

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

When requesting an infliximab product (Remicade[®], Inflectra[®], Renflexi[®]) 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 reducing signs and symptoms and inducing and maintaining clinical remission in adults patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. Infliximab is indicated for reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing Crohn's disease.

Infliximab is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy.

Infliximab is indicated for 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 who have had an inadequate response to conventional therapy.

Infliximab is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.

Infliximab is indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patient with moderately to severely active rheumatoid arthritis.

Infliximab is indicated for reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patient with psoriatic arthritis.

Infliximab is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.

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

Approved Non-Oncology Off-Label Compensial 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

Coverage Guidelines

Rheumatoid arthritis (RA)

Initial authorization:

- Had a 3-month trial of at least one biologic agent OR 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:

- Has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR
- Had ileocolonic resection OR
- Has tried one other agent (e.g., certolizumab, adalimumab, vedolizumab, ustekinumab, methotrexate, 6-mercaptopurine,) OR
- Has tried or is currently taking corticosteroids OR
- Is contraindicated to corticosteroids therapy AND
- Infliximab is prescribed by or in consultation with a gastroenterologist

Ulcerative colitis (UC)

Initial authorization:

- Has tried at least one systemic agent including a biologic unless had an intolerance (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
- Infliximab is prescribed by or in consultation with a gastroenterologist

Plaque psoriasis (PP)

Initial authorization:

- Had a 3-month trial of or intolerance to at least one biologic agent OR
- Had a 3-month trial of or intolerance to at least one traditional systemic agent (e.g., methotrexate, cyclosporine, acitretin) OR
- Is contraindicated 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:

- Has ophthalmic manifestations of Behcet's disease OR
- 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:

- Is currently receiving at least one of the following medications in combination with infliximab: corticosteroids, anti-thymocyte globulin, cyclosporine, thalidomide, tacrolimus, mycophenolate mofetil OR
- Has tried at least one conventional treatment for GVHD (e.g., cyclosporine, thalidomide, tacrolimus) 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 including a biologic (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 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 (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 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 had a trial of either etanercept (Enbrel) or adalimumab (Humira) OR
- Has tried periocular/intraocular/systemic corticosteroids or immunosuppressive agent AND
- Infliximab is prescribed by or in consultation with an ophthalmologist

Re-authorization (for all indications):

- Has responded to infliximab therapy

Approval duration (initial):

- GVHD: 1 month
- Colitis, indeterminate/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:

The recommended dose is 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Some adult patients who initially respond to treatment may benefit from increasing the dose to 10 mg/kg if they later lose their response

Ulcerative colitis:

The recommended dose is 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks.

Rheumatoid arthritis:

The recommended dose is 3 mg/kg at 0, 2 and 6 weeks, then every 8 weeks. Some patients may benefit from increasing the dose up to 10 mg/kg or treating as often as every 4 weeks.

Ankylosing spondylitis:

The recommended dose is 5 mg/kg at 0, 2 and 6 weeks, then every 6 weeks.

Psoriatic arthritis and plaque psoriasis:

The recommended dose is 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks.

References

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