

Infliximab (Remicade[®], Inflectra[®], Renflexis[®], Avsola[™])



When requesting an infliximab product (Remicade, Inflectra, Renflexis, Avsola) for non-oncology indications, the individual requiring treatment must be diagnosed with an FDA-approved indication or approved off-label compendial use and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indications

Infliximab is indicated for the treatment of:

- Crohn's disease
- Ulcerative colitis
- Rheumatoid arthritis
- Psoriatic arthritis
- Plaque psoriasis
- Ankylosing spondylitis

Approved Off-label Compendial Uses

- Behcet's disease
- Graft-versus-host disease
- Hidradenitis suppurativa
- Colitis, indeterminate
- Juvenile idiopathic arthritis
- Pyoderma gangrenosum
- Sarcoidosis
- Scleritis or sterile corneal ulceration
- Still's disease
- Spondyloarthritis, other subtypes
- Uveitis
- Immunotherapy-related toxicities associated with checkpoint inhibitor therapy

Coverage Guidelines

The individual must meet the following criteria for select indications:

Rheumatoid arthritis (RA)

Initial authorization:

- Had a 3-month trial of at least one biologic agent; OR
- Had a 3-month trial of at least one conventional synthetic disease-modifying antirheumatic drug (DMARD); AND
- Infliximab is prescribed by or in consultation with a rheumatologist.

Ankylosing spondylitis (AS)

Initial authorization:

- Infliximab is prescribed by or in consultation with a rheumatologist.

Psoriatic arthritis (PsA)

Initial authorization:

- Infliximab is prescribed by or in consultation with a rheumatologist or a dermatologist.

Crohn's disease (CD)

Initial authorization:

- Meets one of the following conditions:
 - Has enterocutaneous (perianal or abdominal) or rectovaginal fistulas;
 - Had ileocolonic resection;
 - Has tried one other agent (e.g., certolizumab, adalimumab, vedolizumab, ustekinumab, methotrexate, 6-mercaptopurine,);
 - Has tried or is currently taking corticosteroids; OR
 - Has a contraindication to corticosteroid therapy; AND
- Is 6 years of age or older; AND
- Infliximab is prescribed by or in consultation with a gastroenterologist.

Ulcerative colitis (UC)

Initial authorization:

- Has tried or had an intolerance to at least one systemic agent (e.g., adalimumab, vedolizumab, 6-mercaptopurine, azathioprine); OR
- Has pouchitis and has tried at least one of the following therapies: antibiotic, probiotic, corticosteroid enema, or Rowasa (mesalamine) enema; AND
- Is 6 years of age or older; AND
- Infliximab is prescribed by or in consultation with a gastroenterologist.

Plaque psoriasis (PP)

Initial authorization:

- Meets one of the following conditions:
 - Had a 3-month trial of or intolerance to at least one biologic agent;
 - Had a 3-month trial of or intolerance to at least one traditional systemic agent (e.g., methotrexate, cyclosporine, acitretin); OR
 - Has a contraindication to methotrexate therapy; AND
- Is 18 years of age or older; AND
- Infliximab is prescribed by or in consultation with a dermatologist.

Behcet's disease

Initial authorization:

- Meets one of the following conditions:
 - Has ophthalmic manifestations of Behcet's disease;
 - Had a trial of at least one tumor necrosis factor (TNF) inhibitor (e.g., adalimumab, etanercept); OR
 - Has tried at least one conventional therapy (e.g., systemic corticosteroids, immunosuppressant, interferon alfa); AND
- Infliximab is prescribed by or in consultation with one of the following specialists: rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist.

Graft-versus-host disease (GVHD)*Initial authorization:*

- Has tried at least one conventional systemic treatment for GVHD (e.g., cyclosporine, thalidomide, tacrolimus, mycophenolate mofetil, corticosteroids); AND
- Infliximab is prescribed by or in consultation with an oncologist, hematologist, or a physician affiliated with a transplant center.

Hidradenitis suppurativa*Initial authorization:*

- Has tried one other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin); AND
- Infliximab is prescribed by or in consultation with a dermatologist.

Colitis, indeterminate*Initial authorization:*

- Has tried all of the following agents: one systemic corticosteroid, mesalamine, and azathioprine/6-mercaptopurine; AND
- Is 6 years of age or older; AND
- Infliximab is prescribed by or in consultation with a gastroenterologist.

Juvenile idiopathic arthritis*Initial authorization:*

- Has tried one other agent for this condition (e.g., adalimumab, etanercept, methotrexate, non-steroidal anti-inflammatory drug [NSAID]); OR
- Has aggressive disease; AND
- Infliximab is prescribed by or in consultation with a rheumatologist.

Pyoderma gangrenosum*Initial authorization:*

- Has tried one systemic corticosteroid; OR
- Had a 2-month trial of or intolerance to at least one immunosuppressive agent (e.g., mycophenolate, cyclosporine); AND
- Infliximab is prescribed by or in consultation with a dermatologist.

Sarcoidosis*Initial authorization:*

- Has tried at least one systemic corticosteroid; AND
- Has tried at least one immunosuppressive agent (e.g., methotrexate, azathioprine, cyclosporine); AND
- Infliximab is prescribed by or in consultation with a pulmonologist, ophthalmologist, or dermatologist.

Scleritis or sterile corneal ulceration*Initial authorization:*

- Has tried one other therapy for this condition (e.g., corticosteroid, methotrexate, cyclosporine, NSAID); AND
- Infliximab is prescribed by or in consultation with an ophthalmologist.

Still's disease

Initial authorization:

- Has tried one corticosteroid; AND
- Had a 2-month trial of or intolerance to at least one conventional synthetic DMARD (e.g., methotrexate); AND
- Infliximab is prescribed by or in consultation with a rheumatologist.

Spondyloarthritis (SpA), other subtypes

Initial authorization:

- Has axial spondyloarthritis and has objective signs of inflammation defined as one of the following:
 - C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory; OR
 - Sacroiliitis reported on MRI; OR
- Has arthritis primarily in the knees, ankles, elbows, wrist, hands, and/or feet and has tried at least one conventional synthetic DMARD (e.g., methotrexate, leflunomide); AND
- Infliximab is prescribed by or in consultation with a rheumatologist.

Uveitis

Initial authorization:

- Had a trial of either an etanercept product (e.g., Enbrel) or an adalimumab product (e.g., Humira); OR
- Has tried periocular/intraocular/systemic corticosteroids or immunosuppressive agent; AND
- Infliximab is prescribed by or in consultation with an ophthalmologist.

Immunotherapy-related toxicities associated with checkpoint inhibitor therapy

Initial authorization:

- Developed an immunotherapy-related toxicity involving the gastrointestinal system, inflammatory arthritis, or ocular toxicity; AND
- Developed the immune-related toxicity while receiving a checkpoint inhibitor (e.g., Keytruda, Opdivo, Yervoy, Tecentriq, Bavancio, Imfinzi); AND
- Has tried a systemic corticosteroid (e.g., methylprednisolone, prednisone); AND
- Infliximab is prescribed by or in consultation with an oncologist, gastroenterologist, rheumatologist, or ophthalmologist.

For reauthorization (for all indications):

The individual must have responded to infliximab therapy for reauthorization.

Approval duration (initial):

- GVHD: 1 month
- Colitis, indeterminate or pyoderma gangrenosum: 4 months
- All others: 3 months

Approval duration (renewal):

- GVHD: 3 months
- All others: 12 months

Dosing Recommendations

Infliximab is administered by intravenous infusion over a period of not less than 2 hours.

Crohn's disease, ulcerative colitis, indeterminate colitis, plaque psoriasis, psoriatic arthritis, hidradenitis suppurativa, and pyoderma gangrenosum

Approve initial therapy up to 5 mg/kg at 0, 2 and 6 weeks, then no more frequently than once every 8 weeks. Patients currently receiving infliximab may receive approval up to a maximum dose of 10 mg/kg administered no more frequently than once every 4 weeks.

Graft-versus-host disease

Approve up to a maximum dose of 10 mg/kg administered no more frequently than once weekly.

Rheumatoid arthritis

Approve initial therapy up to 3 mg/kg at 0, 2 and 6 weeks, then no more frequently than once every 8 weeks. Patients currently receiving infliximab may receive approval up to a maximum dose of 10 mg/kg administered no more frequently than once every 4 weeks.

Ankylosing spondylitis, Behcet's disease, sarcoidosis, and spondyloarthritis

Approve initial therapy up to 5 mg/kg at 0, 2 and 6 weeks, then no more frequently than once every 6 weeks. Patients currently receiving infliximab may receive approval up to a maximum dose of 10 mg/kg administered no more frequently than once every 4 weeks.

Uveitis and immunotherapy-related toxicities associated with checkpoint inhibitor therapy

Approve initial therapy up to 10 mg/kg at 0, 2 and 6 weeks, then no more frequently than once every 4 weeks. Patients currently receiving infliximab may receive approval up to a maximum dose of 10 mg/kg administered no more frequently than once every 4 weeks.

Juvenile idiopathic arthritis and Still's disease

Approve initial therapy up to 6 mg/kg at 0, 2 and 6 weeks, then no more frequently than once every 8 weeks. Patients currently receiving infliximab may receive approval up to a maximum dose of 10 mg/kg administered no more frequently than once every 4 weeks.

Scleritis or sterile corneal ulceration

Approve initial therapy up to 10 mg/kg at baseline followed by up to three additional doses (for example, given 2, 6 and 8 weeks after the initial infusion). Patients currently receiving infliximab may receive approval up to a maximum dose of 10 mg/kg administered no more frequently than once every 4 weeks.

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