Reference number(s)
1979-A

Standard Medicare Part B Management infliximab

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Remicade	infliximab
Avsola	infliximab-axxq
Inflectra	infliximab-dyyb
Renflexis	infliximab-abda
Zymfentra	infliximab-dyyb
infliximab (unbranded Remicade)	infliximab
infliximab-abda (unbranded Renflexis)	infliximab-abda

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1-7]

Avsola/Inflectra/infliximab/infliximab-abda/Remicade/Renflexis

Crohn's Disease

- Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease (CD) who have had an inadequate response to conventional therapy.

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- Reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing CD.

Pediatric Crohn's Disease

Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active CD who have had an inadequate response to conventional therapy.

Ulcerative Colitis

Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response to conventional therapy.

Pediatric Ulcerative Colitis

Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active UC who have had an inadequate response to conventional therapy.

Rheumatoid Arthritis in Combination with Methotrexate

Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (RA).

Ankylosing Spondylitis

Reducing signs and symptoms in adult patients with active ankylosing spondylitis (AS).

Psoriatic Arthritis

Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in adult patients with psoriatic arthritis (PsA).

Plaque Psoriasis

Treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis (PsO) who are candidates for systemic therapy and when other systemic therapies are medically less appropriate.

Zymfentra

- Maintenance treatment of moderately to severely active ulcerative colitis in adults following treatment with an infliximab product administered intravenously.
- Maintenance treatment of moderately to severely active Crohn's disease in adults following treatment with an infliximab product administered intravenously.

Compendial Uses[8-47,49,50]

- Adult-onset Still's disease
- Arthritis in Crohn's disease
- Non-radiographic axial spondyloarthritis

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- Behcet's disease
- Gastrointestinal tract transplantation organ rejection
- Giant cell arteritis
- Acute graft versus host disease
- Hidradenitis suppurativa
- Juvenile idiopathic arthritis
- Kawasaki disease
- Necrobiosis lipoidica diabeticorum
- Polyarteritis nodosa
- Pyoderma gangrenosum
- Rheumatoid arthritis as monotherapy
- Severe, refractory SAPHO (synovitis, acne, pustulosis, hyperostosis, and osteitis) syndrome
- Sarcoidosis
- Subcorneal pustular dermatosis
- Synovitis
- Takayasu's arteritis
- Uveitis
- Immune checkpoint inhibitor-related toxicity
- Multisystem inflammatory syndrome in children (MIS-C)

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all submissions:

Crohn's disease (CD), ulcerative colitis (UC), rheumatoid arthritis (RA), ankylosing spondylitis (AS), non-radiographic axial spondyloarthritis (nr-axSpA), psoriatic arthritis (PsA), plaque psoriasis (PsO), adult-onset Still's disease (AOSD), hidradenitis suppurativa, juvenile idiopathic arthritis (JIA), uveitis, and immune checkpoint inhibitor-related inflammatory arthritis

Continuation requests

Chart notes or medical record documentation supporting benefit of therapy.

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Coverage Criteria

Crohn's Disease (CD)[1-7]

Authorization of 12 months may be granted for treatment of moderately to severely active Crohn's disease.

Ulcerative Colitis (UC)[1-7]

Authorization of 12 months may be granted for treatment of moderately to severely active ulcerative colitis.

Rheumatoid Arthritis (RA) (Avsola/Inflectra/infliximab/infliximab-abda/Remicade/Renflexis only)[1-6]

Authorization of 12 months may be granted for treatment of moderately to severely active rheumatoid arthritis.

Ankylosing Spondylitis (AS) and Non-Radiographic Axial Spondyloarthritis (nr-axSpA) (Avsola/Inflectra/infliximab/infliximab-abda/Remicade/Renflexis only)[1-6,14]

Authorization of 12 months may be granted for treatment of active ankylosing spondylitis and active non-radiographic axial spondyloarthritis.

Psoriatic Arthritis (PsA) (Avsola/Inflectra/infliximab/infliximab-abda/Remicade/Renflexis only)[1-6]

Authorization of 12 months may be granted for treatment of active psoriatic arthritis.

Plaque Psoriasis (PsO) (Avsola/Inflectra/infliximab/infliximab-abda/Remicade/Renflexis only)[1-6]

Authorization of 12 months may be granted for treatment of plaque psoriasis.

Adult-Onset Still's Disease (AOSD) (Avsola/Inflectra/infliximab/infliximab-abda/Remicade/Renflexis only)[8]

Authorization of 12 months may be granted for treatment of active adult-onset Still's disease.

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Arthritis In Crohn's Disease (CD) (Avsola/Inflectra/infliximab/infliximab-abda/Remicade/Renflexis only)[8]

Authorization of 12 months may be granted for treatment of arthritis in a member with Crohn's disease.

Behcet's Disease (Avsola/Inflectra/infliximab/infliximab-abda/Remicade/Renflexis only)[8]

Authorization of 12 months may be granted for treatment of Behcet's disease.

Gastrointestinal Tract Transplantation Organ Rejection (Avsola/Inflectra/infliximab/infliximab-abda/Remicade/Renflexis only)[8]

Authorization of 6 months may be granted for treatment of gastrointestinal tract transplantation organ rejection.

Giant Cell Arteritis (Avsola/Inflectra/infliximab/infliximab-abda/Remicade/Renflexis only)[8]

Authorization of 3 months may be granted for treatment of giant cell arteritis.

Acute Graft Versus Host Disease (Avsola/Inflectra/infliximab/infliximab-abda/Remicade/Renflexis only)[8,15]

Authorization of 12 months may be granted for treatment of acute graft versus host disease.

Hidradenitis Suppurativa (Avsola/Inflectra/infliximab/infliximab-abda/Remicade/Renflexis only)[8,18]

Authorization of 12 months may be granted for treatment of hidradenitis suppurativa.

Juvenile Idiopathic Arthritis (JIA) (Avsola/Inflectra/infliximab/infliximab-abda/Remicade/Renflexis only)[8,13,19,28]

Authorization of 12 months may be granted for treatment of active juvenile idiopathic arthritis.

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Kawasaki Disease (Avsola/Inflectra/infliximab/infliximab-abda/Remicade/Renflexis only)[8]

Authorization of 1 month may be granted for treatment of Kawasaki disease.

Necrobiosis Lipoidica Diabeticorum (Avsola/Inflectra/infliximab/infliximab-abda/Remicade/Renflexis only)[8]

Authorization of 12 months may be granted for treatment of necrobiosis lipoidica diabeticorum.

Polyarteritis Nodosa (Avsola/Inflectra/infliximab/infliximab-abda/Remicade/Renflexis only)[8]

Authorization of 12 months may be granted for treatment of polyarteritis nodosa.

Pyoderma Gangrenosum (Avsola/Inflectra/infliximab/infliximab-abda/Remicade/Renflexis only)[8]

Authorization of 12 months may be granted for treatment of pyoderma gangrenosum.

SAPHO (synovitis, acne, pustulosis, hyperostosis, and osteitis) syndrome (Avsola/Inflectra/ infliximab/infliximab-abda/Remicade/Renflexis only)[8]

Authorization of 12 months may be granted for treatment of severe, refractory SAPHO syndrome.

Sarcoidosis (Avsola/Inflectra/infliximab/infliximab-abda/Remicade/Renflexis only)[8]

Authorization of 12 months may be granted for treatment of sarcoidosis.

Subcorneal Pustular Dermatosis (Avsola/Inflectra/infliximab/infliximab-abda/Remicade/Renflexis only)[8]

Authorization of 6 months may be granted for treatment of subcorneal pustular dermatosis.

Synovitis (Avsola/Inflectra/infliximab/infliximab-abda/Remicade/Renflexis only)[8]

Authorization of 12 months may be granted for treatment of synovitis.

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Takayasu's Arteritis (Avsola/Inflectra/infliximab/infliximab-abda/Remicade/Renflexis only)[8]

Authorization of 12 months may be granted for treatment of Takayasu's arteritis.

Uveitis (Avsola/Inflectra/infliximab/infliximab-abda/Remicade/Renflexis only)[8,21,29]

Authorization of 12 months may be granted for treatment of uveitis.

Immune Checkpoint Inhibitor-Related Inflammatory Arthritis (Avsola/Inflectra/infliximab/infliximab-abda/Remicade/Renflexis only)[15]

Authorization of 12 months may be granted for treatment of moderate or severe immune checkpoint inhibitor-related inflammatory arthritis.

Immune Checkpoint Inhibitor-Related Toxicity (Avsola/Inflectra/infliximab/infliximab-abda/Remicade/Renflexis only)[15]

Authorization of 6 months may be granted for treatment of immune checkpoint inhibitor-related toxicity.

Multisystem Inflammatory Syndrome in Children (MIS-C) (Avsola/Inflectra/infliximab/infliximab-abda/Remicade/Renflexis only)[8]

Authorization of 1 month may be granted for treatment of multisystem inflammatory syndrome in children (MIS-C) post severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection who have failed to respond to standard pharmacologic therapy.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Crohn's Disease (CD) and Ulcerative Colitis (UC)

Authorization for 12 months may be granted when both of the following criteria are met:

- The member is currently receiving therapy with an infliximab product.
- The member is receiving benefit from therapy.

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Gastrointestinal Tract Transplantation Organ Rejection, Giant Cell Arteritis, Kawasaki Disease, Subcorneal Pustular Dermatosis, Immune Checkpoint Inhibitor-Related Toxicity, And Multisystem Inflammatory Syndrome In Children (MIS-C) (Avsola/Inflectra/infliximab/infliximab-abda/Remicade/Renflexis only)[15]

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria.

All Other Indications (Avsola/Inflectra/infliximab/infliximab-abda/Remicade/Renflexis only)

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with Avsola, Inflectra, infliximab, infliximab-abda, Remicade, or Renflexis.
- The requested medication is being used to treat an indication in the coverage criteria section.
- The member is receiving benefit from therapy.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for infliximab, Remicade, and its biosimilars.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2022 update.
- 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis.
- EULAR recommendations on management of Behcet's syndrome.
- North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations: Part II: Topical, intralesional, and systemic medical management.

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- British Association of Dermatologists guidelines for the management of hidradenitis suppurativa (acne inversa) 2018.
- 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis.
- 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis.
- Diagnosis, treatment, and long-term management of Kawasaki disease: a scientific statement for health professionals from the American Heart Association.
- 2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Polyarteritis Nodosa.
- Etiology and management of pyoderma gangrenosum: a comprehensive review.
- European Respiratory Society (ERS) clinical practice guidelines on treatment of sarcoidosis.
- Comparison of ultrasonographic assessment of synovitis and joint vascularity with radiographic evaluation in a randomized, placebo-controlled study of infliximab therapy in early rheumatoid arthritis.
- Very early treatment with infliximab in addition to methotrexate in early, poor-prognosis rheumatoid arthritis reduces magnetic resonance imaging evidence of synovitis and damage, with sustained benefit after infliximab withdrawal: results from a twelve-month randomized, double-blind, placebo-controlled trial.
- Recommendations of the Italian Society of Rheumatology for the treatment of the primary large-vessel vasculitis with biological agents.
- Efficacy and tolerance of infliximab in refractory Takayasu arteritis: French multicentre study.
- A review of systemic biologics and local immunosuppressive medications in uveitis.
- Expert panel recommendations for the use of anti-tumor necrosis factor biologic agents in patients with ocular inflammatory disorders.
- NCCN guideline: Hematopoietic cell transplantation.
- NCCN guideline: Management of immunotherapy-related toxicities.
- COVID-19 Treatment Guidelines Panel: Coronavirus disease 2019 (COVID-19) treatment guidelines.

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for infliximab, Remicade, and its biosimilars (excluding Zymfentra) are covered in addition to the following:

- Adult-onset Still's disease
- Arthritis in Crohn's disease
- Non-radiographic axial spondyloarthritis
- Behcet's disease
- Gastrointestinal tract transplantation organ rejection
- Giant cell arteritis
- Acute graft versus host disease

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- Hidradenitis suppurativa
- Juvenile idiopathic arthritis
- Kawasaki disease
- Necrobiosis lipoidica diabeticorum
- Polyarteritis nodosa
- Pyoderma gangrenosum
- Severe, refractory SAPHO (synovitis, acne, pustulosis, hyperostosis, and osteitis) syndrome
- Sarcoidosis
- Subcorneal pustular dermatosis
- Synovitis
- Takayasu's arteritis
- Uveitis
- Immune checkpoint inhibitor toxicity
- Multisystem inflammatory syndrome in children (MIS-C)

Explanation of Rationale

Support for FDA-approved indications (Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis) can be found in the manufacturer's prescribing information.

Support for using infliximab for non-radiographic axial spondyloarthritis can be found in the 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network recommendations for the treatment of ankylosing spondylitis and non-radiographic axial spondyloarthritis. The guidelines recommend that in patients who still have active ankylosing spondylitis (AS) despite treatment with NSAIDs, tumor necrosis factor inhibitor (TNFi) such as infliximab are recommended but the guideline does not recommend any particular TNFi.

Support for using infliximab to treat adult-onset Still's disease can be found in two published case series. Kraetsch et al reported adult-onset Still's disease (AOSD) appears to favorably respond to treatment with infliximab. In a small, pilot study, 6 patients diagnosed with AOSD (4 with early onset of disease, and 2 with disease durations of 3 and 5 years, respectively) received an initial course of intravenous infusions of infliximab 5 mg/kg, at 0, 2, and 6 weeks. Further treatment with infliximab was given at 6- to 8-week intervals, contingent upon patient response. At the time of study enrollment, all patients had massive polyarthralgia, 5 had polyarthritis, 5 had persistent fever, 5 had a characteristic rash, 5 had persistent leukocytosis, 4 had splenomegaly, and all 6 patients had elevations of erythrocyte sedimentation rate (ESR) and elevated serum concentrations of C-reactive protein. Hyperferritinemia was seen in 3 patients. All patients showed a beneficial response to treatment, with complete resolution of rash, fever, myalgias, and splenomegaly (the latter after 3 treatments); arthralgia/arthritis resolved in 5 of 6 patients. Normalization also occurred in serological markers of disease activity (CRP, ESR, and ferritin concentration) in all patients. Favorable effects of treatment were evident after the first course of treatment with infliximab and were sustained with continuing infliximab treatment at 6-to-8 week

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intervals, with treatment durations extending from 5 to 28 months. In the 2 patients with long-standing disease of 3- and 5-years duration, swollen joint counts declined from 30 to 3, and from 3 to 0 joints, respectively; tender joint count declined similarly, from 33 to 3 and from 7 to 2 joints, respectively. Infliximab was tolerated well; 1 patient showed a moderate infusion reaction during the second treatment yet was able to resume infliximab therapy after a brief discontinuation of the infusion.

Cavagna et al indicated that infliximab appeared to induce clinical remission in 3 patients with chronically active, treatment-refractory, adult Still Disease (ASD). Each patient had a disease history of between 4- and 7-years duration, during which time they exhibited relapsing or refractory disease despite treatment with NSAIDs, prednisone, methotrexate (n=3), and cyclosporine (n=1). Patients were given intravenous infusions of infliximab 3 mg/kg at weeks 0, 2, 6, and then once every 8 weeks. Infliximab was to be given once every 4 weeks from week 30 thereafter, and methotrexate was maintained throughout the duration of the study. All patients experienced rapid regression of ASD symptoms (arthralgia, cutaneous rash, fever, pharyngitis), accompanied by progressive reductions in serum concentrations of ferritin, C-reactive protein, and erythrocyte sedimentation rate. One patient developed a diffuse, urticarial rash shortly after the fifth infliximab infusion, necessitating withdrawal from therapy at week 22. The 2 remaining patients both experienced brief relapses on weeks 20 and 28; both rapidly regained a state of remission following repeat infusions of infliximab, and continued to receive infliximab beyond 30 weeks, without signs of relapse. These 2 patients also tolerated tapered reductions in prednisone dosing. Neither of the remaining patients showed development of anticardiolipin antibodies, anti-double stranded DNA, or antinuclear antibodies after prolonged treatment.

Support for using infliximab to treat arthritis in Crohn's disease can be found in a case series by Elman et al. Infliximab appeared to be effective in suppressing joint inflammation associated with arthritis secondary to Crohn's disease. In a series of case reports, patients with treatment-refractory, joint inflammation associated with long-standing Crohn's disease (9 to 31 years duration; n=4) were given intravenous infliximab 5 mg/kg at 8 to 16-week intervals after the initial induction schedule. All patients had prolonged episodes of joint and back pain associated with periods of quiescence in their inflammatory bowel disease; 2 patients had "sausage-shaped" finger and toe swelling, and 3 patients presented with pain in the sacroiliac joint (SI-joint). No patient had radiographic abnormalities of the SI-joint. All patients had been receiving treatment with prednisone up to 40 mg per day, accompanied by 1 or more antiarthritic agents including azathioprine, methotrexate, minocycline, and sulfasalazine. Patients had favorable responses to infliximab, experiencing clinically meaningful reductions in joint pain and swelling, allowing for dose reductions or withdrawals of corticosteroid and antiarthritic agents. One patient discontinued infliximab therapy due to anorexia and insomnia.

Support for Behcet's disease can be found in the European League Against Rheumatism (EULAR) recommendations on management of Behcet syndrome (BS). Hatemi and colleagues (2018) noted that several new therapeutic modalities with different mechanisms of action have been studied in patients with BS. These researchers updated the recommendations in the light of these new data under the auspices of EULAR Standing Committee for Clinical Affairs. The recommendations on the medical management of muco-cutaneous, joint, eye, vascular, neurological and GI involvement of BS were modified; 5 overarching principles and a new recommendation about the surgical management of vascular involvement were added. For BS with eye involvement, among the monoclonal anti-TNF antibodies, although there is more

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accumulated experience with infliximab (IFX), adalimumab (ADA) also appeared to be an effective alternative. Switching between these agents appeared to be possible in patients with primary or secondary unresponsiveness or adverse events. Patients presenting with an initial or recurrent episode of acute sight-threatening uveitis should be treated with high-dose glucocorticoids, IFX or interferon-alpha. Intravitreal glucocorticoid injection is an option in patients with unilateral exacerbation as an adjunct to systemic treatment.

Support for using infliximab to treat gastrointestinal tract organ transplantation rejection can be found in two case reports by Pascher et al. In 2 case reports, infliximab was effective in the treatment of steroid and OKT3 (muromonab-CD3)-refractory moderate to severe acute cellular rejection in intestinal transplant recipients. Following either 5 or 10 days of treatment with OKT3 and enhanced baseline immunosuppressive therapy, acute cellular rejection persisted. Patients were then treated with 3 mg/kg intravenous (IV) infliximab; both patients received 4 infusions, 2 to 4 weeks apart. Improvement was observed within 1 week of the first infusion. Absence of clinical symptoms and histological signs of rejection persisted for at least 8 months for 1 patient and at least 10 months for the other.

Support for using infliximab to treat giant cell arteritis can be found in an open-label case study (Cantini et al). Administration of infliximab was effective in provoking remission in patients with active, steroid-dependent giant cell arteritis (GCA). In an open-label case study, 4 patients with long-standing GCA (disease duration ranging from 42 to 54 months) were unable to tolerate the tapering of their daily corticosteroid dose to less than 12.5 mg. They were given a 3-dose regimen of intravenous infliximab 3 mg/kg, at 0, 2, and 6 weeks, concurrent with reduction of their steroid dose to prednisone 5 mg per day. Three patients experienced a complete response to infliximab therapy, exhibiting both clinical and humeral evidence of remission (resolution of cranial and systemic symptoms, articular symptoms, visual symptoms, and normalization of erythrocyte sedimentation rate and serum concentration of C-reactive protein) after the second dose of infliximab. These responders remained in remission for up to 6 months after the third infliximab infusion, without requiring further treatment with corticosteroid. The fourth patient initially showed a partial response to the first infusion; however, she experienced clinical relapse at the time of her second infusion, causing her to withdraw from the study per the prospectively established protocol. Infliximab was well tolerated by all patients, and adverse events were neither reported nor observed.

Support for hidradenitis suppurativa can be found in the North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations: Part II: Topical, intralesional, and systemic medical management. The guideline indicates infliximab is recommended for moderate-to-severe disease. Dose ranging studies are needed to determine the optimal dosage for management.

Support for juvenile idiopathic arthritis can be found in the 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Non-Systemic Polyarthritis, Sacroiliitis, and Enthesitis. Using infliximab in combination with a disease-modifying antirheumatic drug (DMARD) was a strong recommendation despite the low quality of evidence, primarily given more extensive experience with the need for combination therapy to reduce the risk of antidrug antibody formation.

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Support for Kawasaki disease (KD) can be found in the following document produced by the American Heart Association: Diagnosis, treatment, and long-term management of Kawasaki disease: a scientific statement for health professionals from the American Heart Association. A 2-center, randomized, double-blind, placebo-controlled trial of infliximab plus IVIG for intensification of initial treatment enrolled 196 subjects. The study was powered for the primary outcome measure of reducing IVIG resistance from 20% to 5%. Secondary outcome measures included reduction of inflammatory parameters and the change in coronary artery Z scores. Although the number of fever days was shortened and inflammatory parameters normalized more rapidly in the infliximab-treated subjects, the rates of IVIG resistance were identical between the 2 arms. A striking finding was the complete prevention of IVIG infusion reactions in children randomized to the infliximab arm compared with a 13% reaction rate in subjects who received placebo before their IVIG infusion. There was a significant decrease in Z score for the left anterior descending (LAD) in favor of infliximab. However, there was no difference in the rate of coronary artery aneurysms between the groups, although the study was inadequately powered for this end point. On the basis of current information, addition of infliximab to initial therapy with IVIG is safe but does not prevent recrudescent fever.

A phase I multicenter, randomized, open clinical trial of infliximab (5 mg/kg intravenously over 2 hours) versus a second infusion of intravenous immune globulin (IVIG) (2 g/kg) was performed to determine the safety, tolerability, and pharmacokinetics of infliximab for rescue therapy for patients who had fever at least 36 hours after the end of the initial IVIG infusion. The study enrolled 24 subjects with IVIG-resistant KD and determined that infliximab was well tolerated in infants and children with KD and that the pharmacokinetics were similar to adults, with circulating levels of the monoclonal antibody detected out to 10 weeks. In the Japanese trial, 20 KD patients resistant to 2 consecutive IVIG infusions (2 g/kg each) were treated with infliximab (5 mg/kg), and an apparent clinical response was achieved in 18 (90%). The 2 unresponsive patients were treated with plasma exchange with resolution of their inflammation. The coronary artery abnormalities detected by echocardiogram all subsequently resolved. There were no adverse reactions attributed to infliximab among the study subjects.

A retrospective review of 2 centers that consistently administered either a second dose of IVIG or infliximab to IVIG-resistant patients suggested that patients receiving infliximab had shorter hospitalization and fewer days of fever, but coronary artery outcomes and adverse events were similar. On the basis of these retrospective data, infliximab can be considered as an alternative to a second infusion of IVIG for resistant patients.

Support for using infliximab to treat necrobiosis lipoidica diabeticorum can be found in a case report by Kolde et al. Infliximab was an effective treatment for refractory ulcerated necrobiosis lipoidica in a 33-year-old man with diabetes mellitus. The patient received once monthly infusions of infliximab (5 mg/kg) for 2 months. Following treatment with infliximab, clinical improvement was reported, including healing of ulcerations, fading of erythematous infiltration, flattening of the raised margin, and substantial reduction in pain. Improvement of the necrobiosis lipoidica was sustained after the cessation of infliximab. The only reported adverse event was the development of miliary tuberculosis after the second infusion, which was possibly drug-related due to the temporal association with infliximab treatment.

Support for polyarteritis nodosa can be found in the 2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Polyarteritis Nodosa. The guidelines recommend use of

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tumor necrosis factor inhibitors (TNFi) instead of cyclophosphamide to prevent strokes in patients with clinical manifestations of deficiency of adenosine deaminase 2 (DADA2) associated with polyarteritis nodosa (PAN). In addition, a case report by Matusuo et al describes a 64-year-old man with a diagnosis of PAN who continually relapsed following treatments of glucocorticoids, methotrexate, cyclophosphamide, rituximab, and tacrolimus. After the fifth relapse, infliximab 5 mg/kg was administered at 0, 2, and 6 weeks, followed by 400 mg every 8 weeks. Clinical symptoms and laboratory values improved dramatically within 3 months of starting infliximab and daily prednisolone dose was tapered to 10 mg.

Support for pyoderma gangrenosum (PG) can be found in a study by Ahronowitz et al. Infliximab, an anti-TNFα monoclonal antibody binding both soluble and membrane-bound TNFα, is the only biologic that has shown efficacy in classic PG in a randomized, double-blind, controlled trial (level I evidence). Thirty patients were given either infliximab 5 mg/kg or placebo. At 2 weeks, 6 of 13 patients in the infliximab group showed improvement in the severity and/or size of ulcers, versus only 1 of 17 in the placebo group. After 2 weeks, the 16 non-responders in the placebo group were switched to infliximab and by week 6, 20 of 29 patients treated with infliximab demonstrated improvement in their PG lesions, with 6 of 29 showing complete resolution. Further studies are needed to determine the efficacy of infliximab in idiopathic PG.

Support for sarcoidosis can be found in the practice guidelines from the European Respiratory Society. The practice guidelines recommend the addition of infliximab to improve and/or preserve forced vital capacity (FVC) and quality of life in patients with symptomatic pulmonary sarcoidosis believed to be at higher risk for future mortality or permanent disability from sarcoidosis who have been treated with glucocorticoids or other immunosuppressive agents and have continued disease. Additionally, the guideline recommends the addition of infliximab (compared to no additional treatment) for patients with cutaneous sarcoidosis who have been treated with glucocorticoids and/or other immunosuppressive agents and have continued cosmetically important active skin disease. In patients with neurosarcoidosis that have been treated with glucocorticoids and a second-line agent (methotrexate, azathioprine, mycophenolate mofetil) with continued disease, the guidelines suggest adding infliximab.

Support for using infliximab to treat subcorneal pustular dermatosis can be found in a case report by Voightlander et al. Infliximab was effective in producing remission in a 79-year-old woman with treatment-refractory subcorneal pustular dermatosis (Sneddon-Wilkinson disease). The patient presented with disease flare (progressive, widespread erythema and pustular eruptions on the legs, forearms, trunk, and abdomen) that was recalcitrant to treatment with acitretin and methylprednisolone. Intravenous infliximab 5 mg/kg was given as a 2-hour infusion. Within 24 hours of treatment, serum analysis revealed a rapid decline in the number of peripheral granulocytes, accompanied by a decline (to within normal limits) in concentration of C-reactive protein. Complete resolution of pustules occurred within 2 days of infusion, leaving a residual scaling of the affected skin. The patient was able to tolerate the withdrawal of methylprednisolone over 3 days. Disease flare occurred 12 days after the first dose of infliximab; a second infliximab infusion (5 mg/kg) was given, provoking a complete remission within a day of the second treatment. Other than a mild, corticosteroid-responsive relapse, the patient remained in complete remission for a minimum of 6 months while receiving a maintenance therapy regimen of acitretin.

Support for synovitis can be found in a randomized, double-blind, placebo-controlled trial (n=20), significant reductions from baseline in MRI-measured synovitis were seen at 14 weeks and 1 year with infliximab plus methotrexate therapy. Disease Modifying Antirheumatic Drug- or oral corticosteroid-I

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rheumatoid arthritis patients with recent symptom onset (less than 12 months) and with metacarpophalangeal joint involvement were randomized to methotrexate 7.5 mg once weekly plus infliximab 3 mg/kg or placebo infusion at 0, 2, 6, and then every 8 weeks. MRI-measured synovitis at week-14 (primary endpoint) and at week-54 (secondary endpoint) from baseline were compared between the infliximab and placebo groups. At week 14, median total synovitis score was significantly lower in the infliximab group (5.5 to 3.4) as compared with the placebo arm (6.2 to 5.9) (p less than 0.05). After 54 weeks, median total synovitis score was significantly lower in the infliximab group (3.8) as compared with the placebo arm (6.6) (p less than 0.05). Adverse effects with infliximab included infusion reaction (n=1), elevated liver function enzyme (n=1), and cutaneous vasculitis (n=1).

Additionally, in a placebo-controlled trial (n=24), infliximab plus methotrexate showed a significant percent reduction in total synovial thickness from baseline at 18 weeks compared with methotrexate alone. Patients with early phase rheumatoid arthritis (less than 2 years mean duration) with a minimum of 2 swollen metacarpophalangeal joints despite methotrexate treatment were randomized to methotrexate (escalating dose) plus infliximab 5 mg/kg or placebo infusion at 0, 2, 6, and then every 8 weeks. After 18 weeks, high frequency ultrasonography showed a 50% median reduction in synovial thickness with the infliximab group as opposed to a 1.2% median increase in synovial thickness in the placebo group (p=0.014).

Support for Takayasu's arteritis can be found in the Recommendations of the Italian Society of Rheumatology for the treatment of the primary large-vessel vasculitis with biological agents. According to the recommendations, tumor necrosis factor alpha-inhibiting agents are recommended in patients with persistently active Takayasu Arteritis for 6 months or more, or with 2 or more flares or relapses despite glucocorticoid therapy; this is in addition to 1 or more immunosuppressive agent unless not tolerated or contraindicated.

In a 12-month, multicenter, retrospective study (n=15), infliximab therapy resulted in a response rate of 73% to 87% and significantly reduced corticosteroid use in patients with refractory Takayasu arteritis. Patients (median age, 41 years; range, 17 to 61 years) with Takayasu arteritis (median time from disease onset to infliximab therapy, 37 months; range, 6 to 365 months) that was refractory to other nonsteroid immunosuppressive agents or steroids received infliximab 3 mg/kg (n=5) or 5 mg/kg (n=10) IV every 4 to 8 weeks (median, every 6 weeks). Patients were concomitantly receiving steroids (n=14; median prednisone dose, 20 mg; range, 5 to 35 mg/day) and other nonsteroid immunosuppressive therapies (methotrexate, n=7; azathioprine, n=4) with doses that were not modified in the 3 months before infliximab initiation. After a median follow-up of 43 months (range, 4 to 71 months), overall response (including partial or good response; determined by physician in change and by the presence of clinical and biological activity) was achieved in 87% (n=13/15), 77% (n=10/13), and 73% (n=8/11), respectively, at 3, 6, and 12 months. The percentage of patients with disease activity was significantly decreased from 73% at baseline to 20% at 3 months (p less than 0.005), 31% at 6 months (p less than 0.05), and 27% at 12 months (p less than 0.05). The median prednisone dose also significantly decreased from 20 mg (range, 5 to 35 mg) at baseline to 15 mg (range, 5 to 20 mg) at 3 months (p less than 0.005), 7.5 mg (range, 5 to 18 mg) at 6 months (p less than 0.05), and 6 mg (range, 2.5 to 30 mg) at 12 months (p less than 0.05). Additionally, C-reactive protein was decreased from a median of 30 mg/L (range, 4 to 70 mg/L) at baseline to 5 mg/L (range, 0 to 57 mg/L) at 3 months (p less than 0.05) and 6 mg/L (range, 0 to 50 mg/L) at 6 months (p less

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than 0.05); however, there was no significant difference from baseline at month 12. Adverse events included acute infusion reactions in 2 patients that led to discontinuation of infliximab therapy.

In a single center retrospective study (n=25), partial or complete remission occurred in 18 of 21 patients who received infliximab therapy for the treatment of refractory Takayasu arteritis. Patients (mean age, 35 years; range, 15 to 64 years; median disease duration, 116 months; range, 39 to 344 months; concurrent nonsteroid immunosuppressive therapy, n=18) with Takayasu arteritis who could not achieve stable remission with the use of low-dose prednisone (less than 10 mg/day) and who had received at least 1 additional immunosuppressive agent received infliximab (n=21) or etanercept (n=9). Five patients who were initially treated with etanercept were switched to infliximab. After a median follow-up of 28 months (range, 2 to 84 months), infliximab therapy (median dose 5 mg/kg IV (range, 4 to 10 mg/kg) every 6 weeks (range, 4 to 8 weeks)) resulted in remission (primary endpoint) in 18 patients (complete remission, n=12; partial remission, n=6). In patients who received either etanercept or infliximab, the median prednisone dose was 19 mg (range, 5 to 50 mg) prior to therapy compared with 0 mg (range, 0 to 30 mg) after therapy; 60% of patients were able to completely discontinue prednisone. Relapse occurred in 12 of the 18 patients who initially achieved remission with infliximab; 6 patients required an increase in the dose of infliximab, and steroid therapy was added in 4 patients. Adverse events that required discontinuation of infliximab therapy included abnormal liver function tests (n=1), primary histoplasmosis in a patient who traveled to an endemic region (n=1), and breast cancer (n=1).

Support for uveitis can be found in the Expert Panel Recommendation for the use of anti-tumor necrosis factor biologic agents in patients with ocular inflammatory disorders. A committee of the American Uveitis Society performed a systematic review of literature to generate guidelines for use of these agents in ocular inflammatory conditions. A systematic review of published studies was performed. Recommendations were generated using the Grading of Recommendations Assessment, Development, and Evaluation group criteria. Based on these studies, the expert panel recommends infliximab and adalimumab can be considered as potential second-line immunomodulatory agents for the treatment of severe ocular inflammatory conditions including posterior uveitis, panuveitis, severe uveitis associated with seronegative spondyloarthropathy, and scleritis in patients requiring immunomodulation in patients who have failed or who are not candidates for antimetabolite or calcineurin inhibitor immunomodulation. Infliximab and adalimumab can be considered in these patients in preference to etanercept, which seems to be associated with lower rates of treatment success.

Support for acute graft versus host disease (GVHD) can be found in the National Comprehensive Cancer Network's guideline for hematopoietic cell transplantation. The NCCN Guideline for hematopoietic cell transplantation supports the use of infliximab in conjunction with systemic corticosteroids following no response (steroid-refractory disease) to first-line therapy options. Therapy for steroid-refractory acute GVHD is often used in conjunction with the original immunosuppressive agent.

Support for using infliximab to manage immune checkpoint inhibitor-related toxicity can be found in the National Comprehensive Cancer Network's guideline for the management of immunotherapy-related toxicities. The NCCN Guideline for the management of immunotherapy-related toxicities supports the use of adding infliximab for the management of the following immunotherapy- related conditions:

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- Myocarditis, as a further intervention if no improvement within 24 to 48 hours of starting high-dose methylprednisolone
- Mild (G1) diarrhea or colitis if persistent or progressive symptoms and positive lactoferrin/calprotectin
- Moderate (G2) and strongly consider for severe (G3-4) diarrhea or colitis
- Moderate or severe inflammatory arthritis as additional disease modifying antirheumatic drug (DMARD) therapy if no improvement after holding immunotherapy and treating with oral corticosteroids or if unable to taper corticosteroids, or no response to conventional synthetic DMARDs
- G1-4 uveitis that is refractory to high-dose systemic corticosteroids
- Moderate (G2) pneumonitis if no improvement after 48-72 hours of corticosteroids or severe (G3-4) pneumonitis if no improvement after 48 hours of methylprednisolone
- Stage 3 acute kidney injury/elevated serum creatinine if toxicity remains more than stage 2 after four to six weeks of corticosteroids or if creatinine increases during steroid taper (once off steroids)

Support for the use of infliximab to treat multisystem inflammatory syndrome in children (MIS-C) can be found in the COVID-19 Treatment Guidelines Panel: Coronavirus disease 2019 (COVID-19) treatment guidelines. National Institutes of Health (NIH). In pediatric patients hospitalized with multisystem inflammatory syndrome in children (MIS-C) associated with SARS-CoV-2 (COVID19), initial first line treatment is IVIG with low to moderate dose glucocorticoids, such as methylprednisolone (recommendation rating, A; evidence rating, based on nonrandomized trials or observation cohort studies) and should be used in most patients (level of consensus, moderate). The risks versus benefits of treating immunocompromised MIS-C patients with immunomodulatory agents should be evaluated on an individual basis.

If MIS-C is refractory (no improvement within 24 hours of IV immune globulin and steroid initiation), initiate intensification immunomodulatory therapy (recommendation rating, A; evidence rating, expert opinion) (level of consensus, moderate) with higher-dose glucocorticoids, anakinra, or infliximab (recommendation rating, B; evidence rating, based on nonrandomized trials or observation cohort studies) (level of consensus, moderate). Infliximab should not be used in patients with MIS-C and features of macrophage activation syndrome (MAS) (level of consensus, moderate).

Severe illness may warrant dual therapy with higher-dose glucocorticoids plus anakinra (recommendation rating, B; evidence rating, expert opinion), or higher-dose glucocorticoids plus infliximab (recommendation rating, B; evidence rating, expert opinion). Anakinra and infliximab should not be given in combination.

Infliximab can be considered in patients with contraindications to long-term use of glucocorticoids (level of consensus, moderate). The effects of infliximab likely persist for weeks, which may provide a steroid-sparing effect.

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