

PRIOR AUTHORIZATION POLICY

POLICY: Inflammatory Conditions – Adalimumab Products Prior Authorization Policy

- Amjevita® (adalimumab-atto SC injection – Amgen)
- Humira® (adalimumab subcutaneous injection – AbbVie)

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OVERVIEW

Adalimumab products are tumor necrosis factor inhibitors (TNFi) approved for the following uses:¹

- **Ankylosing spondylitis**, for reducing signs and symptoms in patients with active disease.
- **Crohn's disease**, for treatment of moderately to severely active disease in patients ≥ 6 years of age.
- **Hidradenitis suppurativa**, for the treatment of moderate to severe disease in patients ≥ 12 years of age.
- **Juvenile idiopathic arthritis (JIA)**, \pm methotrexate for reducing signs and symptoms of moderately to severely active polyarticular disease in patients ≥ 2 years of age.
- **Plaque psoriasis**, for the treatment of adults with moderate to severe chronic disease who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate.
- **Psoriatic arthritis (PsA)**, \pm conventional synthetic disease-modifying antirheumatic drugs (DMARDs), for reducing the signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function.
- **Rheumatoid arthritis**, \pm methotrexate or other conventional synthetic DMARDs to reduce the signs and symptoms, induce major clinical response, inhibit the progression of structural damage, and improve physical function in adults with moderately to severely active disease.
- **Ulcerative colitis**, for treatment of moderately to severely active disease in patients ≥ 5 years of age. However, efficacy has not been established in patients with ulcerative colitis who have lost response or were intolerant to another TNFi.
- **Uveitis**, in patients ≥ 2 years of age with noninfectious intermediate, posterior, and panuveitis.

Guidelines

TNFi feature prominently in guidelines for treatment of inflammatory conditions.

- **Ankylosing Spondylitis and Spondyloarthritis:** Guidelines for ankylosing spondylitis and non-radiographic axial spondylitis are published by the American College of Rheumatology (ACR)/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network (2019).³ TNFi are recommended for the initial biologic. In those who are secondary non-responders to a TNFi, a second TNFi is recommended over switching out of the class.
- **Crohn's Disease:** The American College of Gastroenterology (ACG) has guidelines for Crohn's disease (2018).⁴ TNFi are listed as an option for disease that is resistant to corticosteroids, severely active disease, perianal fistulizing disease, and maintenance of remission. In post-operative Crohn's disease, a TNFi should be started within 4 weeks of surgery to prevent recurrence. Guidelines from the American Gastroenterological Association (AGA) [2021] include TNFi among the therapies for moderate to severe Crohn's disease, for induction and maintenance of remission.¹⁷
- **JIA:** There are guidelines from ACR and the Arthritis Foundation for the treatment of JIA (2021) which address oligoarthritis and temporomandibular joint (TMJ) arthritis. For oligoarthritis, a biologic is recommended following a trial of a conventional synthetic DMARD.⁶ In patients with TMJ arthritis, scheduled nonsteroidal anti-inflammatory drugs (NSAIDs) and/or intra-articular

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glucocorticoids are recommended first-line. A biologic is a therapeutic option if there is an inadequate response or intolerance. Additionally, rapid escalation to a biologic ± conventional synthetic DMARD (methotrexate preferred) is often appropriate given the impact and destructive nature of TMJ arthritis. In these guidelines, there is not a preferred biologic that should be initiated for JIA. ACR guidelines (2019) are also available specifically for juvenile non-systemic polyarthritis, sacroiliitis, and enthesitis.⁵ TNFis are the biologics recommended for polyarthritis, sacroiliitis, and enthesitis. Biologics are recommended following other therapies (e.g., following DMARDs for active polyarthritis or following an NSAID for active JIA with sacroiliitis or enthesitis). However, there are situations where initial therapy with a biologic may be preferred over other conventional therapies (e.g., if there is involvement of high-risk joints such as the cervical spine, wrist, or hip; high disease activity; and/or those judged to be at high risk of disabling joint damage).

- **Plaque Psoriasis:** Guidelines from the American Academy of Dermatologists and National Psoriasis Foundation (2019) recommend adalimumab as a monotherapy treatment option for adults with moderate to severe disease.⁷
- **PsA:** Guidelines from ACR (2019) recommend TNFis over other biologics for use in treatment-naïve patients with PsA and in those who were previously treated with an oral therapy.⁸
- **Rheumatoid Arthritis:** Guidelines from ACR (2021) recommend addition of a biologic or a targeted synthetic DMARD for a patient taking the maximum tolerated dose of methotrexate who is not at target.²
- **Ulcerative Colitis:** Guidelines from the ACG for ulcerative colitis (2019) note that the following agents can be used for induction of remission in moderately to severely active disease: budesonide extended-release tablets, oral or intravenous systemic corticosteroids, Entyvio® (vedolizumab intravenous infusion), Xeljanz®/XR (tofacitinib tablest/extended-release tablets), or TNFis.⁹ Guidelines from the AGA (2020) recommend Xeljanz only after failure of or intolerance to a TNFi.¹⁰ In addition to the approved indication, clinical guidelines for the management of pouchitis (2009) indicate that first-line therapy for pouchitis is antibiotic therapy (e.g. metronidazole, ciprofloxacin).¹¹ Other treatment options include maintenance probiotics, oral or topical budesonide, anti-inflammatory drugs (e.g., mesalamine), or immunosuppressive agents (e.g., infliximab).
- **Uveitis and Ocular Inflammatory Disorders:** American Academy of Ophthalmology (AAO) guidelines (2014) note that adalimumab may be used in patients with uveitis due to various causes (e.g., spondyloarthritis-associated or human leukocyte antigen [HLA]-B27-associated uveitis, JIA-associated uveitis, and other posterior uveitides and panuveitis syndromes).¹² Adalimumab should be considered second-line in vision-threatening JIA-associated uveitis when methotrexate has failed or is not tolerated (strong recommendation) and may be used as corticosteroid-sparing treatment for vision-threatening chronic uveitis from seronegative spondyloarthritis (strong recommendation). Adalimumab may also be considered in other patients who have vision-threatening or corticosteroid-dependent disease who have failed first-line therapies. Adalimumab should be considered as a second-line immunomodulatory agent for severe ocular inflammatory conditions including chronic and severe scleritis. ACR/Arthritis Federation guidelines (2019) for uveitis associated with JIA make recommendations for use of conventional systemic DMARDs and biologics. In patients with severe active chronic anterior uveitis associated with sight-threatening complications, a TNFi (monoclonal antibody) + methotrexate is recommended.¹⁹

Other Uses with Supportive Evidence

There are guidelines and/or published data supporting the use of adalimumab products in the following conditions:

- **Behcet's Disease:** The European Union Against Rheumatism (EULAR) recommendations (2018) include TNFis for initial or recurrent sight-threatening uveitis.¹³ For patients refractory to first-line treatments (e.g., corticosteroids), TNFis are among the treatment options for mucocutaneous manifestations, venous thrombosis, severe or refractory gastrointestinal disease, and recurrent/chronic joint involvement. Recommendations for the use of TNFis in ocular inflammatory disorders from the AAO (2014) note that TNFis may be used first-line in patients with ophthalmic manifestations of Behcet's disease and for acute exacerbations of preexisting Behcet's disease.¹²
- **Pyoderma Gangrenosum:** Although guidelines are not current, multiple topical and systemic therapies have been used for pyoderma gangrenosum. Oral prednisone is the most common initial immunosuppressant medication.¹⁴ Other systemic therapies include cyclosporine, methotrexate, azathioprine, cyclophosphamide, mycophenolate mofetil, and TNFis (i.e., infliximab, etanercept, and adalimumab products). In case reports, TNFis have been effective.
- **Sarcoidosis:** Recommendations for best practice in the management of pulmonary and systemic sarcoidosis recommend glucocorticoids as first-line therapy.¹⁵ Patients who cannot be weaned to a prednisone-equivalent dose of < 10 mg/day are appropriate candidates for steroid-sparing treatment with cytotoxic agents (e.g., methotrexate, azathioprine, leflunomide). If these agents fail or cause toxicity, adalimumab, infliximab, cyclophosphamide, or mycophenolate mofetil are proposed. According to European Respiratory Society guidelines for sarcoidosis (2021), for pulmonary and neurosarcoidosis, a TNFi is recommended after a trial of glucocorticoids and immunosuppressants.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of adalimumab products. All approvals are for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with adalimumab products as well as the monitoring required for adverse events and long-term efficacy, initial approval requires the agent to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of adalimumab products is recommended in those who meet one the following criteria:

FDA-Approved Indications

1. **Ankylosing Spondylitis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
 - A) **Initial Therapy.** Approve for 6 months if prescribed by or in consultation with a rheumatologist.
 - B) **Patient is Currently Receiving an Adalimumab Product.** Approve for 1 year if the patient meets BOTH of the following (i and ii):
 - i. Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with an adalimumab product is reviewed under criterion A (Initial Therapy).
 - ii. Patient meets at least one of the following (a or b):

- a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an adalimumab product); OR
Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), Health Assessment Questionnaire for the Spondyloarthropathies (HAQ-S), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
 - b) Compared with baseline (prior to initiating an adalimumab product), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.
2. **Crohn's Disease.** Approve for the duration noted if the patient meets ONE of the following (A or B):
- A) **Initial Therapy.** Approve for 6 months if the patient meets the following criteria (i, ii, and iii):
- i. Patient is ≥ 6 years of age; AND
 - ii. Patient meets ONE of the following conditions (a, b, c, or d):
 - a) Patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated in this patient; OR
Note: Examples of corticosteroids are prednisone or methylprednisolone.
 - b) Patient has tried one other conventional systemic therapy for Crohn's disease; OR
Note: Examples of conventional systemic therapy for Crohn's disease include azathioprine, 6-mercaptopurine, or methotrexate. An exception to the requirement for a trial of or contraindication to steroids or a trial of one other conventional systemic agent can be made if the patient has already tried at least one biologic other than the requested medication. A biosimilar of the requested biologic does not count. Refer to [Appendix](#) for examples of biologics used for Crohn's disease. A trial of mesalamine does not count as a systemic agent for Crohn's disease.
 - c) Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; OR
 - d) Patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence); AND
 - iii. The medication is prescribed by or in consultation with a gastroenterologist.
- B) **Patient is Currently Receiving an Adalimumab Product.** Approve for 1 year if the patient meets BOTH of the following (i and ii):
- i. Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with an adalimumab product is reviewed under criterion A (Initial Therapy).
 - ii. Patient meets at least one of the following (a or b):
 - a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an adalimumab product); OR
Note: Examples of objective measures include fecal markers (e.g., fecal lactoferrin, fecal calprotectin), serum markers (e.g., C-reactive protein), imaging studies (magnetic resonance enterography [MRE], computed tomography enterography [CTE]), endoscopic assessment, and/or reduced dose of corticosteroids.
 - b) Compared with baseline (prior to initiating an adalimumab product), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or blood in stool.
3. **Juvenile Idiopathic Arthritis (JIA) [or juvenile rheumatoid arthritis] {regardless of type of onset}**. Approve for the duration noted if the patient meets ONE of the following (A or B):
Note: This includes a patient with juvenile spondyloarthritis/active sacroiliac arthritis.

- A) Initial Therapy. Approve for 6 months if the patient meets the following criteria (i and ii):
- i. Patient meets ONE of the following conditions (a, b, c, or d):
 - a) Patient has tried one other systemic therapy for this condition; OR
Note: Examples of other systemic therapies for JIA include methotrexate, sulfasalazine, leflunomide, or a nonsteroidal anti-inflammatory drug (NSAID) [e.g., ibuprofen, naproxen]. A previous trial of one biologic other than the requested medication also counts as a trial of one systemic therapy for JIA. A biosimilar of the requested biologic does not count. Refer to [Appendix](#) for examples of biologics used for JIA.
 - b) Patient will be starting on adalimumab concurrently with methotrexate, sulfasalazine, or leflunomide; OR
 - c) Patient has an absolute contraindication to methotrexate, sulfasalazine, or leflunomide; OR
Note: Examples of contraindications to methotrexate include pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias.
 - d) Patient has aggressive disease, as determined by the prescriber; AND
 - ii. The medication is prescribed by or in consultation with a rheumatologist.
- B) Patient is Currently Receiving an Adalimumab Product. Approve for 1 year if the patient meets BOTH of the following (i and ii):
- i. Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with an adalimumab product is reviewed under criterion A (Initial Therapy).
 - ii. Patient meets at least one of the following (a or b):
 - a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an adalimumab product); OR
Note: Examples of objective measures include Physician Global Assessment (MD global), Parent/Patient Global Assessment of Overall Well-Being (PGA), Parent/Patient Global Assessment of Disease Activity (PDA), Juvenile Arthritis Disease Activity Score (JDAS), Clinical Juvenile Arthritis Disease Activity Score (cJDAS), Juvenile Spondyloarthritis Disease Activity Index (JSpADA), serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.
 - b) Compared with baseline (prior to initiating an adalimumab product), patient experienced an improvement in at least one symptom, such as improvement in limitation of motion, less joint pain or tenderness, decreased duration of morning stiffness or fatigue, or improved function or activities of daily living.
4. **Hidradenitis Suppurativa**. Approve for the duration noted if the patient meets ONE of the following (A or B):
- A) Initial Therapy. Approve for 3 months if the patients meets BOTH of the following (i and ii):
- i. Patient has tried at least ONE other therapy; AND
Note: Examples include intralesional or oral corticosteroids (such as triamcinolone or prednisone), systemic antibiotics (e.g., clindamycin, dicloxacillin, or erythromycin), or isotretinoin.
 - ii. The medication is prescribed by or in consultation with a dermatologist.
- B) Patient is Currently Receiving an Adalimumab Product. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
- i. Patient has been established on therapy for at least 90 days; AND
Note: A patient who has received < 90 days of therapy or who is restarting therapy with an adalimumab product is reviewed under criterion A (Initial Therapy).
 - ii. When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an adalimumab product); AND
Note: Examples of objective measures include Hurley staging, Sartorius score, Physician Global Assessment, and Hidradenitis Suppurativa Severity Index.

- iii. Compared with baseline (prior to initiating an adalimumab product), patient experienced an improvement in at least one symptom, such as decreased pain or drainage of lesions, nodules, or cysts.
- 5. Plaque Psoriasis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
- A) Initial Therapy. Approve for 3 months if the patient meets the following criteria (i, ii, and iii):
 - i. Patient is \geq 18 years of age; AND
 - ii. Patient meets ONE of the following conditions (a or b):
 - a) Patient has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant; OR
Note: Examples include methotrexate, cyclosporine, acitretin, or psoralen plus ultraviolet A light (PUVA). An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic other than the requested medication. A biosimilar of the requested biologic does not count. Refer to [Appendix](#) for examples of biologics used for psoriasis. A patient who has already tried a biologic for psoriasis is not required to “step back” and try a traditional systemic agent for psoriasis.
 - b) Patient has a contraindication to methotrexate, as determined by the prescriber; AND
 - iii. The medication is prescribed by or in consultation with a dermatologist.
 - B) Patient is Currently Receiving an Adalimumab Product. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
 - i. Patient has been established on therapy for at least 90 days; AND
Note: A patient who has received < 90 days of therapy or who is restarting therapy with an adalimumab product is reviewed under criterion A (Initial Therapy).
 - ii. Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating an adalimumab product) in at least one of the following: estimated body surface area affected, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND
 - iii. Compared with baseline (prior to receiving an adalimumab product), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.
- 6. Psoriatic Arthritis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
- A) Initial Therapy. Approve for 6 months if prescribed by or in consultation with a rheumatologist or a dermatologist.
 - B) Patient is Currently Receiving an Adalimumab Product. Approve for 1 year if the patient meets BOTH of the following (i and ii):
 - i. Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with an adalimumab product is reviewed under criterion A (Initial Therapy).
 - ii. Patient meets at least one of the following (a or b):
 - a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an adalimumab product); OR
Note: Examples of objective measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsADAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
 - b) Compared with baseline (prior to initiating an adalimumab product), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or

fatigue; improved function or activities of daily living; or decreased soft tissue swelling in joints or tendon sheaths.

7. Rheumatoid Arthritis. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii):

- i. Patient has tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months; AND

Note: Examples include methotrexate (oral or injectable), leflunomide, hydroxychloroquine, and sulfasalazine. An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the patient has already has a 3-month trial at least one biologic other than the requested medication. A biosimilar of the requested biologic does not count. Refer to [Appendix](#) for examples of biologics used for rheumatoid arthritis. A patient who has already tried a biologic for rheumatoid arthritis is not required to “step back” and try a conventional synthetic DMARD.

- ii. The medication is prescribed by or in consultation with a rheumatologist.

B) Patient is Currently Receiving an Adalimumab Product. Approve for 1 year if the patient meets BOTH of the following (i and ii):

- i. Patient has been established on therapy for at least 6 months; AND

Note: A patient who has received < 6 months of therapy or who is restarting therapy with an adalimumab product is reviewed under criterion A (Initial Therapy).

- ii. Patient meets at least one of the following (a or b):

- a) Patient experienced a beneficial clinical response when assessed by at least one objective measure; OR

Note: Examples of objective measures of disease activity include Clinical Disease Activity Index (CDAI), Disease Activity Score (DAS) 28 using erythrocyte sedimentation rate or C-reactive protein, Patient Activity Scale (PAS)-II, Rapid Assessment of Patient Index Data 3 (RAPID-3), and/or Simplified Disease Activity Index (SDAI).

- b) Patient experienced an improvement in at least one symptom, such as decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; or decreased soft tissue swelling in joints or tendon sheaths.

8. Ulcerative Colitis. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii, and iii):

- i. Patient is ≥ 5 years of age; AND

- ii. Patient meets ONE of the following conditions (a or b):

- a) Patient has tried one systemic therapy; OR

Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone or methylprednisolone. A trial of one biologic other than the requested medication also counts as a trial of one systemic agent for ulcerative colitis. A biosimilar of the requested biologic does not count. Refer to [Appendix](#) for examples of biologics used for ulcerative colitis.

- b) Patient meets BOTH of the following [(1) and (2)]:

(1) Patient has pouchitis; AND

(2) Patient has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema; AND

Note: Examples of antibiotics include metronidazole and ciprofloxacin. Examples of corticosteroid enemas include hydrocortisone enema.

- iii. The medication is prescribed by or in consultation with a gastroenterologist.

B) Patient is Currently Receiving an Adalimumab Product. Approve for 1 year if the patient meets BOTH of the following (i and ii):

required to “step back” and try a conventional therapy. A biosimilar of the requested biologic does not count.

- b) Patient has ophthalmic manifestations of Behcet’s disease; AND
 - ii. The medication is prescribed by or in consultation with a rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist.
- B) Patient is Currently Receiving an Adalimumab Product.** Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
- i. Patient has been established on therapy for at least 90 days; AND
Note: A patient who has received < 90 days of therapy or who is restarting therapy with an adalimumab product is reviewed under criterion A (Initial Therapy).
 - ii. When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an adalimumab product); AND
Note: Examples of objective measures are dependent upon organ involvement but may include best-corrected visual acuity (if ophthalmic manifestations); serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate); or ulcer depth, number, and/or lesion size.
 - iii. Compared with baseline (prior to initiating an adalimumab product), patient experienced an improvement in at least one symptom, such as decreased pain or improved visual acuity (if ophthalmic manifestations).

10. Pyoderma Gangrenosum. Approve for the duration noted if the patient meets ONE of the following (A or B):

- A) Initial Therapy.** Approve for 4 months if the patient meets BOTH of the following (i and ii):
- i. Patient meets ONE of the following conditions (a or b):
 - a) Patient has tried one systemic corticosteroid; OR
Note: An example is prednisone.
 - b) Patient has tried one other immunosuppressant for at least 2 months or was intolerant to one of these agents; AND
Note: Examples include mycophenolate mofetil and cyclosporine.
 - ii. The medication is prescribed by or in consultation with a dermatologist.
- B) Patient is Currently Receiving an Adalimumab Product.** Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
- i. Patient has been established on therapy for at least 4 months; AND
Note: A patient who has received < 4 months of therapy or who is restarting therapy with an adalimumab product is reviewed under criterion A (Initial Therapy).
 - ii. Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating an adalimumab product) in at least one of the following: size, depth, and/or number of lesions; AND
 - iii. Compared with baseline (prior to initiating an adalimumab product), patient experienced an improvement in at least one symptom, such as decreased pain and/or tenderness of affected lesions.

11. Sarcoidosis. Approve for the duration noted if the patient meets ONE of the following (A or B):

- A) Initial Therapy.** Approve for 3 months if the patient meets ALL of the following (i, ii, and iii):
- i. Patient has tried at least one corticosteroid; AND
Note: An example is prednisone.
 - ii. Patient has tried at least one immunosuppressive medication; AND
Note: Examples include methotrexate, leflunomide, azathioprine, mycophenolate mofetil, cyclosporine, Leukeran (chlorambucil tablets), cyclophosphamide, Thalomid (thalidomide capsules), an infliximab product, or chloroquine.
 - iii. The medication is prescribed by or in consultation with a pulmonologist, ophthalmologist, or dermatologist.

B) Patient is Currently Receiving an Adalimumab Product. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):

- i. Patient has been established on therapy for at least 90 days; AND
Note: A patient who has received < 90 days of therapy or who is restarting therapy with an adalimumab product is reviewed under criterion A (Initial Therapy).
- ii. When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an adalimumab product); AND
Note: Examples of objective measures are dependent upon organ involvement but may include lung function (e.g., predicted forced vital capacity and/or 6-minute walk distance); serum markers (e.g., C-reactive protein, liver enzymes, N-terminal pro-brain natriuretic peptide [NT-proBNP]); improvement in rash or skin manifestations, neurologic symptoms, or rhythm control; or imaging (e.g., if indicated, chest radiograph, magnetic resonance imaging [MRI], or echocardiography).
- iii. Compared with baseline (prior to initiating an adalimumab product), patient experienced an improvement in at least one symptom, such as decreased cough, fatigue, pain, palpitations, neurologic symptoms, and/or shortness of breath.

12. Scleritis or Sterile Corneal Ulceration. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii):

- i. Patient has tried one other therapy for this condition; AND
Note: Examples include oral nonsteroidal anti-inflammatory drugs (NSAIDs) such as indomethacin, naproxen, or ibuprofen; oral, topical (ophthalmic), or intravenous corticosteroids (such as prednisone, prednisolone, methylprednisolone); methotrexate; cyclosporine; or other immunosuppressants.
- ii. The medication is prescribed by or in consultation with an ophthalmologist.

B) Patient is Currently Receiving an Adalimumab Product. Approve for 1 year if the patient meets BOTH of the following (i and ii):

- i. Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with an adalimumab product is reviewed under criterion A (Initial Therapy).
- ii. Patient meets at least one of the following (a or b):
 - a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an adalimumab product); OR
Note: Examples of objective measures are serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
 - b) Compared with baseline (prior to initiating an adalimumab product), patient experienced an improvement in at least one symptom, such as decreased eye pain, redness, light sensitivity, tearing, and/or improvement in visual acuity.

13. Spondyloarthritis, Other Subtypes. Approve for the duration noted if the patient meets ONE of the following (A or B):

Note: This includes undifferentiated arthritis, non-radiographic axial spondyloarthritis, reactive arthritis (Reiter's disease), or arthritis associated with inflammatory bowel disease. For ankylosing spondylitis or psoriatic arthritis, refer to the respective criteria under FDA-approved indications.

A) Initial Therapy. Approve for 6 months if the patient meets BOTH of the following (i and ii):

- i. Patient meets one of the following conditions (a or b):
 - a) Patient meets both of the following [(1) and (2)]:
 - (1) Patient has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet;AND

- (2) Patient has tried at least one conventional synthetic disease-modifying antirheumatic drug (DMARD); OR
Note: Examples include methotrexate, leflunomide, or sulfasalazine.
 - b) Patient has axial spondyloarthritis AND has objective signs of inflammation, defined as at least one of the following [(1) or (2)]:
 - (1) C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory; OR
 - (2) Sacroiliitis reported on magnetic resonance imaging (MRI); AND
 - ii. The medication is prescribed by or in consultation with a rheumatologist.
- B) Patient is Currently Receiving an Adalimumab Product.** Approve for 1 year if the patient meets BOTH of the following (i and ii):
- i. Patient has been established on therapy for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with an adalimumab product is reviewed under criterion A (Initial Therapy).
 - ii. Patient meets at least one of the following (a or b):
 - a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating an adalimumab product); OR
Note: Examples of objective measures include Ankylosing Spondylitis Disease Activity Score (ASDAS) and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).
 - b) Compared with baseline (prior to initiating an adalimumab product), patient experienced an improvement in at least one symptom, such as decreased pain or stiffness, or improvement in function or activities of daily living.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of adalimumab products is not recommended in the following situations:

- 1. Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (DMARD).** An adalimumab product should not be administered in combination with another biologic or with a targeted synthetic DMARD used for an inflammatory condition (see [Appendix](#) for examples). Combination therapy is generally not recommended due to a potentially higher rate of adverse events with combinations and lack of data supportive of additional efficacy.
Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) in combination with an adalimumab product.
- 2. Polymyalgia Rheumatica (PMR).** EULAR/ACR guidelines for the management of PMR (2015) strongly recommend against the use of TNFis for treatment of PMR.¹⁷ This recommendation is based on lack of evidence for benefit as well as considerable potential for harm.
- 3.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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Type of Revision	Summary of Changes	Review Date
Early Annual Revision	Ulcerative Colitis: To align with the updated labeling, the age requirement for initial approval was changed to be ≥ 5 years of age (previously was ≥ 18 years of age).	03/03/2021
Selected Revision	<p>Ankylosing Spondylitis: Initial approval duration was changed to 6 months (previously was 3 months). For a patient currently receiving an adalimumab product, it was clarified that this applies to a patient who has received an adalimumab product for ≥ 6 months. A requirement was added for a patient who is currently receiving an adalimumab product to have at least one objective or subjective response to therapy. For continuation, approvals were changed to be 1 year in duration. Previously, response was more general and according to the prescriber, and approvals were for 3 years.</p> <p>Crohn's Disease: Initial approval duration was changed to 6 months (previously was 3 months). Note was clarified to state that a previous trial of a biologic applies to one biologic other than the requested drug. A biosimilar of the requested biologic <u>does not count</u>. For a patient currently receiving an adalimumab product, it was clarified that this applies to a patient who has received an adalimumab product for ≥ 6 months. A requirement was added for a patient who is currently receiving an adalimumab product to have at least one objective or subjective response to therapy. For continuation, approvals were changed to be 1 year in duration. Previously, response was more general and according to the prescriber, and approvals were for 3 years.</p> <p>Juvenile Idiopathic Arthritis: Initial approval duration was changed to 6 months (previously was 3 months). Note was clarified to state that a previous trial of a biologic applies to one biologic other than the requested drug. A biosimilar of the requested biologic <u>does not count</u>.</p>	12/01/2021

	<p>For a patient currently receiving an adalimumab product, it was clarified that this applies to a patient who has received an adalimumab product for ≥ 6 months. A requirement was added for a patient who is currently receiving an adalimumab product to have at least one objective or subjective response to therapy. For continuation, approvals were changed to be 1 year in duration. Previously, response was more general and according to the prescriber, and approvals were for 3 years.</p> <p>Hidradenitis Suppurativa: For a patient currently receiving an adalimumab product, it was clarified that this applies to a patient who has received an adalimumab product for ≥ 90 days. Requirements were added that for a patient who is currently receiving an adalimumab product, the patient must have at least one objective <u>and</u> at least one subjective response to therapy. For continuation, approvals were changed to be 1 year in duration. Previously, response was more general and according to the prescriber, and approvals were for 3 years.</p> <p>Plaque Psoriasis: Note was clarified to state that a previous trial of a biologic applies to one biologic other than the requested drug. A biosimilar of the requested biologic <u>does not count</u>. For a patient currently receiving an adalimumab product, it was clarified that this applies to a patient who has received an adalimumab product for ≥ 90 days. Requirements were added that for a patient who is currently receiving an adalimumab product, the patient must have at least one objective <u>and</u> at least one subjective response to therapy. For continuation, approvals were changed to be 1 year in duration. Previously, response was more general and according to the prescriber, and approvals were for 3 years.</p> <p>Psoriatic Arthritis: Initial approval duration was changed to 6 months (previously was 3 months). For a patient currently receiving an adalimumab product, it was clarified that this applies to a patient who has received an adalimumab product for ≥ 6 months. A requirement was added for a patient who is currently receiving an adalimumab product to have at least one objective or subjective response to therapy. For continuation, approvals were changed to be 1 year in duration. Previously, response was more general and according to the prescriber, and approvals were for 3 years.</p> <p>Rheumatoid Arthritis: Initial approval duration was changed to 6 months (previously was 3 months). Note was clarified to state that a previous trial of a biologic applies to one biologic other than the requested drug. A biosimilar of the requested biologic <u>does not count</u>. For a patient currently receiving an adalimumab product, it was clarified that this applies to a patient who has received an adalimumab product for ≥ 6 months. A requirement was added for a patient who is currently receiving an adalimumab product to have at least one objective or subjective response to therapy. For continuation, approvals were changed to be 1 year in duration. Previously, response was more general and according to the prescriber, and approvals were for 3 years.</p> <p>Ulcerative Colitis: Initial approval duration was changed to 6 months (previously was 3 months). Note was clarified to state that a previous trial of a biologic applies to one biologic other than the requested drug. A biosimilar of the requested biologic <u>does not count</u>. For a patient currently receiving an adalimumab product, it was clarified that this applies to a patient who has received an adalimumab product for ≥ 6 months. A requirement was added for a patient who is currently receiving an adalimumab product to have at least one objective or subjective response to therapy. For continuation, approvals were changed to be 1 year in duration. Previously, response was more general and according to the prescriber, and approvals were for 3 years.</p> <p>Uveitis: Initial approval duration was changed to 6 months (previously was 3 months). Note was clarified to state that a previous trial of a biologic applies to one biologic other than the requested drug. A biosimilar of the requested biologic <u>does not count</u>. For a patient currently receiving an adalimumab product, it was clarified that this applies to a patient who has received an adalimumab product for ≥ 6 months. A requirement was added for a patient who is currently receiving an adalimumab product to have at least one objective or subjective response to therapy. For continuation, approvals were changed to be 1 year in duration. Previously, response was more general and according to the prescriber, and approvals were for 3 years.</p> <p>Behcet’s Disease: Note was clarified to state that a previous trial of a biologic applies to one biologic other than the requested drug. A biosimilar of the requested biologic <u>does not count</u>. For a patient currently receiving an adalimumab product, it was clarified that this applies to a patient who has received an adalimumab product for ≥ 90 days. Requirements were added that for a patient who is currently receiving an adalimumab product, the patient must have at least one objective <u>and</u> at least one subjective response to therapy. Previously, response was more general and according to the prescriber.</p> <p>Pyoderma Gangrenosum: For a patient currently receiving an adalimumab product, it was clarified that this applies to a patient who has received an adalimumab product for ≥ 4 months.</p>	
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	<p>Requirements were added that for a patient who is currently receiving an adalimumab product, the patient must have at least one objective <u>and</u> at least one subjective response to therapy. Previously, response was more general and according to the prescriber.</p> <p>Sarcoidosis: For a patient currently receiving an adalimumab product, it was clarified that this applies to a patient who has received an adalimumab product for ≥ 90 days. Requirements were added that for a patient who is currently receiving an adalimumab product, the patient must have at least one objective <u>and</u> at least one subjective response to therapy. Previously, response was more general and according to the prescriber.</p> <p>Scleritis or Sterile Corneal Ulceration: Initial approval duration was changed to 6 months (previously was 3 months). For a patient currently receiving an adalimumab product, it was clarified that this applies to a patient who has received an adalimumab product for ≥ 6 months. A requirement was added for a patient who is currently receiving an adalimumab product to have at least one objective or subjective response to therapy. Previously, response was more general and according to the prescriber.</p> <p>Spondyloarthritis, Other Subtypes: Initial approval duration was changed to 6 months (previously was 3 months). For a patient currently receiving an adalimumab product, it was clarified that this applies to a patient who has received an adalimumab product for ≥ 6 months. A requirement was added for a patient who is currently receiving an adalimumab product to have at least one objective or subjective response to therapy. Previously, response was more general and according to the prescriber.</p>	
Annual Revision	No criteria changes.	03/23/2022
Selected Revision	Amjevita was added to the policy. The criteria for Amjevita are the same as the existing criteria for Humira. There are no other changes to the criteria.	01/11/2023

APPENDIX

* Not an all-inclusive list of indications (e.g., oncology indications and rare inflammatory conditions are not listed). Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn’s disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous; PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis.