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Developed By: Medical Criteria Committee	

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Description:

Remicade® (Infliximab) is a monoclonal antibody administered by intravenous infusion. It binds to and inhibits tumor necrosis factor alpha (TNF-alpha), a cytokine that plays an important role in a variety of inflammatory processes. During inflammation, cells in the immune system release TNF-alpha. Elevated concentrations of TNF-alpha have been found in the joints of patients with rheumatoid arthritis and in the stools of patients with Crohn's disease. It is believed that Remicade reduces inflammation by binding to and neutralizing TNF-alpha before it reaches its cell bound receptor.

Criteria:

Remicade will be covered to plan limitations when the following criteria are met for each indicated diagnosis:

1. Crohn's disease:
 - a. Moderate to severely active disease with an inadequate response to conventional therapy or refractory to conventional therapy, including mesalamine or sulfasalazine or immunomodulators (methotrexate, 6-mercaptopurine, azathioprine) or for patients who are steroid dependent.

OR

 - b. Fistulizing Crohn's disease with active draining enterocutaneous fistulae and failure of conventional therapy
2. Rheumatoid Arthritis:
 - a. Moderate to severe RA that has had an inadequate response to a 3 month trial of methotrexate (unless intolerant), and has failed another DMARD; and
 - b. Patient is under the treatment of a rheumatologist.
3. Ulcerative Colitis:

Moderate to severe ulcerative colitis refractory to **one** or more of the following standard therapies:

 - a. Corticosteroids (e.g., prednisone, methylprednisolone); or
 - b. 5-aminosalicylic acid agents (e.g., sulfasalazine, mesalamine, balsalazide); or
 - c. Immunosuppressants (e.g., azathioprine, cyclosporine, 6-mercaptopurine)
4. Ankylosing Spondylitis:

Active ankylosing spondylitis with evidence of inflammatory disease that has had an inadequate response or intolerance to two NSAIDs (used for 3 months or more) **and** to any one of the disease-modifying anti-rheumatic drugs (DMARDs) (sulfasalazine, methotrexate, corticosteroids, azathioprine, cyclosporine, cyclophosphamide).
5. Psoriatic Arthritis:

Active, severe psoriatic arthritis with documentation of **all** of the following:

 - a. At least 3 swollen joints; and
 - b. At least 3 tender joints; and
 - c. Inadequate response or intolerance to any one of the non-steroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, diclofenac, naproxen, indomethacin, sulindac, celecoxib, meloxicam, valdecoxib) (unless contraindicated) ; and
 - d. Inadequate response to two of the following DMARDs (methotrexate, cyclosporine, sulfasalazine, mercaptopurine, gold compounds, or corticosteroids)

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6. Psoriasis:

Moderate to severe chronic plaque psoriasis with documentation of **all** of the following:

- a. Patient is 18 years of age or older; and
- b. Ten percent or more body surface area is affected by plaque psoriasis; and
- c. Twelve months duration of psoriasis, and
- d. Patient has tried topical therapies, such as corticosteroids, Tarorac, Dovonex, anthralin, salicylic acid, or tars and has failed to adequately respond; and
- e. Patient has failed or treatment is contraindicated with methotrexate, cyclosporine or acitretin; and
- f. Patient has failed to adequately respond to or is intolerant to a 3 or more month trial of one of the following phototherapies:
 - i. Psoralens (methoxsalen, trioxsalen) with UVA light (PUVA); or
 - ii. UVB with coal tar or dithranol

(Patients who have received > 1,000 joules cumulative dosage of PUVA, who are treated with anti-TNF agents have a 6-fold increased risk of non-melanoma skin cancer; it is recommended that these patients receive annual skin checks from a dermatologist.

Not Covered:

*Remicade used for any condition other than described above is considered experimental or investigational.

*ODS considers measurements of serum levels of Infliximab and antibodies to Infliximab (human anti-chimeric antibodies (HACA)) experimental and investigational because their clinical values for individuals receiving Infliximab therapy have not been established.

Benefit Guidelines:

For patients who meet the above criteria, Infliximab may be authorized at 0, 2, and 6 weeks, then every 8 weeks thereafter. Initial approval is for six months; additional therapy may be approved if documentation demonstrates improvement of the disease process. Infliximab may be administered more frequently than every 8 weeks for patients that have had an inadequate response to less frequent dosing.

Information to be Submitted with Pre-Authorization Request:

1. Consultations and evaluations related to the diagnosis.
2. Pre-Infliximab clinical assessment. The preferred assessment is the American College of Rheumatology (ACR) set of parameters. Equivalent assessments or clinical documentation may be accepted in lieu of the ACR tool.
3. For subsequent authorization: clinical documentation of symptom improvement and current treatment plan.

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