Infliximab Products Clinical Resource

Agents

- Zymfentra (Infliximab-dyyb)
- Avsola (infliximab-axxq)
- Inflectra (infliximab-dyyb)
- Remicade (infliximab)
- Renflexis (infliximab-abda)
- Infliximab unbranded

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OVERVIEW

Select infliximab biosimilar products do not require prior authorization; however, the use of BRAND Remicade, Zymfentra, Renflexis, and infliximab unbranded will require an evaluation of medical necessity.

Infliximab is a recombinant chimeric monoclonal antibody that binds to and inhibits the biologic activity of tumor necrosis factor-alpha (TNF-α).

Infliximab is indicated for the following uses:

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

GUIDELINES

The use of infliximab is supported in various clinical practice guidelines which vary based on indication for use. For all indications, prescribing should be in consultation with a specialist in area of expertise (e.g. Rheumatology, gastroenterology, dermatology, ect).

FDA APPROVED INDICATIONS

Ankylosing spondylitis.

Dosing: 5 mg/kg at 0, 2, and 6 weeks, followed by 5 mg/kg every 6 weeks thereafter.

Consider if the patient meets the following:

- Patient has tried prior therapy such as NSAIDs (non-steroidal anti-inflammatory medications)

Moderate to Severe Crohn's disease induction and maintenance of remission. Use in combination with an immunomodulator is generally preferred.

Induction dosing: 5 mg/kg at 0, 2, and 6 weeks.

Maintenance Dosing: 5 mg/kg every 8 weeks starting at week 14; dose may be increased to 10 mg/kg every 8 weeks in patients who respond but then lose their response. If no response by week 14, consider discontinuing therapy.

Consider if the patient meets the following:

A) High-risk individual with characteristics such as age <30 at diagnosis, extensive anatomic involvement, perianal and/or several rectal disease, deep ulcers, prior surgical resection and/or penetrating behavior, fistulizing disease, extraintestinal manifestations of inflammation

OR

B) Low risk individual that has failed prior conventional therapy (e.g. azathioprine, balsalazide, steroids, mesalamine, mercaptopurine, methotrexate, or sulfasalazine), is steroid dependent, or is not a candidate for conventional therapy based on location of disease.

Moderate to Severe Plaque Psoriasis.

Dosing: 5 mg/kg at 0, 2, and 6 weeks, followed by 5 mg/kg every 8 weeks thereafter. **Note**: Some patients may require 10 mg/kg and/or dosing as frequently as every 4 weeks during the maintenance phase

Consider if the patient meets the following:

A) Documentation of moderate to severe disease as demonstrated by significant functional disability, body surface area (BSA) involvement ≥ 3%, debilitating palmer/plantar psoriasis or involvement in other vulnerable areas that are difficult to treat (e.g. nails, scalp, genitals, or intertriginous areas
B) Trial of prior topical therapy

Moderate to severe Psoriatic Arthritis with or without methotrexate.

Dosing: 5mg/kg at 0, 2, and 6 weeks, followed by 5 mg/kg every 8 weeks thereafter.

Consider if the patient meets the following:

Presenting with at least ONE of the following: actively inflamed joints, axial disease, active skin/nail/scalp psoriasis involvement, dactylitis, or enthesitis

Rheumatoid arthritis in combination with methotrexate.

Induction Dosing: 3 mg/kg at 0, 2, and 6 weeks

Maintenance dosing: 3 mg/kg every 8 weeks thereafter; for patients who have incomplete responses, consider adjusting the dose up to 10 mg/kg every 8 weeks or treating as often as every 4 weeks, although consider the risk of serious infections is increased at higher doses or with more frequent administration.

Consider if the patient meets the following:

Prior trial of non-biologic therapy such as methotrexate, leflunomide, hydroxychloroquine, sulfasalazine

Ulcerative Colitis.

Induction dosing: 5 mg/kg at 0, 2, and 6 weeks.

Maintenance dosing: 5mg/kg every 8 weeks starting at week 14. Doses up to 10 mg/kg were studied in clinical trials with similar efficacy observed with both doses; combination therapy with a thiopurine (eg, azathioprine, mercaptopurine) has shown increased efficacy.

Consider if the patient meets the following:

A) High-risk individual with characteristics such as extensive colitis, deep ulcers, age <40 at diagnosis, high C-reactive protein and erythrocyte sedimentation rate labs, steroid-requiring disease, history of hospitalization due to UC, history of *C difficile*/CMV infection
B) Prior use of corticosteroids

OTHER USES WITH SUPPORTIVE EVIDENCE

1. Adult-onset Still's disease.
2. Bechet's Syndrome.
3. Colitis, immune checkpoint inhibitor induced. For grade 2, 3, or 4 colitis with either high-risk endoscopic features on initial endoscopy examination or with persistent symptoms despite 3 days of corticosteroid therapy, consider adding infliximab to the treatment regimen.
   Dosing: 5 mg/kg at week 0, a second dose may be repeated 2 weeks later, and a third dose may be considered at 6 weeks if needed; use in combination with a corticosteroid.
4. COVID-19, hospitalized. For use in patients who are hospitalized who require oxygen (eg, high-flow oxygen, noninvasive ventilation) and those with lower but increasing oxygen requirements and evidence of systemic inflammation who cannot use preferred agents.
   Dosing: 5 mg/kg as a single dose as part of an appropriate combination regimen
5. Graft vs. Host Disease.
6. Hidradenitis suppurativa, severe, refractory.
7. Juvenile idiopathic arthritis, severe, refractory.
8. Kawasaki disease.
9. Multisystem inflammatory syndrome in children, refractory associated with SARS-CoV2.
10. Polyarteritis nodosa.
11. Pustular psoriasis
    Dosing: 5 mg/kg at week 0, 2, and 6, followed by 5 mg/kg every 8 weeks for up to 46 weeks.
12. Rejection of intestine transplant, acute refractory.
13. Rheumatoid arthritis, monotherapy
    Dosing: 1 to 10mg/kg
14. SAPHO syndrome, severe refractory.

15. Sarcoidosis, refractory. For use as adjunctive therapy in patients in whom treatment goals have not been met despite glucocorticoids and other immunosuppressant therapy (eg, methotrexate); use in combination with glucocorticoids and/or methotrexate may prevent infliximab autoantibody formation.
    Initial dosing: 3 to 5 mg/kg at weeks 0, 2, and 6.
    Maintenance dosing: 3 to 5 mg/kg every 4 to 8 weeks thereafter. The optimal frequency and duration of therapy are not known and must be individualized based on response; after a stable response is achieved (eg, after ≥6 to 12 months of therapy), may consider gradually prolonging the dosing interval (eg, up to every 12 weeks) or reducing the dose and discontinue if response remains adequate after although approaches vary.
16. Scleritis, noninfectious, refractory.
17. Synovitis.
18. Takayasu's disease.
19. Uveitis.
    Dosing: 3 to 5 mg/kg IV at 0, 2, 6 weeks, and every 4 to 8 weeks thereafter.

CONDITIONS LACKING SUPPORTIVE EVIDENCE

Coverage of infliximab products is not recommended in the following situations, as their lacks conclusive evidence to support use:

1. Congestive heart failure
2. Celiac disease
3. Necrobiosis lipoidica diabeticorum
4. Polymyalgia rheumatica
5. Pyoderma gangrenosum
6. Subcorneal pustular dermatosis
7. Temporal arteritis

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