

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



When requesting infliximab (Remicade[®], Inflectra[®], Renflexi[®]), the individual requiring treatment must be diagnosed with an FDA-approved indication 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 Off-Label Compendial Use

Granulomatosis with polyangiitis

Coverage Guidelines

For all approved indications, the individual must meet **all** of the following criteria for approval:

- Does not have an active infection including localized infection
- Infliximab will not be used in combination with another biologic agent (e.g., IL-inhibitor, rituximab, TNF-inhibitor, T-cell costimulation modulator)
- Infliximab dose will not exceed 5 mg/kg in an individual with New York Heart Association (NYHA) functional class III or IV congestive heart failure (CHF)
- For an initial authorization request, an individual has been screened for latent tuberculosis (TB). For positive latent TB, an individual has started/completed or will be treated for TB prior to starting infliximab
- For a re-authorization request, an individual's condition has improved or stabilized with infliximab therapy

For rheumatoid arthritis initial authorization:

- Had an inadequate response or intolerance to prior biologic agent or targeted synthetic DMARD (i.e., tofacitinib) OR
- Has moderately to severely active disease AND
- Had an inadequate response to at least 3 months of methotrexate therapy unless contraindicated or intolerant to methotrexate OR
- Had an inadequate response to at least 3 months of leflunomide or sulfasalazine unless contraindicated or intolerant to leflunomide or sulfasalazine

For psoriatic arthritis initial authorization:

- Had an inadequate response or intolerance to prior biologic agent or targeted synthetic DMARD (i.e., tofacitinib) OR
- Had an inadequate response to methotrexate unless contraindicated or intolerant to methotrexate

For ankylosing spondylitis initial authorization:

- Had an inadequate response or intolerance to prior biologic agent OR
- Had an inadequate response or intolerance to at least 2 different non-steroidal anti-inflammatory drugs (NSAIDs) unless contraindicated

For plaque psoriasis initial authorization:

- Has an inadequate response or intolerance to prior biologic therapy OR
- Has affected body surface area (BSA) greater than 5% OR has psoriasis in vulnerable areas such as the face, genitals, hands and feet, or scalp and adversely affects quality of life AND

- Has tried and failed phototherapy or traditional systemic therapy (e.g., methotrexate, cyclosporine, acitretin) unless has one of the following conditions:
 - o Contraindicated to traditional systemic therapy
 - o Intolerant to traditional systemic therapy
 - o Phototherapy not accessible/available

For Crohn's disease initial authorization:

- Had an inadequate response or intolerance to prior biologic agent OR
- Has moderately to severely active disease AND
- Had an inadequate response to intolerance to at least one conventional therapy (e.g., 6-mercaptopruine, azathioprine, cyclosporine, methotrexate) OR
- Had an inadequate response, intolerance, or dependency to corticosteroid OR
- Has fistulizing Crohn's disease OR
- Has severe/fulminant disease with Crohn's Disease Activity Index (CDAI) score greater than 450

For ulcerative colitis initial authorization:

- Had an inadequate response or intolerance to prior biologic agent OR
- Has moderately to severely active disease AND
- Had an inadequate response to intolerance to at least one conventional therapy (e.g., 6-mercaptopruine, azathioprine, cyclosporine, methotrexate) OR
- Has inadequate response or intolerance to corticosteroid OR
- Has contraindication to both corticosteroid and immunosuppressive agent(s)

For granulomatosis with polyangiitis:

- Disease is refractory AND
- Infliximab will be used in combination with corticosteroids

Approval duration (initial and renewal): 12 months

Dosing Recommendations

Remicade 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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