A)
    A. Individual has a diagnosis of steroid-refractory acute or chronic GVHD; **AND**
    D. Individual is initiating etanercept in combination with systemic corticosteroids.

Continuation requests for Enbrel (etanercept), Erelzi (etanercept-szzs), or Eticovo (etanercept-ykro) may be approved if the following criteria are met:

I. Individual has been receiving and is maintained on a stable dose of etanercept; **AND**
II. There is clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

Requests for Enbrel (etanercept), Erelzi (etanercept-szzs), or Eticovo (entanercept-ykro) may not be approved for the following:

I. In combination with oral or topical JAK inhibitors, ozanimod, apremilast, etrasimod, deucravacitinib, cyclophosphamide, or any of the following biologic immunomodulators: Other TNF antagonists, IL-23 inhibitors, IL-17 inhibitors, IL-6 inhibitors, IL-1 inhibitors, vedolizumab, ustekinumab, abatacept, rituximab, or natalizumab; **OR**
II. Tuberculosis (TB), other active serious infections, or a history of recurrent infections [repeat TB testing not required for ongoing authorization]; **OR**
III. If initiating therapy, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
IV. When the above criteria are not met and for all other indications.

Adalimumab Agents [Humira (adalimumab); Adalimumab (unbranded agent); Abrilada (adalimumab-afzb); Amjevita (adalimumab-atto); Cyltezo (adalimumab-adbm); Hadlima (adalimumab-bwwd); Hulio (adalimumab-fkjp); Hyrimoz (adalimumab-adaz); Idacio (adalimumab-aacf); Simlandi (adalimumab-ryvk); Yuflyma (adalimumab-aaty), Yusimry (adalimumab-aqvh)]

Initial requests for Humira (adalimumab), Adalimumab (unbranded agent); Abrilada (adalimumab-afzb); Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hadlima (adalimumab-bwwd), Hulio (adalimumab-fkjp), Hyrimoz (adalimumab-adaz), Idacio (adalimumab-aacf), Simlandi (adalimumab-ryvk); Yuflyma (adalimumab-aaty), or Yusimry (adalimumab-aqvh) may be approved for the following:

I. Crohn's disease (CD) when each of the following criteria are met:
    A. Individual is 6 years of age or older with moderate to severe CD; **AND**
    B. Individual has had an inadequate response to or is intolerant of conventional therapy (such as systemic corticosteroids or immunosuppressants [such as thiopurines or methotrexate]); **OR**
    C. Individual has a contraindication to systemic corticosteroids or thiopurines or methotrexate;

OR

II. Ulcerative colitis (UC) when each of the following criteria are met:
    A. Individual is 5 years of age or older with moderate to severe UC; **AND**
    B. Individual has had an inadequate response to or is intolerant of conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants [such as thiopurines]); **OR**
    C. Individual has a contraindication to 5-ASA products or systemic corticosteroids or thiopurines;

OR

III. Rheumatoid arthritis (RA) when each of the following criteria are met:
    A. Individual is 18 years of age or older with moderate to severe RA; **AND**

B. Documentation is provided that individual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021); **OR**
C. Documentation is provided that if methotrexate is not tolerated, individual has had an inadequate response to or is intolerant of other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine); **OR**
D. Documentation is provided that individual has a contraindication to methotrexate, sulfasalazine, leflunomide, and hydroxychloroquine;

OR

IV. Ankylosing spondylitis (AS) when each of the following criteria are met:
A. Individual is 18 years of age or older with moderate to severe AS; **AND**
B. Individual has had an inadequate response to or is intolerant of conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)]; **OR**
C. Individual has a contraindication to NSAIDs or sulfasalazine;

OR

V. Polyarticular juvenile idiopathic arthritis (PJIA) when each of the following criteria are met:
A. Individual is 2 years of age or older with moderate to severe PJIA; **AND**
B. Individual has had an inadequate response to or is intolerant of conventional therapy [nonbiologic DMARDs (such as methotrexate)] (ACR 2019); **OR**
C. Individual has a contraindication to methotrexate;

OR

VI. Psoriatic arthritis (PsA) when each of the following criteria are met:
A. Individual is 18 years of age or older with moderate to severe PsA; **AND**
B. Individual has had an inadequate response to or is intolerant of conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, cyclosporine, or leflunomide)]; **OR**
C. Individual has a contraindication to methotrexate, sulfasalazine, cyclosporine, and leflunomide;

OR

VII. Plaque psoriasis (Ps) when each of the following criteria are met:
A. Individual is 18 years of age or older with chronic moderate to severe (that is, extensive or disabling) plaque Ps with either of the following (AAD 2019):
1. Plaque Ps involving greater than three percent (3%) body surface area (BSA); **OR**
2. Plaque Ps involving less than or equal to three percent (3%) BSA involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia); **AND**
B. Individual has had an inadequate response to or is intolerant of phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate); **OR**
C. Individual has a contraindication to phototherapy, acitretin, cyclosporine, and methotrexate;

OR

VIII. Non-infectious uveitis (UV) when each of the following criteria are met:
A. Individual has chronic, recurrent, treatment-refractory or vision-threatening disease; **AND**
B. Individual has had an inadequate response toor is intolerant of conventional therapy [such as corticosteroids or immunosuppressants (azathioprine, cyclosporine, or methotrexate)]; **OR**
C. Individual has a contraindication to azathioprine, cyclosporine, and methotrexate;

OR

IX. Hidradenitis suppurativa (HS) when each of the following criteria are met:
A. Individual is 12 years of age or older; **AND**
B. Individual has moderate to severe HS (Hurley stage II or Hurley stage III disease); **AND**
C. Individual has had an inadequate response to or is intolerant of conventional therapy (such as oral antibiotics); **OR**
D. Individual has a contraindication to oral antibiotics;

OR

X. Sarcoidosis when each of the following criteria are met (Sweiss 2014):
A. Individual is 18 years of age or older; **AND**
B. Individual has chronic, progressive, treatment-refractory disease; **AND**
C. Individual has had an inadequate response to, is intolerant of, or has a contraindication to systemic corticosteroids; **AND**
A. Individual has had an inadequate response to or is intolerant of non-biologic DMARDs (such as methotrexate or azathioprine); **OR**
B. Individual has a contraindication to methotrexate and azathioprine.

OR

XI. Immune checkpoint inhibitor therapy-related toxicities in an individual with any of the following conditions (NCCN 2A):
A. Moderate to Severe inflammatory arthritis unresponsive to corticosteroids or nonbiologic DMARDs.

Continuation requests for Humira (adalimumab), Adalimumab (unbranded agent); Abrilada (adalimumab-afzb), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hadlima (adalimumab-bwwd), Hulio (adalimumab-fkjp), Hyrimoz (adalimumab-adaz), Idacio (adalimumab-aacf), Simlandi (adalimumab-ryvk); Yuflyma (adalimumab-aaty), or Yusimry (adalimumab-aqvh) may be approved if the following criteria are met:

I. Individual has been receiving and is maintained on a stable dose of adalimumab; **AND**
II. There is clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

Requests for Humira (adalimumab), Adalimumab (unbranded agent); Abrilada (adalimumab-afzb), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hadlima (adalimumab-bwwd), Hulio (adalimumab-fkjp), Hyrimoz (adalimumab-adaz), Idacio (adalimumab-aacf), Simlandi (adalimumab-ryvk); Yuflyma (adalimumab-aaty), or Yusimry (adalimumab-aqvh) may not be approved for the following:

I. In combination with oral or topical JAK inhibitors, ozanimod, etrasimod, apremilast, deucravacitinib, or any of the following biologic immunomodulators: Other TNF antagonists, IL-23 inhibitors, IL-17 inhibitors, IL-6 inhibitors, IL-1 inhibitors, vedolizumab, ustekinumab, abatacept, rituximab, or natalizumab; **OR**
II. Tuberculosis (TB), other active serious infections, or a history of recurrent infections [repeat TB testing not required for ongoing authorization]; **OR**
III. If initiating therapy, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
IV. When the above criteria are not met and for all other indications.

Infliximab Agents [Remicade (infliximab); Avsola (infliximab-axxq); Inflectra (infliximab-dyyb); Infliximab (unbranded); Ixifi (infliximab-qbtx), Renflexis (infliximab-adba)]

NOTE: Please see individual's pharmacy benefit for preferred products; Zymfentra is not a preferred product for CarelonRx pharmacy benefit.

Initial requests for Remicade (infliximab), Avsola (infliximab-axxq), Inflectra (infliximab-dyyb), Infliximab (unbranded); Ixifi (infliximab-qbtx), or Renflexis (infliximab-adba) may be approved for the following:

I. Crohn's disease (CD) when each of the following criteria are met:
   A. Individual is 6 years of age or older with moderate to severe CD; **AND**
   B. Individual has had an inadequate response to or is intolerant of conventional therapy (such as systemic corticosteroids or immunosuppressants [such as thiopurines or methotrexate]); **OR**
   C. Individual has a contraindication to systemic corticosteroids or thiopurines or methotrexate; **OR**
   D. Individual is 6 years of age or older with fistulizing CD;

OR

II. Ulcerative colitis (UC) when each of the following criteria are met:
   A. Individual is 6 years of age or older with moderate to severe UC; **AND**
   B. Individual has had an inadequate response to or is intolerant of conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants [such as thiopurines]); **OR**
   C. Individual has a contraindication to 5-ASA products or systemic corticosteroids or thiopurines;

OR

III. Rheumatoid arthritis (RA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe RA; **AND**
   B. Documentation is provided that individual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021); **OR**
   C. Documentation is provided that if methotrexate is not tolerated, individual has had an inadequate response to or is intolerant of other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine); **OR**
   D. Documentation is provided that individual has a contraindication to methotrexate, sulfasalazine, leflunomide, and hydroxychloroquine;

OR

IV. Ankylosing spondylitis (AS) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe AS; **AND**
   B. Individual has had an inadequate response to or is intolerant of conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)] (ACR 2019); **OR**
   C. Individual has a contraindication to NSAIDs or sulfasalazine;

OR

V. Psoriatic arthritis (PsA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe PsA; **AND**
   B. Individual has had an inadequate response to or is intolerant of conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, cyclosporine, or leflunomide)]; **OR**
   C. Individual has a contraindication to methotrexate, sulfasalazine, cyclosporine, and leflunomide;

OR

VI. Plaque psoriasis (Ps) when each of the following criteria are met:
   A. Individual is 18 years of age or older with chronic moderate to severe (that is, extensive or disabling) plaque Ps with either of the following (AAD 2019):
      1. Plaque Ps involving greater than three percent (3%) body surface area (BSA); **OR**
      2. Plaque Ps involving less than or equal to three percent (3%) BSA involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia); **AND**
   B. Individual has had an inadequate response to or is intolerant of phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate); **OR**
   C. Individual has a contraindication to phototherapy, acitretin, cyclosporine, and methotrexate;

OR

VII. Polyarticular juvenile idiopathic arthritis (PJIA) when each of the following criteria are met (DP B IIb, Lahdenne 2003, Gerloni 2005):
   A. Individual is 2 years of age or older with moderate~~ly~~ to severe PJIA; **AND**
   B. Individual has had an inadequate response to or is intolerant of conventional therapy [nonbiologic DMARDs (such as methotrexate)] (ACR 2019); **OR**
   C. Individual has a contraindication to methotrexate;

OR

VIII. Non-infectious uveitis (UV) when each of the following criteria are met (Levy-Clarke 2014):
   A. Individual has chronic, recurrent, treatment-refractory or vision-threatening disease; **AND**
   B. Individual has had an inadequate response to or is intolerant of conventional therapy [such as corticosteroids or immunosuppressants (azathioprine, cyclosporine, or methotrexate)]; **OR**
   C. Individual has a contraindication to azathioprine, cyclosporine, and methotrexate;

OR

IX. Immune checkpoint inhibitor therapy-related toxicities in an individual with any of the following conditions (NCCN 2A):
   A. Moderate to Severe diarrhea or colitis unresponsive to high-dose systemic corticosteroids; **OR**
   B. Moderate to Severe pneumonitis if no improvement after 48 hours of high-dose systemic corticosteroids; **OR**
   C. Acute kidney injury/elevated serum creatinine if toxicity remains greater than stage 2 after 4-6 weeks of corticosteroids or if creatinine increases during steroid taper (or once off steroids); **OR**
   D. Myocarditis if unresponsive to high-dose systemic corticosteroids; **OR**
   E. Moderate to severe inflammatory arthritis unresponsive to corticosteroids or nonbiologic DMARDs; **OR**
   F. Grade 1-4 uveitis that is refractory to high-dose systemic corticosteroids;

OR

X. Acute Graft-versus-host disease (GVHD) when each of the following criteria are met (NCCN 2A)
   A. Individual has a diagnosis of steroid-refractory acute GVHD; **AND**
   B. Individual is initiating infliximab in combination with systemic corticosteroids;

OR

XI. Sarcoidosis when each of the following criteria are met (Sweiss 2014):
   A. Individual is 18 years of age or older; **AND**
   B. Individual has chronic, progressive, treatment-refractory disease; **AND**
   C. Individual has had an inadequate response to, is intolerant of, or has a contraindication to systemic corticosteroids; **AND**
   D. Individual has had an inadequate response to or is intolerant of nonbiologic DMARDs (such as methotrexate or azathioprine); **OR**
   E. Individual has a contraindication to methotrexate and azathioprine.

Continuation requests for Remicade (infliximab), Avsola (infliximab-axxq), Inflectra (infliximab-dyyb), Infliximab (unbranded); Ixifi (infliximab-qbtx), or Renflexis (infliximab-adba) may be approved if the following criteria are met:

I. Individual has been receiving and is maintained on a stable dose of infliximab; **AND**
II. There is clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

Requests for Remicade (infliximab), Avsola (infliximab-axxq), Inflectra (infliximab-dyyb), Infliximab (unbranded); Ixifi (infliximab-qbtx), or Renflexis (infliximab-adba) may not be approved for the following:

I. In combination with oral or topical JAK inhibitors, ozanimod, etrasimod, apremilast, deucravacitinib, or any of the following biologic immunomodulators: Other TNF antagonists, IL-23 inhibitors, IL-17 inhibitors, IL-6 inhibitors, IL-1 inhibitors, vedolizumab, ustekinumab, abatacept, rituximab, or natalizumab; **OR**
II. Tuberculosis (TB), other active serious infections, or a history of recurrent infections [Repeat TB testing not required for ongoing authorization]; **OR**
III. If initiating therapy, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
IV. When the above criteria are not met and for all other indications.

Simponi, Simponi Aria (golimumab)

Initial requests for Simponi (golimumab) may be approved for the following:
I. Ulcerative colitis (UC) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe UC; **AND**
   B. Individual has had an inadequate response to or is intolerant of conventional therapy (such as 5-Aminosalicylic acid products, systemic corticosteroids, or immunosuppressants [such as thiopurines]); **OR**
   C. Individual has a contraindication to 5-ASA products or systemic corticosteroids or thiopurines;

OR

II. Ankylosing spondylitis (AS) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe AS; **AND**
   B. Individual has had an inadequate response to or is intolerant of conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)]; **OR**
   C. Individual has a contraindication to NSAIDs or sulfasalazine;

OR

III. Psoriatic arthritis (PsA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe PsA; **AND**
   B. Individual has had an inadequate response to or is intolerant of conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, cyclosporine, or leflunomide)]; **OR**
   C. Individual has a contraindication to methotrexate, sulfasalazine, cyclosporine, and leflunomide;

OR

IV. Rheumatoid arthritis (RA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe RA; **AND**
   B. Documentation is provided that individual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021); **OR**
   C. Documentation is provided that if methotrexate is not tolerated, individual has had an inadequate response to or is intolerant of other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine)**; OR**
   D. Documentation is provided that individual has a contraindication to methotrexate, sulfasalazine, leflunomide, and hydroxychloroquine;

OR

V. Immune checkpoint inhibitor therapy-related toxicities in an individual with any of the following conditions (NCCN 2A):
   A. Moderate to Severe inflammatory arthritis unresponsive to corticosteroids or nonbiologic DMARDs.

Initial requests for Simponi Aria (golimumab) may be approved if the following criteria are met:
I. Ankylosing spondylitis (AS) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe AS; **AND**
   B. Individual has had an inadequate response to or is intolerant of conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)]; **OR**
   C. Individual has a contraindication to NSAIDs or sulfasalazine;

OR

II. Psoriatic arthritis (PsA) when each of the following criteria are met:
   A. Individual is 2 years of age or older with moderate to severe PsA; **AND**
   B. Individual has had an inadequate response to or is intolerant of conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, cyclosporine, or leflunomide)]; **OR**
   C. Individual has a contraindication to methotrexate, sulfasalazine, cyclosporine, and leflunomide;

OR

III. Rheumatoid arthritis (RA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe RA; **AND**

B. Documentation is provided that individual has had an inadequate response to methotrexate titrated to maximally tolerated dose (ACR 2021); **OR**
C. Documentation is provided that if methotrexate is not tolerated, individual has had an inadequate response to or is intolerant of other conventional therapy (sulfasalazine, leflunomide, or hydroxychloroquine); **OR**
D. Documentation is provided that individual has a contraindication to methotrexate, sulfasalazine, leflunomide, and hydroxychloroquine;

OR

IV. Polyarticular juvenile idiopathic arthritis (PJIA) when each of the following criteria are met:
A. Individual is 2 years of age or older with moderate to severe PJIA; **AND**
B. Individual has had an inadequate response to or is intolerant of conventional therapy [nonbiologic DMARDs (such as methotrexate)] (ACR 2019); **OR**
C. Individual has a contraindication to methotrexate;

OR

V. Immune checkpoint inhibitor therapy-related toxicities in an individual with any of the following conditions (NCCN 2A):
A. Moderate to, Severe inflammatory arthritis unresponsive to corticosteroids or nonbiologic DMARDs.

Continuation requests for Simponi and Simponi Aria (golimumab) may be approved if the following criteria are met:
I. Individual has been receiving and is maintained on a stable dose of Simponi/Simponi Aria; **AND**
II. There is clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

Requests for Simponi and Simponi Aria (golimumab) may not be approved for the following:
I. In combination with oral or topical JAK inhibitors, ozanimod, apremilast, etrasimod, deucravacitinib, or any of the following biologic immunomodulators: Other TNF antagonists, IL-23 inhibitors, IL-17 inhibitors, IL-6 inhibitors, IL-1 inhibitors, vedolizumab, ustekinumab, abatacept, rituximab, or natalizumab; **OR**
II. Tuberculosis (TB), other active serious infections, or a history of recurrent infections [repeat TB testing not required for ongoing authorization]; **OR**
III. If initiating therapy, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
IV. When the above criteria are not met and for all other indications.

Zymfentra (infliximab-dyyb)

Initial requests for Zymfentra (infliximab-dyyb) may be approved for the following:
I. Individual is 18 years of age or older; **AND**
II. Individual has moderate to severe or fistulizing Crohn's disease (CD) or moderate to severe Ulcerative colitis (UC); **AND**
III. Individual has completed an intravenous induction regimen with an infliximab product and is using Zymfentra for subcutaneous maintenance therapy; **OR**
IV. Individual has been stabilized on intravenous infliximab maintenance therapy and is switching to Zymfentra for subcutaneous maintenance therapy.

Continuation requests for Zymfentra (infliximab-dyyb) may be approved if the following criteria are met:
I. Individual has been receiving and is maintained on a stable dose of Zymfentra; **AND**
II. There is clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

Requests for Zymfentra (infliximab-dyyb) may not be approved for the following:
I. In combination with oral or topical JAK inhibitors, ozanimod, etrasimod, apremilast, deucravacitinib, or any of the following biologic immunomodulators: Other TNF antagonists, IL-23 inhibitors, IL-17 inhibitors, IL-6 inhibitors, IL-1 inhibitors, vedolizumab, ustekinumab, abatacept, rituximab, or natalizumab**; OR**
II. Tuberculosis (TB), other active serious infections, or a history of recurrent infections [repeat TB testing not required for ongoing authorization]; **OR**
III. If initiating therapy, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis (unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
IV. When the above criteria are not met and for all other indications.

Step Therapy

Note: When a tumor necrosis factor antagonist is deemed approvable based on the clinical criteria above, the benefit plan may have additional criteria requiring the use of a preferredP[1] agent or agents.

Infliximab Agents Step Therapy

A list of the preferred tumor necrosis factor antagonist(s) is available here.

Requests for a non-preferred infliximab reference agent (Remicade) or corresponding unbranded Infliximab or biosimilar agent (Avsola, Inflectra, Renflexis) may be approved when the following criteria are met:

I. Individual has had a trial of and has an allergy to an inactive ingredient in the preferred agent which interferes with the individual's ability to use the product, and the same allergy is not expected with the non-preferred product;

OR

II. Individual is currently receiving and maintained on a stable dose of the requested non-preferred agent; **AND**
III. Individual has previously undergone at least one switch between infliximab agents (reference or biosimilar agents);

OR

IV. Individual is currently receiving and maintained on a stable dose of the requested non-preferred agent; **AND**
V. Individual is less than 18 years of age; **AND**
VI. Individual has a diagnosis of Ulcerative Colitis or Crohn's Disease.

[1]Preferred, as used herein, refers to agents that were deemed to be clinically comparable to other agents in the same class or disease category but are preferred based upon clinical evidence and cost effectiveness.

Quantity Limits

Cimzia (certolizumab pegol) Quantity Limits

Drug	Limit
Cimzia (certolizumab pegol) 200 mg/mL vial kit*‡	1 vial kit (2 x 200 mg vials) per 28 days
Cimzia (certolizumab pegol) 200 mg/mL prefilled syringe kit*‡	1 syringe kit (2 x 200 mg/mL syringes) per 28 days
Cimzia (certolizumab pegol) 200 mg/mL starter kit*	1 starter kit (6 x 200 mg/mL syringes) (28 day supply, one time fill)
Override Criteria	
*Initiation of therapy for Crohn's Disease (CD), Rheumatoid Arthritis (RA), Psoriatic Arthritis (PsA), Plaque Psoriasis (Ps), ~~or~~ Ankylosing Spondylitis (AS), or non-radiographic axial spondyloarthritis (nr-axSpA): May approve one starter kit OR up to three vial kits (2 x 200 mg vials per kit) or syringe kits (2 x 200 mg/mL syringes per kit) in the first month (28 days) of treatment. ‡In the treatment of Plaque Psoriasis (Ps): May approve up to an additional 1 vial kit (2 x 200 mg vials) or syringe kit (2 x 200 mg/mL syringes) every 28 days. ‡For CD, may approve increased dosing, up to 2 syringe/vial kits every 4 weeks (i.e. four total syringes/vials every 4 weeks) if the following criteria are met: A. Individual has been treated with standard maintenance dosing (i.e. 400 mg every 4 weeks) for *at least* 4 doses or 16 weeks; **AND** B. The increased dosing is being prescribed by or in consultation with a gastroenterologist; **AND** C. Individual initially achieved an adequate response to standard maintenance dosing but has subsequently lost response, as determined by the prescriber; **OR** D. Individual partially responded but had an inadequate response to standard maintenance dosing as determined by the prescriber; **AND** E. Symptoms, if present, are not due to active infections or any other gastrointestinal disorder other than the primary disease; **AND** F. Requested dosing does not exceed up to 2 syringe/vial kits every 4 weeks.	

Initial approval duration for increased dosing for CD: 16 weeks

‡Requests for continued escalated dosing for CD may be approved if the following criteria are met:

A. Requested dosing does not exceed up to 2 syringe/vial kits every 4 weeks; **AND**
B. Individual has subsequently regained response or achieved adequate response following increased dosing, as shown by improvement in signs and symptoms of the disease (including but not limited to reduction in stool frequency/bloody stools, improvement abdominal pain, or endoscopic response); **AND**
C. Individual is not experiencing unacceptable adverse effects from increased dosing; **AND**
D. Individual will be assessed regularly for dose de-escalation.

Continued approval duration for increased dosing for CD: 6 months

‡For CD, Increased dosing may not be approved for the following:

A. Individual has had no response to Cimzia at standard maintenance dosing (i.e. 400 mg every 4 weeks); **OR**
B. Individual is requesting dose escalation in absence of signs and symptoms of the disease (for example, requesting based on results of therapeutic drug level or anti-drug antibody testing alone).

Adalimumab Agents Quantity Limits

Drug	Limit
Abrilada (adalimumab-afzb) 10 mg/0.2 mL, 20 mg/0.4 mL¥ prefilled syringe	2 syringes per 28 days
Abrilada (adalimumab-afzb) 40 mg/0.8 mL prefilled pen/syringe#*^§†‡¥◊@¶	2 pens/syringes per 28 days
Amjevita (adalimumab-atto) 10 mg/0.2 mL, 20 mg/0.4 mL prefilled syringe¥	2 syringes per 28 days
Amjevita (adalimumab-atto) 40 mg/0.8 mL prefilled syringe#*^§†‡¥◊@¶	2 syringes per 28 days
Amjevita (adalimumab-atto) 40 mg/0.8 mL prefilled SureClick® autoinjector#*^§†‡¥◊@¶	2 autoinjectors per 28 days
Amjevita (adalimumab-atto) 20 mg/0.2 mL prefilled syringe¥	2 autoinjectors per 28 days
Amjevita (adalimumab-atto) 40 mg/0.4 mL prefilled SureClick® autoinjector /syringe#*^§†‡¥◊@¶	2 autoinjectors/syringes per 28 days
Amjevita (adalimumab-atto) 80 mg/0.8 mL prefilled SureClick® autoinjector /syringe∞*^†‡◊@¶	2 autoinjectors/syringes per 28 days∞
Cyltezo (adalimumab-adbm) 10 mg/0.2 mL, 20 mg/0.4 mL prefilled syringe¥	2 syringes per 28 days
Cyltezo (adalimumab-adbm) 40 mg/0.8 mL prefilled pen/syringe#*^§†‡¥◊@¶	2 pens/syringes per 28 days
Cyltezo (adalimumab-adbm) Crohn's disease, Ulcerative colitis or Hidradenitis Suppurativa Starter Package 40 mg/0.8 mL pens†*@	1 pack (28 day supply, one time fill)
Cyltezo (adalimumab-adbm) Psoriasis or Uveitis Starter Package 40 mg/0.8 mL pens^‡	1 pack (28 day supply, one time fill)
Hadlima (adalimumab-bwwd) 40 mg/0.8 mL PushTouch Autoinjector#*^§†‡ ¥◊@¶	2 autoinjectors per 28 days
Hadlima (adalimumab-bwwd) 40 mg/0.4 mL PushTouch Autoinjector#*^§†‡¥◊@¶	2 autoinjectors per 28 days
Hadlima (adalimumab-bwwd) 40 mg/0.8 mL prefilled syringe#*^§†‡¥◊@¶	2 syringes per 28 days
Hadlima (adalimumab-bwwd) 40 mg/0.4 mL prefilled syringe#*^§†‡¥◊@¶	2 syringes per 28 days
Hulio (adalimumab-fkjp) 20 mg/0.4 mL¥ prefilled syringe	2 syringes per 28 days
Hulio (adalimumab-fkjp) 40 mg/0.8 mL prefilled pen/syringe#*^§†‡¥◊@¶	2 pens/syringes per 28 days
Humira (adalimumab) 10 mg/0.2 mL, 20 mg/0.4 mL¥ prefilled syringe	2 syringes per 28 days
Humira (adalimumab) 10 mg/0.1 mL, 20 mg/0.2 mL¥ prefilled syringe	2 syringes per 28 days
Humira (adalimumab) 40 mg/0.8 mL prefilled pen/syringe#*^§†‡¥◊@¶	2 pens/syringes per 28 days
Humira (adalimumab) 40 mg/0.4 mL prefilled pen/syringe#*^§†‡¥◊@¶	2 pens/syringes per 28 days
Humira (adalimumab) 80 mg/0.8 mL prefilled pen∞*^†‡◊@¶	2 pens per 28 days∞
Humira (adalimumab) pediatric Ulcerative Colitis starter pack 80 mg/0.8 mL prefilled syringe◊	1 pack (28 day supply, one time fill)
Humira (adalimumab) pediatric Crohn's Disease starter pack 80 mg/0.8 mL prefilled syringe†	1 pack (28 day supply, one time fill)
Humira (adalimumab) pediatric Crohn's Disease starter pack 80 mg/0.8 mL + 40 mg/0.4 mL prefilled syringe†	1 pack (28 day supply, one time fill)
Humira (adalimumab) pediatric Crohn's Disease starter pack 40 mg/0.8 mL prefilled syringe†	1 pack (28 day supply, one time fill)

Humira (adalimumab) Crohn's Disease/Ulcerative Colitis/ Hidradenitis Suppurativa starter pack 80 mg/0.8 mL prefilled pen†*@	1 pack (28 day supply, one time fill)
Humira (adalimumab) Crohn's Disease/Ulcerative Colitis/ Hidradenitis Suppurativa starter pack 40 mg/0.4 mL prefilled pen†*@	1 pack (28 day supply, one time fill)
Humira (adalimumab) Crohn's Disease/Ulcerative Colitis/ Hidradenitis Suppurativa starter pack 40 mg/0.8 mL prefilled pen†*@	1 pack (28 day supply, one time fill)
Humira (adalimumab) Psoriasis/Uveitis/adolescent Hidradenitis Suppurativa starter pack 80 mg/0.8 mL + 40 mg/0.4 mL prefilled pen^‡@	1 pack (28 day supply, one time fill)
Humira (adalimumab) Psoriasis/Uveitis/adolescent Hidradenitis Suppurativa starter pack 40 mg/0.4 mL prefilled pen^‡@	1 pack (28 day supply, one time fill)
Humira (adalimumab) Psoriasis/Uveitis/adolescent Hidradenitis Suppurativa starter pack 40 mg/0.8 mL prefilled pen^‡@	1 pack (28 day supply, one time fill)
Hyrimoz (adalimumab-adaz) 10 mg/0.2 mL, 20 mg/0.4 mL¥ prefilled syringe	2 syringes per 28 days
Hyrimoz (adalimumab-adaz) 10 mg/0.1 mL, 20 mg/0.2 mL¥ prefilled syringe	2 syringes per 28 days
Hyrimoz (adalimumab-adaz) 40 mg/0.8 mL prefilled pen/syringe#*^§†‡¥◊@¶	2 pens/syringes per 28 days
Hyrimoz (adalimumab-adaz) 40 mg/0.4 mL prefilled pen/syringe#*^§†‡¥◊@¶	2 pens/syringes per 28 days
Hyrimoz (adalimumab-adaz) 80 mg/0.8 mL prefilled pen/syringe∞*^†‡◊@¶	2 pens/syringes per 28 days∞
Hyrimoz (adalimumab-adaz) Crohn's disease and Ulcerative colitis or Hidradenitis Suppurativa Starter Package 80 mg/0.8 mL pen†*@	1 pack (28 day supply, one time fill)
Hyrimoz (adalimumab-adaz) Crohn's disease, Ulcerative colitis or Hidradenitis Suppurativa Starter Package 80 mg/0.8 mL + 40 mg/0.4 mL pens†*@	1 pack (28 day supply, one time fill)
Hyrimoz (adalimumab-adaz) Plaque Psoriasis or Uveitis Starter Package pack 80 mg/0.8 mL + 40 mg/0.4 mL pens^‡	1 pack (28 day supply, one time fill)
Hyrimoz (adalimumab-adaz) pediatric Crohn's Disease starter pack 80 mg/0.8 mL prefilled syringe†	1 pack (28 day supply, one time fill)
Hyrimoz (adalimumab-adaz) pediatric Crohn's Disease starter pack 80 mg/0.8 mL + 40 mg/0.4 mL prefilled syringe†	1 pack (28 day supply, one time fill)
Idacio (adalimumab-aacf) 40 mg/0.8 mL prefilled pen/syringe#*^§†‡¥◊@¶	2 pens/syringes per 28 days
Idacio (adalimumab-aacf) Crohn's Disease/Ulcerative Colitis/Hidradenitis Suppurativa starter pack 40 mg/0.8 mL prefilled pen†*@	1 pack (28 day supply, one time fill)
Idacio (adalimumab-aacf) Psoriasis starter pack 40 mg/0.8 mL prefilled pen^	1 pack (28 day supply, one time fill)
Simlandi (adalimumab-ryvk) 40 mg/0.4 mL prefilled autoinjector#*^§†‡¥◊@¶	2 autoinjectors per 28 days
Yuflyma (adalimumab-aaty) 20 mg/0.2 mL¥ prefilled syringe	2 syringes per 28 days
Yuflyma (adalimumab-aaty) 40 mg/0.4 mL prefilled auto-injector/syringe#*^§†‡¥◊@¶	2 auto-injector/syringes per 28 days
Yuflyma (adalimumab-aaty) Psoriasis starter pack 40 mg/0.4 mL prefilled autoinjector^	1 pack (28 day supply, one time fill)
Yuflyma (adalimumab-aaty) Psoriasis starter pack 80 mg/0.8 mL + 40 mg/0.4 mL prefilled autoinjector^	1 pack (28 day supply, one time fill)
Yuflyma (adalimumab-aaty) Crohn's Disease, Pediatric Crohn's disease, Ulcerative Colitis or Hidradenitis Suppurativa Starter Pack 40 mg/0.4 mL prefilled autoinjector†*@	1 pack (28 day supply, one time fill)
Yuflyma (adalimumab-aaty) Crohn's Disease, Ulcerative Colitis or Hidradenitis Suppurativa Starter Pack 80 mg/0.8 mL prefilled autoinjector†*@	1 pack (28 day supply, one time fill)
Yuflyma (adalimumab-aaty) Pediatric Crohn's disease Starter Pack 80 mg/0.8 mL + 40 mg/0.4 mL prefilled autoinjector†	1 pack (28 day supply, one time fill)
Yuflyma (adalimumab-aaty) Pediatric Crohn's disease Starter Pack 80 mg/0.8 mL prefilled autoinjector†	1 pack (28 day supply, one time fill)
Yuflyma (adalimumab-aaty) 80 mg/0.8 mL prefilled autoinjector/syringe∞*^†‡◊@¶	2 autoinjectors/syringes per 28 days∞
Yusimry (adalimumab-aqvh) 40 mg /0.8 mL prefilled pen/syringe#*^§†‡¥◊@¶	2 pens/syringes per 28 days
Override Criteria	
#In the treatment of Rheumatoid Arthritis (RA): May approve up to 4 (four) syringes, autoinjectors, or pens (40mg) [up to an additional 2 (two) syringes, autoinjectors, or pens] every 28 days if the individual is unable to take concomitant methotrexate. *Initiation of therapy for adult Crohn's Disease (CD) or Ulcerative Colitis (UC) or Hidradenitis Suppurativa (HS): May approve 1 (one) Crohn's Disease/Ulcerative Colitis/Hidradenitis Suppurativa starter pack OR up to 4 (four)	

additional 40 mg pens or syringes OR up to a total of 3 (three) 80 mg pens in the first month (28 days) of treatment.

^Initiation of therapy for Plaque Psoriasis (Ps): May approve 1 (one) Psoriasis starter pack OR up to 2 (two) additional 40 mg pens, autoinjectors, or syringes OR up to 1 (one) 80 mg pen in the first month (28 days) of treatment.

§ Maintenance therapy for Hidradenitis Suppurativa (HS): May approve up to 2 (two) additional 40 mg pens or syringes per each 28 days.

@ Initiation of therapy for adolescent Hidradenitis Suppurativa (HS): Depending on individual's weight, may approve one (1) adolescent or adult Hidradenitis Suppurativa starter pack OR up to 4 (four) additional 40 mg pens or syringes OR up to a total of 3 (three) 80 mg pens in the first month (28 days) of treatment.

†Initiation of therapy for pediatric Crohn's Disease (CD): Depending on individual's weight, may approve one (1) pediatric or adult Crohn's Disease starter pack OR up to 4 (four) additional 40 mg pens or syringes OR up to a total of 3 (three) 80 mg pens in the first month (28 days) of treatment.

‡Initiation of therapy for Uveitis (UV): May approve1 (one) Uveitis starter pack OR up to 2 (two) additional 40 mg pens, autoinjectors, or syringes in the first month (28 days) of treatment.

¥In the treatment of Ulcerative Colitis (UC): May approve up to 4 (four) syringes, autoinjectors, or pens (40mg) [up to an additional 2 (two) syringes, autoinjectors, or pens] every 28 days for individuals 5-17 years of age weighing at least 40 kg (88 lbs)Δ. May approve up to 4 (four) syringes, autoinjectors, or pens (20mg) [up to an additional 2 (two) syringes, autoinjectors, or pens] every 28 days for individuals 5-17 years of age weighing 20 kg (44 lbs) to 40 kg (88 lbs)Δ.

◊Initiation of therapy for pediatric Ulcerative Colitis (UC): Depending on individual's weight, may approve one (1) pediatric Ulcerative Colitis starter pack OR up to 5 (five) additional 40 mg pens or syringes OR up to a total of 4 (four) 80 mg pens in the first month (28 days) of treatment.

ᵒRequests for 80mg/ 0.8 mL pen for maintenance dosing require clinical review. Initial requests for maintenance treatment of up to 2 pens per 28 days may be approved if the following criteria are metΔ:

I. Individual has a diagnosis of Rheumatoid Arthritis (RA); **AND**
II. Individual is unable to take concomitant methotrexate;
OR
III. Individual has a diagnosis of Hidradenitis Suppurativa (HS);
OR
IV. Individual has a diagnosis of Ulcerative Colitis (UC); **AND**
V. Individual is 5 to 17 years of age; **AND**
VI. Individual weighs at least 40 kg (88 lbs).

Δ*Individuals with UC who initiated therapy at age 17 or below and who are well controlled on 20 to 40 mg every week or 80 mg every other week regimen may continue therapy.*

¶For individuals requesting escalated dosing for CD or UC, up to one 40 mg syringe/pen/autoinjector per week **OR** one 80 mg syringe every 2 weeks (i.e. four 40 mg syringes/pens/autoinjectors or two 80 mg syringes per month) may be approved if the following criteria are met:

A. Individual has been treated with standard maintenance dosing (i.e. 40 mg every 2 weeks) for *at least* 8 doses or 16 weeks; **AND**
B. The increased dosing is being prescribed by or in consultation with a gastroenterologist;
AND
C. Individual initially achieved an adequate response to standard maintenance dosing but has subsequently lost response, as determined by the prescriber; **OR**
D. Individual partially responded but had an inadequate response to standard maintenance dosing as determined by the prescriber;
AND
E. Symptoms, if present, are not due to active infections or any other gastrointestinal disorder other than the primary disease; **AND**
F. Requested dosing does not exceed up to one 40 mg syringe/pen/autoinjector per week OR one 80 mg syringe every 2 weeks (i.e. four 40 mg syringes/pens/autoinjectors or two 80 mg syringes per month).

Initial approval duration for increased dosing for CD or UC: 16 weeks

¶Requests for continued escalated dosing for CD and UC may be approved if the following criteria are met:

A. Requested dosing does not exceed up to one 40 mg syringe/pen/autoinjector per week OR one 80 mg syringe every 2 weeks (i.e. four 40 mg syringes/pens/autoinjectors or two 80 mg syringes per month); **AND**
B. Individual has subsequently regained response or achieved adequate response following increased dosing, as shown by improvement in signs and symptoms of the disease (including but not limited to reduction in stool frequency/bloody stools, improvement abdominal pain, or endoscopic response); **AND**
C. Individual is not experiencing unacceptable adverse effects from increased dosing; **AND**
D. Individual will be assessed regularly for dose de-escalation.

Continued approval duration for increased dosing CD or UC: 6 months

¶For CD or UC, Increased dosing may not be approved for the following:

A. Individual has had no response to adalimumab at standard maintenance dosing (i.e. 40 mg every 2 weeks); **OR**
B. Individual is requesting dose escalation in absence of signs and symptoms of the disease (for example, requesting based on results of therapeutic drug level or anti-drug antibody testing alone).

Etanercept Agents Quantity Limits

Drug	Limit
Erelzi (etanercept-szzs) 25 mg/0.5 mL prefilled syringe*	8 syringes per 28 days
Erelzi (etanercept-szzs) 50 mg/0.5 mL prefilled syringe*, Sensoready® pen*	4 syringes/pens per 28 days
Enbrel (etanercept) 25 mg/mL vial*	8 vials per 28 days
Enbrel (etanercept) 25 mg/0.5 mL (0.51 mL) prefilled syringe*	8 syringes per 28 days
Enbrel (etanercept) 50 mg/mL (0.98 mL) prefilled syringe*, SureClick® autoinjector*	4 syringes/autoinjectors per 28 days
Enbrel (etanercept) 50 mg/mL Mini™ prefilled cartridge with AutoTouch™*	4 cartridges per 28 days
Eticovo (etanercept-ykro) 25 mg/0.5 mL prefilled syringe*	8 syringes per 28 days
Eticovo (etanercept-ykro) 50 mg/mL prefilled syringe*	4 syringes per 28 days
Override Criteria	
*Initiation of therapy for adult Plaque Psoriasis (Ps): May approve up to 2 (two) additional 25 mg vials (25 mg/mL) or syringes [(25 mg/0.5 mL (0.51 mL)] OR 1 (one) additional 50 mg syringe [50 mg/mL (0.98 mL)], pen (50 mg/0.5 mL), autoinjector [50 mg/mL (0.98 mL)], or cartridge (50 mg/mL) per week in the first 3 months (84 days) of treatment.	

Zymfentra (infliximab-dyyb) Quantity Limit

Drug	Limit
Zymfentra (infliximab-dyyb) 120 mg/mL prefilled syringe/pen	1 syringe/pen every 2 weeks

Infliximab Quantity Limit

Drug	Limit
Remicade (infliximab) 100 mg vial	5 mg/kg as frequently as every 8 weeks
Avsola (infliximab-axxq) 100 mg vial	5 mg/kg as frequently as every 8 weeks
Renflexis (infliximab-abda) 100 mg vial	5 mg/kg as frequently as every 8 weeks
Inflectra (infliximab-dyyb) 100 mg vial	5 mg/kg as frequently as every 8 weeks
Infliximab 100 mg vial	5 mg/kg as frequently as every 8 weeks
Ixifi (infliximab-qbtx) 100 mg vial	5 mg/kg as frequently as every 8 weeks
Override Criteria	
A. For initiation of therapy, may approve up to 5 mg/kg at weeks 0, 2, and 6; **OR** B. For Ankylosing Spondylitis (AS), may approve 5 mg/kg as frequent as every 6 weeks; **OR**	

C. For Rheumatoid Arthritis (RA), may approve dose escalation up to 10 mg/kg every 8 weeks OR 3 mg/kg every 4 weeks for individuals who have an incomplete response; **OR**
D. For Crohn's Disease (CD), may approve dose escalation up to 10 mg/kg every 8 weeks if the individual has previously achieved response to infliximab at standard dosing and subsequently lost response; **OR**
E. For pediatric individuals less than 18 years of age with severe Crohn's Disease (CD) or severe Ulcerative Colitis (UC), may approve up to 10 mg/kg every 4 weeks for initial or continuation of therapy. Adults with CD or UC who initiated treatment at less than 18 years of age may continue current dosage (up to 10 mg/kg every 4 weeks) if stable; **OR**

For Ulcerative Colitis (UC), may approve increased dosing, up to 10 mg/kg every 8 weeks if the following criteria are met:
A. Individual has been treated with standard maintenance dosing (i.e. 5 mg/kg every 8 weeks) for *at least* 2 doses or 16 weeks; **AND**
B. The increased dosing is being prescribed by or in consultation with a gastroenterologist; **AND**
C. Individual initially achieved an adequate response to standard maintenance dosing but has subsequently lost response, as determined by the prescriber; **OR**
D. Individual partially responded but had an inadequate response to standard maintenance dosing as determined by the prescriber; **AND**
E. Symptoms, if present, are not due to active infections or any other gastrointestinal disorder other than the primary disease; **AND**
F. Requested dosing does not exceed up to up to 10 mg/kg every 8 weeks.

Initial approval duration for increased dosing for UC: 16 weeks

Requests for continued escalated dosing for UC may be approved if the following criteria are met:
A. Requested dosing does not exceed up to 10 mg/kg every 8 weeks; **AND**
B. Individual has subsequently regained response or achieved adequate response following increased dosing, as shown by improvement in signs and symptoms of the disease (including but not limited to reduction in stool frequency/bloody stools, improvement abdominal pain, or endoscopic response); **AND**
C. Individual is not experiencing unacceptable adverse effects from increased dosing; **AND**
D. Individual will be assessed regularly for dose de-escalation.

Continued approval duration for increased dosing for UC: 6 months

For UC, Increased dosing may not be approved for the following:
A. Individual has had no response to infliximab at standard maintenance dosing (i.e. 5 mg/kg every 8 weeks); **OR**
B. Individual is requesting dose escalation in absence of signs and symptoms of the disease (for example, requesting based on results of therapeutic drug level or anti-drug antibody testing alone).

Simponi (golimumab) Quantity Limits

Drug	Limit
Simponi (golimumab) 50 mg/0.5 mL SmartJect® autoinjector	1 autoinjector per 28 days
Simponi (golimumab) 50 mg/0.5 mL prefilled syringe	1 syringe per 28 days
Simponi (golimumab) 100 mg/1 mL SmartJect® autoinjector*	1 autoinjector per 28 days
Simponi (golimumab) 100 mg/1 mL prefilled syringe*	1 syringe per 28 days
Override Criteria	
*Initiation of therapy for Ulcerative Colitis (UC): May approve up to 2 (two) additional syringes or autoinjectors (100 mg/1 mL) in the first month (28 days) of treatment. *For UC, may approve increased dosing, up to 200 mg (two 100 mg syringes/autoinjectors) every 4 weeks if the following criteria are met: A. Individual has been treated with standard maintenance dosing (i.e. 100 mg every 4 weeks) for *at least* 4 doses or 16 weeks; **AND** B. The increased dosing is being prescribed by or in consultation with a gastroenterologist; **AND**	

C. Individual initially achieved an adequate response to standard maintenance dosing but has subsequently lost response, as determined by the prescriber; **OR**
D. Individual partially responded but had an inadequate response to standard maintenance dosing as determined by the prescriber;
AND
E. Symptoms, if present, are not due to active infections or any other gastrointestinal disorder other than the primary disease; **AND**
F. Requested dosing does not exceed up to 200 mg (two 100 mg syringes/autoinjectors) every 4 weeks.

Initial approval duration for increased dosing for UC: 16 weeks

*Requests for continued escalated dosing for UC may be approved if the following criteria are met:
A. Requested dosing does not exceed up to 200 mg (two 100 mg syringes/autoinjectors) every 4 weeks; **AND**
B. Individual has subsequently regained response or achieved adequate response following increased dosing, as shown by improvement in signs and symptoms of the disease (including but not limited to reduction in stool frequency/bloody stools, improvement abdominal pain, or endoscopic response); **AND**
C. Individual is not experiencing unacceptable adverse effects from increased dosing; **AND**
D. Individual will be assessed regularly for dose de-escalation.

Continued approval duration for increased dosing for UC: 6 months

*For UC, Increased dosing may not be approved for the following:
A. Individual has had no response to Simponi at standard maintenance dosing (i.e. 100 mg every 4 weeks); **OR**
B. Individual is requesting dose escalation in absence of signs and symptoms of the disease (for example, requesting based on results of therapeutic drug level or anti-drug antibody testing alone).

Simponi Aria (golimumab) Quantity Limit

Drug	Limit
Simponi Aria (golimumab) 50 mg vial	Adult (≥18 years): 2 mg/kg as frequently as every 8 weeks Pediatric (<18 years): 80 mg/m^2 as frequently as every 8 weeks
Override Criteria	
*For initiation of therapy, may approve up to 2 mg/kg (or 80 mg/m^2 for individuals <18 years of age) at weeks 0 and 4	

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J0135	Injection, adalimumab, 20 mg [Humira]
J0717	Injection, certolizumab pegol, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered) [Cimzia]
J1438	Injection, etanercept; 25 mg (when drug administered under the direct supervision of a physician, not for use when drug is self-administered) [Enbrel]
J1602	Injection, golimumab, 1 mg, for intravenous use [Simponi Aria]
J1745	Injection, infliximab, excludes biosimilar, 10 mg [Remicade]
Q5121	Injection, infliximab-axxq, biosimilar, (Avsola), 10 mg
J3490	Unclassified drugs no specific code for golimumab (Simponi), etanercept-szzs (Erelzi), adalimumab-atto (Amjevita), adalimumab-adbm (Cyltezo), adalimumab-adaz (Hyrimoz), etanercept-ykro (Eticovo), adalimumab-bwwd (Hadlima), Hulio (adalimumab-fkjp), Yusimry (adalimumab-aqvh), Yuflyma ((adalimumab-aaty)