UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Inflammatory Conditions – Infliximab Intravenous Products Utilization Management Medical Policy
- Avsola™ (infliximab-axxq intravenous infusion – Amgen)
- Inflectra® (infliximab-dyyb intravenous infusion – Hospira/Pfizer)
- Infliximab intravenous infusion – Janssen/Johnson & Johnson
- Remicade® (infliximab intravenous infusion – Janssen/Johnson & Johnson)
- Renflexis® (infliximab-abda intravenous infusion – Samsung Bioepis/Organon)

REVIEW DATE: 12/11/2024; selected revision 07/23/2025, 08/13/2025

OVERVIEW

Infliximab products are tumor necrosis factor inhibitors (TNFis) approved for the following indications:[1-3]
- **Ankylosing spondylitis**, for reducing signs and symptoms of active disease.
- **Crohn's disease**, for the following uses:
  - Reducing the signs and symptoms and inducing and maintaining clinical remission in patients ≥ 6 years of age with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy; AND
  - Reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adults with fistulizing Crohn's disease.
- **Plaque psoriasis**, for treatment of adults with chronic severe (i.e., extensive and/or disabling) disease who are candidates for systemic therapy and when other systemic therapies are less appropriate.
- **Psoriatic arthritis**, for reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage and improving physical function.
- **Rheumatoid arthritis**, in combination with methotrexate for reducing signs and symptoms, inhibiting the progression of structural damage and improving physical function in patients with moderately to severely active disease.
- **Ulcerative colitis**, for the following uses:
  - Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adults with moderately to severely active disease who have had an inadequate response to conventional therapy; AND
  - Reducing signs and symptoms and inducing and maintaining clinical remission in patients ≥ 6 years of age with moderately to severely active disease who have had an inadequate response to conventional therapy.

Avsola, Inflectra, and Renflexis were approved as biosimilar to Remicade, indicating no clinically meaningful differences in safety and effectiveness and the same mechanism of action, route of administration, dosage form, and strength as Remicade.[2-3] However, minor differences in clinically inactive components are allowed. At this time, only biosimilarity has been demonstrated (not interchangeability).

Guidelines

TNFis feature prominently in guidelines for treatment of many inflammatory conditions.
- **Ankylosing Spondylitis and Non-Radiographic Spondyloarthritis:** Guidelines for ankylosing spondylitis and non-radiographic axial spondyloarthritis are published by the American College of Rheumatology (ACR)/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network (2019).[4] Following primary nonresponse to a TNFi, an interleukin (IL)-17

blocker is recommended; however, if the patient is a secondary nonresponder, a second TNFi is recommended over switching out of the class. In patients with a contraindication to a TNFi, use of an IL-17 blocker is recommended over traditional oral agents such as methotrexate or sulfasalazine.

- **Crohn's Disease:** The American College of Gastroenterology (ACG) [2025] has guidelines for the management of CD in adults.[5] In moderate to severe disease, systemic corticosteroids or advanced therapies may be utilized for induction of remission. Advanced therapies recommended include tumor necrosis factor (TNF) inhibitors, Entyvio® (vedolizumab), interleukin (IL)-23 inhibitors, IL-12/23 inhibitors, and Rinvoq® (upadacitinib). If steroids are utilized for induction, efforts should be made to introduce steroid-sparing agents for maintenance therapy. Guidelines from the American Gastroenterological Association (AGA) [2021] include infliximab among the therapies for moderate to severe Crohn's disease, for induction and maintenance of remission.[6]
- **Plaque Psoriasis:** Guidelines from the American Academy of Dermatologists (AAD) and National Psoriasis Foundation (NPF) [2019] recommend infliximab as a monotherapy treatment option for adults with moderate to severe disease.[7]
- **Psoriatic Arthritis:** Guidelines from ACR (2019) recommend TNFis over other biologics for use in treatment-naïve patients with psoriatic arthritis, 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 disease modifying anti-rheumatic drug (DMARD) for a patient taking the maximum tolerated dose of methotrexate who is not at target.[9]
- **Ulcerative Colitis:** The AGA (2024) and the ACG (2025) have clinical practice guidelines on the management of moderate to severe UC.[10,11] In moderate to severe disease, systemic corticosteroids or advanced therapies may be utilized for induction of remission. Advanced therapies recommended include TNF inhibitors, Entyvio, IL-23 inhibitors, IL-12/23 inhibitors, sphingosine-1-phosphate (S1P) receptor modulators, and Janus kinase (JAK) inhibitors. If steroids are utilized for induction, efforts should be made to introduce steroid-sparing agents for maintenance therapy. Of note, guidelines state corticosteroids may be avoided entirely when other effective induction strategies are planned.[11] Both guidelines also recommend that any drug that effectively treats induction should be continued for maintenance.[10,11]
- **Behcet's Disease:** The European League 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 American Academy of Ophthalmology (AAO) [2014] note that TNFis may be used first-line in patients with ophthalmic manifestations of Behcet's disease and for acute exacerbations of pre-existing Behcet's disease.[14]
- **Graft-Versus-Host Disease (GVHD):** Guidelines for hematopoietic cell transplantation from the National Comprehensive Cancer network (NCCN) [version 2.2025 – June 3, 2025] list infliximab among the agents used for steroid-refractory acute GVHD.[15] For patients with steroid-refractory acute GVHD, Jakafi® (ruxolitinib tablets) is the only category 1 recommended agent. Other alternative agents recommended by NCCN for acute GVHD (category 2A) include the following: alemtuzumab IV infusion, alpha-1 antitrypsin, anti-thymocyte globulin, Simulect® (basiliximab), calcineurin inhibitors (e.g., tacrolimus, cyclosporine), Enbrel® (etanercept), extracorporeal photopheresis, infliximab, mammalian target of rapamycin inhibitors (e.g., sirolimus), mycophenolate mofetil, Nipent™ (pentostatin), tocilizumab, urinary-derived human chorionic gonadotropin/epidermal growth factor, and Entyvio® (vedolizumab)..[15]
- **Hidradenitis Suppurativa:** Guidelines from the US and Canadian Hidradenitis Suppurativa Foundations make recommendations for topical, intralesional, and systemic medical management of disease.[16] For acute lesions of all stages, antiseptic washes, short-term oral steroids, and

interlesional steroids are among the recommendations. Systemic antibiotics have been a mainstay of treatment. Infliximab is a recommended therapy for moderate to severe disease.

- **Immunotherapy-Related Toxicities Associated with Checkpoint Inhibitors:** NCCN has guidelines (version 1.2025 – December 20, 2024) for Management of Immunotherapy-Related Toxicities.[17] Infliximab is recommended among the alternatives to manage steroid-refractory toxicities related to immune checkpoint inhibitors including inflammatory arthritis, uveitis, hemolytic anemia, myocarditis, stage 3 acute kidney injury/elevated serum creatinine, pneumonitis, esophagitis, gastritis, duodenitis, and diarrhea/colitis. Additionally, the guidelines also note that infliximab has not been tested and is not recommended for hepatotoxicity due to concerns of liver toxicity.
- **Indeterminate Colitis:** Infliximab has been effective in some patients with refractory indeterminate colitis (retrospective reviews).[18,19] When patients who are refractory to standard therapy can be definitively classified as having ulcerative colitis, colectomy is considered an effective long-term surgical treatment. Patient's with Crohn's disease; however, have a high risk of complications after ileal pouch-anal anastomosis and are treated more aggressively with medical interventions since surgical options cannot offer the same likelihood of success as in ulcerative colitis.
- **Juvenile Idiopathic Arthritis (JIA):** There are guidelines from ACR and the Arthritis Foundation for the treatment of JIA (2021) which address oligoarthritis and temporomandibular joint (TMJ) arthritis.[20] For oligoarthritis, a biologic is recommended following a trial of a conventional synthetic DMARD. In patients with TMJ arthritis, scheduled nonsteroidal anti-inflammatory drugs (NSAIDs) and/or intra-articular 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. The ACR/Arthritis Foundation Guideline for the treatment of JIA (2019) provides updated recommendations for juvenile non-systemic polyarthritis, sacroiliitis, and enthesitis.[21] Infliximab is among the TNFis recommended as subsequent therapy following treatment with a conventional synthetic DMARD such as methotrexate. TNF antagonists such as infliximab may also be used as second- or third-line treatment for systemic JIA.[22]
- **Ocular Inflammatory Disorders:** Recommendations for the use of TNFis in ocular inflammatory disorders from the AAO (2014) note that infliximab may be used as second-line corticosteroid-sparing therapy for chronic and severe scleritis.[14] Infliximab may be used in patients with uveitis due to various causes (e.g., spondyloarthropathy-associated or human leukocyte antigen [HLA]-B27-associated uveitis, juvenile idiopathic arthritis-associated uveitis, and other posterior uveitides and panuveitis syndromes). Infliximab should be considered second-line in vision-threatening JIA-associated uveitis when methotrexate has failed or is not tolerated (strong recommendation) and vision-threatening chronic uveitis from seronegative spondyloarthropathy (strong recommendation). Infliximab may also be considered in other patients who have vision-threatening or corticosteroid-dependent disease who have failed first-line therapies. The recommendations point out that studies evaluating infliximab in uveitis included patients with birdshot chorioretinitis (BSCR), a bilateral posterior uveitis generally treated with systemic immunomodulation; these patients showed a good response to infliximab.
- **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.[23] 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:** The European Respiratory Society Task Force has guidelines for treatment of pulmonary, cutaneous, cardiac, and neurologic sarcoidosis.[24] Infliximab is a recommended therapy

after continued disease or relapse while taking systemic corticosteroids and immunosuppressants (e.g., methotrexate, azathioprine, leflunomide, mycophenolate mofetil, hydroxychloroquine).

- **Still's Disease:** Still's disease presents in adults with features similar to those of systemic onset JIA.[25,26] In case series, infliximab has been effective in patients with Still's disease that was refractory to therapy with corticosteroids, methotrexate, azathioprine, and cyclophosphamide.[24]

Dosing Information

The recommended dose of infliximab intravenous is weight-based and varies slightly by indication.[1-3] Dosing increase, interval shortening, or changing to another therapy is generally recommended for attenuation of response. Thus, published recommendations note that the dose and interval of infliximab may be adjusted, as needed, in patients who initially respond but then lose that response.[2] Additionally, data are emerging concerning tapering of infliximab dosage in patients with inflammatory conditions who are in remission or have low disease activity. When the dose of any RA therapy is tapered, it is recommended that there be a comprehensive plan to monitor disease activity and address possible flares.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of infliximab products. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided 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 a patient treated with infliximab products as well as the monitoring required for adverse events and long-term efficacy, initial approval requires infliximab products to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

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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 the patient meets BOTH of the following (i and ii):
- **i.** Patient is ≥ 18 years of age; AND
- **ii.** The medication is prescribed by or in consultation with a rheumatologist; OR

B) Patient is Currently Receiving an Infliximab 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 infliximab 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 infliximab 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 infliximab 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.

Dosing. Approve ONE of the following regimens (A or B):

A) Initial Therapy. Approve up to 5 mg/kg as an intravenous infusion followed by additional similar doses at 2 and 6 weeks after the first infusion, and then no more frequently than once every 6 weeks thereafter; OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

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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 ALL of the following (i, ii, and iii):

i. Patient is ≥ 6 years of age; AND

ii. Patient meets ONE of the following (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 and methylprednisolone.

b) Patient has tried one other conventional systemic therapy for Crohn's disease; OR
Note: Examples of conventional systemic therapies 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 therapy 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; OR

B) Patient is Currently Receiving an Infliximab 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 infliximab 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 infliximab 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 infliximab product), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or blood in stool.

Dosing. Approve ONE of the following regimens (A or B):

A) Initial Therapy. Approve up to 5 mg/kg as an intravenous infusion followed by additional similar doses at 2 and 6 weeks after the first infusion, and then no more frequently than once every 8 weeks thereafter; OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

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3. 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 ALL of the following (i, ii, and iii):

i. Patient is ≥ 18 years of age; AND

ii. Patient meets ONE of the following (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, or acitretin (Soriatane®, generics). A 3-month trial of psoralen plus ultraviolet A light (PUVA) also counts. An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient 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; OR

B) Patient is Currently Receiving an Infliximab 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 3 months; AND

Note: A patient who has received < 3 months of therapy or who is restarting therapy with an infliximab product is reviewed under criterion A (Initial Therapy).

ii. Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating an infliximab 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 infliximab product), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.

Dosing. Approve ONE of the following regimens (A or B):

A) Initial Therapy. Approve up to 5 mg/kg as an intravenous infusion followed by additional similar doses at 2 and 6 weeks after the first infusion, and then no more frequently than once every 8 weeks thereafter; OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

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4. 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 the patient meets BOTH of the following (i and ii):

i. Patient is ≥ 18 years of age; AND
ii. The medication is prescribed by or in consultation with a rheumatologist or a dermatologist; OR

B) Patient is Currently Receiving an Infliximab 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 infliximab 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 infliximab 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 (PsA DAS), 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 infliximab 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.

Dosing. Approve ONE of the following regimens (A or B):
A) Initial Therapy. Approve up to 5 mg/kg as an intravenous infusion followed by additional similar doses 2 and 6 weeks after the first infusion, and then no more frequently than once every 8 weeks thereafter; OR
B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

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5. 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 ALL of the following (i, ii, and iii):
i. Patient is ≥ 18 years of age; AND
ii. 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 already had a 3-month trial of 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 is not required to "step back" and try a conventional synthetic DMARD.
ii. The medication is prescribed by or in consultation with a rheumatologist; OR
B) Patient is Currently Receiving an Infliximab 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 infliximab 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.

Dosing. Approve ONE of the following regimens (A or B):
A) Initial Therapy. Approve up to 3 mg/kg as an intravenous infusion followed by additional similar doses at 2 and 6 weeks after the first infusion, and then no more frequently than once every 8 weeks thereafter; OR
B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

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6. 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 BOTH of the following (i and ii):
i. Patient is ≥ 6 years of age; AND
ii. The medication is prescribed by or in consultation with a gastroenterologist; OR
B) Patient is Currently Receiving an Infliximab 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 infliximab 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 infliximab product); OR
Note: Examples of objective measures include fecal markers (e.g., fecal calprotectin), serum markers (e.g., C-reactive protein), endoscopic assessment, and/or reduced dose of corticosteroids.
b) Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or rectal bleeding.

Dosing. Approve ONE of the following regimens (A or B):
A) Initial Therapy. Approve up to 5 mg/kg as an intravenous infusion followed by additional similar doses 2 and 6 weeks after the first infusion, and then no more frequently than once every 8 weeks thereafter; OR
B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

Other Uses with Supportive Evidence

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7. Behcet's Disease. 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 is ≥ 6 years of age; AND

ii. Patient meets ONE of the following (a or b):
- **a)** Patient has tried at least ONE conventional therapy; OR
  Note: Examples include systemic corticosteroids (e.g., methylprednisolone), immunosuppressants (azathioprine, methotrexate, mycophenolate mofetil, cyclosporine, tacrolimus, Leukeran® [chlorambucil tablet], cyclophosphamide, interferon alfa). An exception to the requirement for a trial of one conventional therapy can be made if the patient has already had a trial of at least one tumor necrosis factor inhibitor (e.g., an adalimumab product, an etanercept product). A patient who has already tried one biologic other than the requested drug for Behcet's disease is not 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

iii. The medication is prescribed by or in consultation with a rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist; OR

B) Patient is Currently Receiving an Infliximab 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 3 months; AND
  Note: A patient who has received < 3 months of therapy or who is restarting therapy with an infliximab 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 infliximab 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 infliximab product), patient experienced an improvement in at least one symptom, such as decreased pain or improved visual acuity (if ophthalmic manifestations).

Dosing. Approve ONE of the following regimens (A or B):

A) Initial Therapy. Approve up to 5 mg/kg as an intravenous infusion followed by additional similar doses at 2 and 6 weeks after the first infusion, then no more frequently than once every 6 weeks thereafter; OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

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8. Graft-Versus-Host Disease. Approve for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 1 month if the patient meets ALL of the following (i, ii, iii, and iv):
- **i.** Patient is ≥ 6 years of age; AND
- **ii.** Patient has acute graft-versus-host disease; AND
- **iii.** Patient has tried at least one systemic medication for graft-versus-host disease; AND
  Note: Examples of systemic medications include corticosteroids (e.g., methylprednisolone), antithymocyte globulin, cyclosporine, tacrolimus, mycophenolate mofetil, Jakafi (ruxolitinib), Simulect (basiliximab), an etanercept product, sirolimus, Nipent (pentostatin), a tocilizumab product, and Entyvio (vedolizumab).
- **iv.** The medication is prescribed by or in consultation with an oncologist, hematologist, or a physician affiliated with a transplant center; OR

B) Patient is Currently Receiving an Infliximab Product. Approve for 3 months if the patient meets BOTH of the following (i and ii):
- **i.** Patient has been established on an infliximab product for at least 1 month; AND

Note: A patient who has received < 1 month of therapy or who is restarting therapy 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 infliximab product); OR
Note: An example of objective measures is normalization of liver function tests, red blood cell count, or platelet count, or resolution of fever or rash.

b) Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as improvement in skin, oral mucosal, ocular, or gastrointestinal symptoms (e.g., nausea, vomiting, anorexia).

Dosing. Approve the following regimens (A and B):

A) The dose is up to 10 mg/kg given intravenously; AND

B) Doses are administered no more frequently than once weekly.

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9. 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 patient meets ALL of the following (i, ii, and iii):

i. Patient is ≥ 18 years of age; AND

ii. Patient has tried one other therapy; AND
Note: Examples include intralesional or oral corticosteroids (e.g., triamcinolone, prednisone), systemic antibiotics (e.g., clindamycin, dicloxacillin, erythromycin), and isotretinoin.

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

B) Patient is Currently Receiving an Infliximab 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 3 months; AND
Note: A patient who has received < 3 months of therapy or who is restarting therapy with an infliximab 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 infliximab 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 infliximab product), patient experienced an improvement in at least one symptom, such as decreased pain or drainage of lesions, nodules, or cysts.

Dosing. Approve ONE of the following regimens (A or B):

A) Initial Therapy. Approve up to 5 mg/kg as an intravenous infusion followed by additional similar doses 2 and 6 weeks after the first infusion, and then no more frequently than once every 8 weeks thereafter; OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

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10. Immunotherapy-Related Toxicities Associated with Checkpoint Inhibitor Therapy. Approve for the duration noted if the patient meets ONE of the following (A or B):
Note: Examples of checkpoint inhibitors include Keytruda (pembrolizumab intravenous [IV] infusion), Opdivo (nivolumab IV infusion), Yervoy (ipilimumab IV infusion), Tecentriq (atezolizumab IV infusion), Bavencio (avelumab IV infusion), or Imfinzi (durvalumab IV infusion).

A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, and v):
- **i.** Patient is ≥ 18 years of age; AND
- **ii.** According to the prescriber, patient developed an immunotherapy-related toxicity other than hepatitis; AND
- **iii.** Patient developed this immunotherapy-related toxicity while receiving a checkpoint inhibitor; AND
- **iv.** Patient has tried one systemic corticosteroid; AND
  Note: Examples include methylprednisolone and prednisone.
- **v.** The medication is prescribed by or in consultation with an oncologist, cardiologist, gastroenterologist, hematologist, nephrologist, pulmonologist, rheumatologist, or ophthalmologist; OR

B) Patient is Currently Receiving an Infliximab 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 infliximab 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 infliximab product); OR
    Note: Examples of objective measures are dependent upon organ involvement but may include clinically significant improvement or normalization of serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), fecal markers (e.g., fecal calprotectin), and/or reduced dosage of corticosteroids.
  - **b)** Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as less joint pain/tenderness, stiffness or swelling (if joint symptoms), stool frequency and/or rectal bleeding (if gastrointestinal symptoms), and/or improved function or activities of daily living.

Dosing. Approve ONE of the following regimens (A or B):

A) Initial Therapy. Approve up to 10 mg/kg as an intravenous infusion followed by additional similar doses at 2 and 6 weeks after the first infusion, then no more frequently than once every 4 weeks thereafter; OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

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11. Indeterminate Colitis. Approve for the duration noted if the patient meets ONE of the following (A or B):
Note: Indeterminate colitis is defined as colitis that cannot be classified with certainty as either ulcerative colitis or Crohn's disease.

A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, and v):
- **i.** Patient is ≥ 6 years of age; AND
- **ii.** Patient has tried one systemic corticosteroid; AND
  Note: Examples include prednisone and methylprednisolone.
- **iii.** Patient has tried mesalamine; AND
- **iv.** Patient has tried either azathioprine or 6-mercaptopurine; AND
- **v.** The medication is prescribed by or in consultation with a gastroenterologist; OR

B) Patient is Currently Receiving an Infliximab 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 infliximab 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 infliximab product); OR
Note: Examples of objective measures include fecal markers (e.g., fecal calprotectin), serum markers (e.g., C-reactive protein), endoscopic assessment, and/or reduced dose of corticosteroids.

b) Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as decreased pain, fatigue, stool frequency, and/or rectal bleeding.

Dosing. Approve ONE of the following regimens (A or B):

A) Initial Therapy. Approve up to 5 mg/kg as an intravenous infusion followed by additional similar doses at 2 and 6 weeks after the first infusion, and then no more frequently than once every 8 weeks thereafter; OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

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12. Juvenile Idiopathic Arthritis (JIA). Approve for the duration noted if the patient meets ONE of the following (A or B):
Note: This includes JIA regardless of type of onset, including a patient with juvenile spondyloarthropathy/active sacroiliac arthritis. JIA is also referred to as Juvenile Rheumatoid Arthritis.

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

i. Patient is ≥ 6 years of age; AND

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

a) Patient has tried one other systemic medication for this condition; OR
Note: Examples of other medications for JIA include methotrexate, sulfasalazine, or leflunomide, 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 medication. A biosimilar of the requested biologic does not count. Refer to Appendix for examples of biologics used for JIA.

b) Patient has aggressive disease, as determined by the prescriber; AND

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

B) Patient is Currently Receiving an Infliximab 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 infliximab 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 infliximab 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 infliximab 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.

Dosing. Approve ONE of the following regimens (A or B):

A) Initial Therapy. Approve up to 6 mg/kg as an intravenous infusion followed by additional similar doses at 2 and 6 weeks after the first infusion, and then no more frequently than once every 8 weeks thereafter; OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

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13. 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 ALL of the following (i, ii, and iii):

i. Patient is ≥ 18 years of age; AND

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

a) Patient has tried one systemic corticosteroid; OR
Note: Examples include prednisone and methylprednisolone.

b) Patient has tried one other immunosuppressant for at least 2 months or was intolerant to one of these medications; AND
Note: Examples include mycophenolate mofetil and cyclosporine.

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

B) Patient is Currently Receiving an Infliximab 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 infliximab product is reviewed under criterion A (Initial Therapy).

ii. Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating an infliximab product) in at least one of the following: size, depth, and/or number of lesions; AND

iii. Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as decreased pain and/or tenderness of affected lesions.

Dosing. Approve ONE of the following regimens (A or B):

A) Initial Therapy. Approve up to 5 mg/kg as an intravenous infusion followed by additional similar doses 2 and 6 weeks after the first infusion, and then no more frequently than once every 8 weeks thereafter; OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

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14. 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, iii, and iv):

i. Patient is ≥ 18 years of age; AND

ii. Patient has tried at least one corticosteroid; AND
Note: Examples include prednisone and methylprednisolone.

iii. Patient has tried at least one immunosuppressive medication; AND

Note: Examples include methotrexate, azathioprine, leflunomide, mycophenolate mofetil, hydroxychloroquine, or chloroquine.

iv. The medication is prescribed by or in consultation with a pulmonologist, ophthalmologist, cardiologist, neurologist, or dermatologist; OR

B) Patient is Currently Receiving an Infliximab 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 3 months; AND
Note: A patient who has received < 3 months of therapy or who is restarting therapy with an infliximab 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 infliximab 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 infliximab product), patient experienced an improvement in at least one symptom, such as decreased cough, fatigue, pain, palpitations, neurologic symptoms, and/or shortness of breath.

Dosing. Approve ONE of the following regimens (A or B):

A) Initial Therapy. Approve up to 5 mg/kg as an intravenous infusion followed by additional similar doses at 2 and 6 weeks after the first infusion, then no more frequently than once every 6 weeks thereafter; OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

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15. 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 ALL of the following (i, ii, and iii):

i. Patient is ≥ 18 years of age; AND

ii. Patient has tried one other therapy for this condition; AND
Note: Examples include oral non-steroidal anti-inflammatory drugs (NSAIDs) such as indomethacin; oral, topical (ophthalmic), or intravenous corticosteroids (such as prednisone, prednisolone, methylprednisolone); methotrexate; cyclosporine; or other immunosuppressants.

iii. The medication is prescribed by or in consultation with an ophthalmologist; OR

B) Patient is Currently Receiving an Infliximab 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 infliximab 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 infliximab 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 infliximab 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.

Dosing. Approve ONE of the following regimens (A or B):

A) Initial Therapy. Approve up to 10 mg/kg as an intravenous infusion administered at baseline and followed by up to three additional similar doses (for example, up to three additional doses given 2, 6, and 8 weeks after the initial infusion); OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

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

Note: Examples of other subtypes include undifferentiated arthritis, non-radiographic axial spondylitis, Reactive Arthritis [Reiter's 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 ALL of the following (i, ii, and iii):

i. Patient is ≥ 18 years of age; AND

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

a) Patient has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet AND has tried at least ONE conventional synthetic disease-modifying antirheumatic drug (DMARD); OR

Note: Examples include methotrexate, leflunomide, and sulfasalazine.

b) Patient has axial spondyloarthritis with 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; AND

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

B) Patient is Currently Receiving an Infliximab 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 infliximab 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 infliximab 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 infliximab 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.

Dosing. Approve ONE of the following regimens (A or B):

A) Initial Therapy. Approve up to 5 mg/kg as an intravenous infusion followed by additional similar doses at 2 and 6 weeks after the first infusion, and then no more frequently than once every 6 weeks thereafter; OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

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17. Still'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 ALL of the following (i, ii, iii, and iv):

i. Patient is ≥ 18 years of age; AND

ii. Patient has tried one corticosteroid; AND
Note: Examples include prednisone and methylprednisolone.

iii. Patient has tried one conventional synthetic disease-modifying antirheumatic drug (DMARD) given for at least 2 months or was intolerant; AND
Note: An example is methotrexate. A previous trial of one biologic other than the requested drug (e.g., Actemra [tocilizumab intravenous injection, tocilizumab subcutaneous injection], Arcalyst [rilonacept subcutaneous injection], Ilaris [canakinumab subcutaneous injection]) also counts towards this requirement for previous therapy for Still's disease. A biosimilar of the requested biologic does not count.

iv. The medication is prescribed by or in consultation with a rheumatologist; OR

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

i. Patient has been established on this medication for at least 6 months; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with an infliximab 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 infliximab product); OR
Note: Examples of objective measures include resolution of fever, improvement in rash or skin manifestations, clinically significant improvement or normalization of serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate), and/or reduced dosage of corticosteroids.

b) Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as less joint pain/tenderness, stiffness, or swelling; decreased fatigue; improved function or activities of daily living.

Dosing. Approve ONE of the following regimens (A or B):

A) Initial Therapy. Approve up to 6 mg/kg as an intravenous fusion followed by additional similar doses at 2 and 6 weeks after the first infusion, and then no more frequently than once every 8 weeks thereafter; OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

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18. Uveitis. Approve for the duration noted if the patient meets ONE of the following (A or B):
Note: This includes other posterior uveitis and panuveitis syndromes.

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

i. Patient is ≥ 6 years of age; AND

ii. Patient has tried one of the following therapies: periocular, intraocular, or systemic corticosteroids, or immunosuppressives; AND
Note: Examples of corticosteroids include prednisolone, triamcinolone, betamethasone, methylprednisolone, prednisone. Examples of immunosuppressives include methotrexate, mycophenolate mofetil, and cyclosporine. An exception to the requirement for a trial of one

of these therapies can be made if the patient has already had a trial of an etanercept product or an adalimumab product for uveitis. A patient who has already tried one biologic other than the requested medication also counts. A biosimilar of the requested biologic does not count.

iii. The medication is prescribed by or in consultation with an ophthalmologist; OR

B) Patient is Currently Receiving an Infliximab 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 infliximab 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 infliximab product); OR
Note: Examples of objective measures include best-corrected visual acuity, assessment of chorioretinal and/or inflammatory retinal vascular lesions, or anterior chamber cell grade or vitreous haze grade.

b) Compared with baseline (prior to initiating an infliximab product), patient experienced an improvement in at least one symptom, such as decreased eye pain, redness, light sensitivity, and/or blurred vision; or improvement in visual acuity.

Dosing. Approve ONE of the following regimens (A or B):

A) Initial Therapy. Approve up to 10 mg/kg as an intravenous infusion followed by additional similar doses at 2 and 6 weeks after the first infusion, then no more frequently than once every 4 weeks thereafter; OR

B) Patient is Currently Receiving an Infliximab Product. Approve up to a maximum dose of 10 mg/kg administered intravenously no more frequently than once every 4 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of infliximab intravenous products is not recommended in the following situations:

1. **Concurrent Use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug.** This medication should not be administered in combination with another biologic or with a targeted synthetic oral small molecule drug used for an inflammatory condition (see Appendix for examples). Combination therapy is generally not recommended due to a potentially higher rate of adverse events and lack of controlled clinical data supporting additive efficacy.
   Note: This does NOT exclude the use of conventional synthetic disease-modifying antirheumatic drug (e.g., methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) in combination with this medication.

2. 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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HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Ulcerative Colitis:** For a patient currently taking, a note was added to clarify that a mesalamine product does not count as a systemic therapy for ulcerative colitis. **Conditions Not Recommended for Approval:** Inflammatory Myopathies and Large Vessel Vasculitis were removed.	11/15/2023
Selected Revision	**Plaque Psoriasis:** For a patient currently taking an infliximab product, the timeframe for established on therapy was changed from 90 days to 3 months. **Behcet's Disease:** For a patient currently taking an infliximab product, the timeframe for established on therapy was changed from 90 days to 3 months. **Hidradenitis Suppurativa:** For a patient currently taking an infliximab product, the timeframe for established on therapy was changed from 90 days to 3 months.	03/27/2024

Type of Revision	Summary of Changes	Review Date
	Sarcoidosis: For a patient currently taking an infliximab product, the timeframe for established on therapy was changed from 90 days to 3 months.	
Selected Revision	**Ankylosing Spondylitis:** For initial approvals, a requirement that the patient is ≥ 18 years of age was added. **Plaque Psoriasis:** In the Note, psoralen plus ultraviolet A light (PUVA) was removed from the examples of traditional systemic therapies. An additional Note was added that a 3-month trial of PUVA counts as a traditional systemic therapy. **Psoriatic Arthritis:** For initial approvals, a requirement that the patient is ≥ 18 years of age was added. **Rheumatoid Arthritis:** For initial approvals, a requirement that the patient is ≥ 18 years of age was added. **Behcet's Disease:** For initial approvals, a requirement that the patient is ≥ 6 years of age was added. **Graft-vs-Host Disease:** For initial approvals, a requirement that the patient is ≥ 6 years of age was added. **Hidradenitis Supprativa:** For initial approvals, a requirement that the patient is ≥ 18 years of age was added. **Immunotherapy-Related Toxicities Associated with Checkpoint Inhibitor Therapy:** For initial approvals, a requirement that the patient is ≥ 18 years of age was added. **Juvenile Idiopathic Arthritis:** For initial approvals, a requirement that the patient is ≥ 6 years of age was added. **Pyoderma Gangrenosum:** For initial approvals, a requirement that the patient is ≥ 18 years of age was added. **Sarcoidosis:** For initial approvals, a requirement that the patient is ≥ 18 years of age was added. **Scleritis or Sterile Corneal Ulceration:** For initial approvals, a requirement that the patient is ≥ 18 years of age was added. **Spondyloarthritis, Other Subtypes:** For initial approvals, a requirement that the patient is ≥ 18 years of age was added. **Still's Disease:** For initial approvals, a requirement that the patient is ≥ 18 years of age was added. **Uveitis:** For initial approvals, a requirement that the patient is ≥ 6 years of age was added. **Conditions Not Recommended for Approval:** Concurrent use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug was changed to as listed (previously oral small molecule drug was listed as Disease-Modifying Antirheumatic Drug).	09/11/2024
Annual Revision	**Immunotherapy-Related Toxicities Associated with Checkpoint Inhibitor Therapy:** Myalgia and myositis were removed from the examples of immunotherapy-related toxicities associated with checkpoint inhibitor therapy.	12/11/2024
Selected Revision	**Ulcerative Colitis:** For initial therapy, removed the following options of approval: (1) the patient has tried one systemic therapy; (2) the patient has pouchitis and tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema.	07/23/2025
Selected Revision	**Graft-versus-Host Disease:** For initial approvals, added the requirement that patient has acute graft-versus-host disease. Modified the requirement that patient has tried at least one conventional systemic treatment to at least one systemic medication. Jakafi (ruxolitinib), Simulect (basiliximab), an etanercept product, sirolimus, Nipent (pentostatin), a tocilizumab product, and Entyvio (vedolizumab) were added to the Note of examples of systemic medications. **Immunotherapy-Related Toxicities Associated with Checkpoint Inhibitor Therapy:** "According to the prescriber" was added to the requirement that patient experienced an immunotherapy-related toxicity while receiving a checkpoint inhibitor and specific examples of immunotherapy-related toxicities were removed. Cardiologist, hematologist, nephrologist, and pulmonologist were added as accepted specialists to the specialist requirement.	08/13/2025

APPENDIX

	Mechanism of Action	Examples of Indications*
Biologics		
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
Cimzia® (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel®, biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA, RA
Infliximab IV Products (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
Zymfentra® (infliximab-dyyb SC injection)	Inhibition of TNF	CD, UC
Simponi®, Simponi Aria® (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PJIA, PsA, RA
Tocilizumab Products (Actemra® IV, biosimilar; Actemra SC, biosimilar)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
Kevzara® (sarilumab SC injection)	Inhibition of IL-6	RA
Orencia® (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PSA, RA
		IV formulation: JIA, PsA, RA
Rituximab IV Products (Rituxan®, biosimilars)	CD20-directed cytolytic antibody	RA
Kineret® (anakinra SC injection)	Inhibition of IL-1	JIA^, RA
Omvoh® (mirikizumab IV infusion, SC injection)	Inhibition of IL-23	CD, UC
Ustekinumab Products (Stelara® IV, biosimilar; Stelara SC, biosimilar)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
Siliq® (brodalumab SC injection)	Inhibition of IL-17	PsO
Cosentyx® (secukinumab SC injection; secukinumab IV infusion)	Inhibition of IL-17A	SC formulation: AS, ERA, nr-axSpA, PsO, PsA
		IV formulation: AS, nr-axSpA, PsA
Taltz® (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Bimzelx® (bimekizumab-bkzx SC injection)	Inhibition of IL-17A/17F	PsO, AS, nr-axSpA, PsA
Ilumya® (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Skyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PSA, PsO, UC
		IV formulation: CD, UC
Tremfya® (guselkumab SC injection, guselkumab IV infusion)	Inhibition of IL-23	SC formulation: CD, PsA, PsO, UC
		IV formulation: CD, UC
Entyvio® (vedolizumab IV infusion, vedolizumab SC injection)	Integrin receptor antagonist	CD, UC
Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs		
Otezla® (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Cibinqo™ (abrocitinib tablets)	Inhibition of JAK pathways	AD
Olumiant® (baricitinib tablets)	Inhibition of JAK pathways	RA, AA
Litfulo® (ritlecitinib capsules)	Inhibition of JAK pathways	AA
Leqselvi® (deuruxolitinib tablets)	Inhibition of JAK pathways	AA
Rinvoq® (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, AS, nr-axSpA, RA, PsA, CD, UC
Rinvoq® LQ (upadacitinib oral solution)	Inhibition of JAK pathways	PsA, PJIA
Sotyktu® (deucravacitinib tablets)	Inhibition of TYK2	PsO
Xeljanz® (tofacitinib tablets/oral solution)	Inhibition of JAK pathways	RA, PJIA, PsA, UC
Xeljanz® XR (tofacitinib extended-release tablets)	Inhibition of JAK pathways	RA, PsA, UC
Zeposia® (ozanimod tablets)	Sphingosine 1 phosphate receptor modulator	UC
Velsipity® (etrasimod tablets)	Sphingosine 1 phosphate receptor modulator	UC

* Not an all-inclusive list of indications. 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; AA – Alopecia areata; TYK2 – Tyrosine kinase 2.