

Subject: Remicade

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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 tissue. Tuality 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 (See Attachment A for ICD 10 codes) 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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- e. Gold compounds including Ridaura (auranofin) and Solganol (aurothioglucose)
- f. Imuran (azathioprine)

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 in fusions 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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Attachment A
(Rheumatoid Arthritis ICD 10 Codes)

M0540	M3302	M05471	M05572	M05779	M0589	M06072	M06272	M06372	M06872
G737	M3312	M05472	M05579	M0579	M059	M06079	M06279	M06379	M06879
M05411	M3322	M05479	M0559	M0580	M0600	M0608	M0628	M0638	M0688
M05412	M3392	M0549	M0570	M05811	M06011	M0609	M0629	M0639	M0689
M05419	M3482	M0550	M05711	M05812	M06012	M0620	M0630	M0680	M069
M05421	M3503	M05511	M05712	M05819	M06019	M06211	M06311	M06811	M0550
M05422	M05411	M05512	M05719	M05821	M06021	M06212	M06312	M06812	G63
M05429	M05412	M05519	M05721	M05822	M06022	M06219	M06319	M06819	M05511
M05431	M05419	M05521	M05722	M05829	M06029	M06221	M06321	M06821	M05512
M05432	M05421	M05522	M05729	M05831	M06031	M06222	M06322	M06822	M05519
M05439	M05422	M05529	M05731	M05832	M06032	M06229	M06329	M06829	M05521
M05441	M05429	M05531	M05732	M05839	M06039	M06231	M06331	M06831	M05522
M05442	M05431	M05532	M05739	M05841	M06041	M06232	M06332	M06832	M05529
M05449	M05432	M05539	M05741	M05842	M06042	M06239	M06339	M06839	M05531
M05451	M05439	M05541	M05742	M05849	M06049	M06241	M06341	M06841	M05532
M05452	M05441	M05542	M05749	M05851	M06051	M06242	M06342	M06842	M05539
M05459	M05442	M05549	M05751	M05852	M06052	M06249	M06349	M06849	M05541
M05461	M05449	M05551	M05752	M05859	M06059	M06251	M06351	M06851	M05542
M05462	M05451	M05552	M05759	M05861	M06061	M06252	M06352	M06852	M05549
M05469	M05452	M05559	M05761	M05862	M06062	M06259	M06359	M06859	M05551
M05471	M05459	M05561	M05762	M05869	M06069	M06261	M06361	M06861	M05552
M05472	M05461	M05562	M05769	M05871	M06071	M06262	M06362	M06862	M05559
M05479	M05462	M05569	M05771	M05872	M0589	M06269	M06369	M06869	M05561
M0549	M05469	M05571	M05772	M05879	M059	M06271	M06371	M06871	M05562
M05569	M05571	M05572	M05579	M0559					

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