



Guidelines for Medication Coverage:

Infliximab (Remicade)

Background:

Tumor Necrosis Factor (TNF) alpha is one of two proinflammatory cytokines that appear to play a dominant role in the inflammatory response in Crohn's disease, ulcerative colitis, rheumatoid arthritis, and other autoimmune causes of joint destruction facilitating cytotoxicity, fibroblast proliferation, and prostaglandin synthesis. Infliximab is an anti-TNF alpha antibody that acts by binding and neutralizing TNF alpha.

Administration:

Infliximab is administered by intravenous infusion. The approved dosage regimens are dependent on the condition treated and are listed below.

The most widely reported side effect of infliximab is an acute infusion reaction consisting of fever, chills, urticaria, pruritis and rare cardiopulmonary symptoms. Other reported adverse reactions include a higher risk of upper respiratory and urinary tract infections, headache, arthralgia/myalgia, and development of antinuclear antibodies. Cases of Lupus-like syndrome have been reported.

Tuberculosis (frequently disseminated or extrapulmonary at clinical presentation) has been observed in patients receiving Remicade. Prior to initiation of Remicade therapy, all patients should be evaluated for latent tuberculosis infection with a tuberculin skin test.

A. Moderate to severe active Crohn's Disease, including Crohn's Disease in pediatric patients:

- 1) Claims submitted with a diagnosis of Crohn's disease do not require prior-authorization.

B. Fistulizing Crohn's Disease:

- 1) Claims submitted with a diagnosis of Fistulizing Crohn's disease do not require prior-authorization.

C. Ulcerative colitis:

- 1) Remicade must be prescribed a by gastroenterologist or the enrollee must be under the care of a gastroenterologist.
- 2) Criteria for authorization:

Active ulcerative colitis despite therapy with conventional agents such as oral corticosteroids, 6-mercaptopurine, and aminosalicylic acid products, or demonstrated intolerance to conventional products.

3) Duration of authorization

Induction: 3 infusion visits over 2 months.

Maintenance: If clinical response is noted after 8 weeks, a maintenance regimen of 5 mg/kg every 8 weeks may be authorized for 6 months. Subsequent authorizations for up to 12 months may be added with documentation of continued response.

D. Active rheumatoid arthritis, including juvenile rheumatoid arthritis:

1) Remicade must be prescribed by a rheumatologist or the enrollee must be under the care of a rheumatologist.

2) Criteria for authorization:

The patient demonstrates disease progression despite optimized therapy with the following agents:

- NSAID's/COX Inhibitors.
- Three month trial of or treatment failure of at least one DMARD
 - Hydroxychloroquine (Plaquenil)
 - Methotrexate
 - Azathioprine (Imuran)
 - Oral or Injectable Gold salts (6 month trial may be required)
 - Sulfasalazine
 - D-penicillamine
 - Leflunomide (Arava),

AND

- Unless a diagnosis of uveitis associated with rheumatoid arthritis exists, documented failure to adequate trial of etanercept (Enbrel) or adalimumab (Humira)

3) Duration of authorization:

Initial therapy: 3 infusion visits over 8 weeks

Maintenance therapy: If clinical response following the initial 3 infusions is documented, ongoing therapy every 8 weeks may be authorized for six months. Subsequent authorizations for up to 12 months may be added with documentation of continued response.

4) Concurrent therapy with methotrexate is recommended to enhance the outcome of infliximab.

E. Ankylosing spondylitis or spondyloarthropathy associated with Reiter's syndrome, psoriatic arthritis, or idiopathic disease (undifferentiated spondyloarthropathy):

1) Remicade must be prescribed by a rheumatologist or the enrollee must be under the care of a rheumatologist.

2) Criteria for authorization:

Clinical diagnosis and documentation of active ankylosing spondylitis or other spondyloarthropathy with inadequate response to conventional therapy (NSAID or COX 2 inhibitor therapy, corticosteroids).

3) Duration of authorization:

Induction: 3 infusion visits over 2 months.

Maintenance: Because information varies, up to 3 infusions over 6 months may be authorized. Subsequent authorizations for up to 12 months may be added with documentation of continued response.

F. Psoriatic arthritis:

1) Remicade must be prescribed by a rheumatologist or the member must be under the care of a rheumatologist.

2) Criteria for Authorization:

Diagnosis of psoriatic arthritis with active psoriatic arthritis with at least three swollen and three tender joints with psoriasis AND disease progression despite optimized therapy with the following agents:

- NSAID's/COX Inhibitors.
- Three month trials or treatment failure of at least one DMARD.
Hydroxychloroquine (Plaquenil)
Methotrexate
Azathioprine
D-Penicillamine
Sulfasalazine
Leflunomide (Arava)
Oral or Injectable gold salts (6 month trial may be required)

AND

- Documented failure to adequate trial of etanercept (Enbrel) or adalimumab (Humira)

3) Duration if Authorization:

Initial Therapy: 3 infusion visits over 2 months

Maintenance Therapy: If clinical response is documented following the initial 3 infusions, therapy every 8 weeks may be authorized for up to 6 months. Subsequent authorizations for up to 12 months may be added with documentation of continued response.

4) Remicade may be administered with or without concurrent methotrexate therapy.

G. Plaque psoriasis:

- 1) Remicade must be prescribed by a dermatologist or rheumatologist or the enrollee must be under the care of and therapy directed by a rheumatologist or dermatologist.
- 2) Criteria for authorization:
 - Diagnosis of moderate-to-severe plaque psoriasis with greater than 10% body surface involvement or severe involvement of the palms, soles, head, neck, or genitalia;
 - AND
 - The patient is a candidate for systemic therapy or phototherapy;
 - AND
 - The plaque psoriasis has been present for greater than 12 months;
 - AND
 - There is documentation of previous unsuccessful treatment or contraindication to treatment with etanercept (Enbrel[®]), efalizumab (Raptiva[®]), or alefacept (Amevive[®]).
- 3) Duration of authorization:

Initial therapy: Three infusions over six weeks

Maintenance Therapy: If clinical response is documented following the initial 3 infusions, therapy every 8 weeks may be authorized for up to 6 months. Subsequent authorizations for up to 12 months may be added with documentation of continued response.

Special Instructions:

- Remicade must be administered by intravenous infusion. Providers must have the capability to monitor patients for potential infusion-related adverse reactions.
- Remicade is covered under the SummaCare medical benefit for Commercial and self-funded enrollees. Coverage for Medicare enrollees is subject to Medicare Part B vs. Part D determination.

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Medical Director

References:

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