Subject: Remicade

Objective:
I. To ensure that Health Share/Tuality Health Alliance (THA) has a process by which the appropriate utilization of Remicade (Infliximab) for members whose diagnosis has indications for specific drug therapy is evaluated objectively.

Policy:
I. Infliximab is in a class of medications called tumor necrosis factor-alpha (TNF-alpha) inhibitors. It works by altering immune response and blocking the action of TNF-alpha, a substance in the body that causes inflammation and causes pain, swelling, and damage) that are believed to be affected by increased levels of TNF in the tissueTuality Health Alliance (THA) will review for medical necessity for Remicade usage in the following diseases:
   A. Rheumatoid Arthritis (RA)- a condition in which the body attacks its own joints, causing pain, swelling, and loss of function.
   B. Juvenile RA (JRA) a pediatric age condition in which the body attacks its own joints, causing pain, swelling, and loss of function.
   C. Ankylosing Spondylitis- a condition in which the body attacks the joints of the spine and other areas causing pain and joint damage
   D. Psoriatic arthritis- a condition in which the body attacks its own joints, causing pain, swelling, and loss of function along with a silvery, red scale on the skin surface
   E. Crohn’s disease- a condition in which the body attacks the lining of the digestive tract, causing pain, diarrhea, weight loss, and fever) that has not improved when treated with other medications
   F. Ulcerative colitis- condition that causes swelling and sores in the lining of the large intestine
   G. Psoriasis- a skin disease in which red, scaly patches form on some areas of the body
   H. Only the above conditions are currently supported by evidence based reports and approved as being established diseases that respond to Infliximab. All other uses are currently considered investigational.
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II. Rheumatoid Arthritis, Juvenile Rheumatoid Arthritis, Ankylosing Spondylitis and Psoriatic Arthritis
   A. Remicade is indicated for the reduction in signs and symptoms of rheumatoid arthritis in patients who have had an inadequate response or adverse reaction to Disease modifying antirheumatic drug (DMARD’s) including methotrexate. Remicade may be is used in combination with methotrexate.

   B. Criteria:
      1. Diagnosed and treated by a Rheumatologist.
      2. Clinical diagnosis compatible with the above indications.
      3. Active rheumatoid arthritis (ICD-9 714.0) as defined by the American College of Rheumatology. A definitive diagnosis is obtained when FOUR of the following are met:
         a. At least six weeks of morning stiffness in and around the joints, lasting at least one hour before maximal improvement.
         b. At least six weeks of arthritis affecting at least three joint areas simultaneously (i.e. metacarpophalangeal, proximal interphalangeal joints).
         c. At least six weeks of soft tissue swelling or fluid accumulation in at least three joints.
         d. At least six weeks of simultaneous involvement of the same or symmetrical groups of joints defined in item D below on both sides of the body (bilateral involvement but without symmetry is also acceptable).
         e. Subcutaneous rheumatoid nodules over bony prominence, or extensor surfaces, or in juxta-articular regions.
         f. Elevated serum rheumatoid factor levels.
         g. Radiographic changes typical of rheumatoid arthritis on posteroanterior hand and wrists radiographs, which must include erosions or unequivocal bony decalcification localized in, or most marked, adjacent to the involved joints (osteoarthritic changes alone do not qualify).
      4. Documented failure or intolerance of one or more disease-modifying anti-rheumatoid drug therapy such as:
         a. Methotrexate after at least an 6-12 week treatment
         b. Aarava (leflunomide)
         c. Plaquenil (hydroxychloroquine)
         d. Azulfidine (sulfasalazine)
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III. Ulcerative Colitis or severe fistulizing Crohn’s Disease
   A. Remicade is indicated for the reduction in the number of draining enterocutaneous fistulae in patients with fistulizing Crohn’s disease. It is also indicated for the acute treatment of Crohn’s disease or ulcerative colitis when the patient is experiencing a disease flare and when conventional treatment has not been effective or there is a documented intolerance with three agents used to treat Crohn’s disease.

   B. Criteria
      1. Diagnosed and treated by a Gastroenterologist
      2. Clinical diagnosis compatible with the above indications.
      3. Failed to respond after a minimum of 8 weeks of therapy or has shown intolerance to at least one agent from one of the following classes of drugs:
         a. Corticosteroids (systemic prednisone 40-60 mg daily for 7-14 days).
         b. Aminosalicylates (sulfasalazine, olsalazine, or mesalamine)
         c. Immunomodulatory medications (azathioprine, mercaptopurine, cyclosporine, or methotrexate)
      4. Unable to be tapered off an adequate dose of systemic corticosteroids without worsening symptoms of the disease.

   C. Maintenance treatment of Crohn’s disease or Ulcerative Colitis
      1. Patient has previously responded to Infliximab
      2. Records provided showing failure, intolerance or contraindication of azathioprine or mercaptopurine.

IV. Chronic Psoriasis-
   A. Criteria- Diagnosed and treated by a Dermatologist or Rheumatologist
   B. Must meet ALL of the following:
      1. Medical records document chronic psoriatic plaque formation on > 10% body surface area per FDA approval.
      2. Records provided showing failure, intolerance or contraindication of topical corticosteroids or other appropriate topical agents (calcipotriene, tazarotene, coal tar).
      3. Records provided showing failure, intolerance or contraindication of phototherapy.
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4. Records provided showing failure, intolerance or contraindication of at least one other systemic immunomodulatory treatment for psoriasis (cyclosporin, methotrexate, acitretin).

5. Documentation of impaired bodily function due to psoriasis.

V. Authorization Period and Limitations

A. Initial Authorization- A maximum of six infusions in a six month period may be authorized when the criteria is met.

B. Continued Authorization

For continued authorization after the initial six-month period, documentation a (including chart notes) indicating that there is disease stability or improvement must be provided. The maximum number of infusions that may be authorized per year are dependent on the diagnosis being treated as follows:

1. For rheumatoid arthritis, a maximum of twelve infusions in a one-year period based on a recommended infusion interval of up to every 4 to 8 weeks.

2. For Ankylosing Spondylitis, a maximum of nine infusions in a one year period based on a recommended infusion interval of every 6 weeks.

3. For psoriatic arthritis, a maximum of seven infusions in a one year period based on a recommended infusion interval of every 7 weeks.

4. For Crohn’s disease, a maximum of seven infusions in a one year period based on a recommended infusion interval of every 7 weeks.

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THA Plan Director

THA Medical Director