Subject: Injectable Infliximab (“Remicade”)*

Effective Date: March 27, 2007

Department: Utilization Management

Policy: Injectable Infliximab is reimbursable under plans administered by QualCare, Inc., when eligible member benefit is in place and medical necessity exists.

Objective: To assure consistent reimbursement for injectable Infliximab as a medically necessary service and to delineate criteria that provides evidence of that Medical necessity.

Procedure: Requests for coverage of injectable Infliximab must be applied against criteria below.

Definition: Infliximab is an injectable, intravenously infused, chimeric monoclonal antibody that binds to tumor necrosis factor alpha (TNF-a). It is believed to be critical to the human body’s reaction to inflammation. TNF-a is a cytokine that is a key biologic response mediator found to be increased in chronic and inflammatory disorders such as Crohn’s disease, rheumatoid arthritis (RA), and other autoimmune diseases.

Criteria: QualCare members are eligible for Infliximab coverage per the indications listed below:

1) Crohn’s Disease: Presence of active Crohn’s disease with manifestation of one or more of the following signs/symptoms:
   - Abdominal pain.
   - Bleeding.
   - Diarrhea.
• Extraintestinal manifestations: arthritis or spondylitis.
• Internal fistulæ.
• Intestinal obstruction caused by active disease and not fixed fibrotic structure.
• Megacolon in conjunction with other standard treatment for this condition (hospitalization, bowel decompression, IV fluids, etc.)
• Perianal disease.
• Weight loss.

AND

Crohn’s disease has remained active despite treatment with = 1 of the following:

• Corticosteroids.
• 6-mercaptopurine/azathioprine

2) Ankylosing Spondylitis and Other Spondyloarthropathies (*reactive arthritis, post-infectious arthritis*): Evidence of inflammatory disease with an inadequate response to = 3 nonsteroidal anti-inflammatory drugs (NSAIDs)


4) Psoriasis: Member is = 18 years of age or has moderate to severe chronic plaque psoriasis and meets the following criteria:

Presence of plaque psoriasis for > 1 year

AND

= 10% of body surface area affected by plaque psoriasis.

AND

Member has failed to adequately respond to, or is intolerant to, a 3- to 4-month trial of one of the following phototherapies (unless contraindicated):
- Psoralens (methoxsalen, trioxsalen) with UVA light (PUVA).
- UVB with coal tar or dithranol.

5) Psoriatic Arthritis: Presence of active psoriatic arthritis, as indicated by both of the following:

- At least three swollen joints.
- At least three tender joints.

Inadequate response to any one of the NSAIDs (e.g., ibuprofen, diclofenac, naproxen, indomethacin, sulindac, celecoxib, meloxicam), unless contraindicated, and to any one of the following disease modifying anti-rheumatic drugs: methotrexate, cyclosporine, sulfasalazine, mercaptopurine, gold compounds or corticosteroids.

6) Rheumatoid Arthritis: Presence of RA with inadequate response or intolerance to methotrexate monotherapy.

7) Ulcerative Colitis: Members experiencing a moderately severe attack or the persistence of a severe or moderately severe attack refractive to = 1 standard treatment (i.e., aminosalicylates, steroids or immunosuppressants [e.g., azathioprine or 6-mercaptopurine]).

References:


*Consistent with Summary Plan Description (SPD). When there is discordance between this policy and the SPD, the provisions of the SPD prevail.