Remicade® (infliximab)

Effective: June 9, 2015

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OVERVIEW

FDA-APPROVED INDICATIONS

Crohn’s Disease
• Remicade is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in adult and pediatric patients with moderately to severely active Crohn’s disease who have had an inadequate response to conventional therapy.
• Remicade is indicated for reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing Crohn’s disease.

Pediatric Crohn’s Disease
• Remicade is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active Crohn’s disease who have had an inadequate response to conventional therapy.

Ulcerative Colitis
• Remicade is indicated for reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.

Pediatric Ulcerative Colitis
• Remicade is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.

Rheumatoid Arthritis
• Remicade, in combination with methotrexate, is indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis.

Ankylosing Spondylitis
• Remicade is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.

Psoriatic Arthritis
• Remicade is indicated for reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis.

Plaque Psoriasis
• Remicade is indicated for the treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate.

PHARMACY COVERAGE GUIDELINES

Tufts Health Plan – Network Health may authorize coverage of Remicade (infliximab) for members when all the following criteria for a particular regimen are met and limitations do not apply:

For Ankylosing Spondylitis
1. The member has a documented diagnosis of ankylosing spondylitis AND
2. The prescription is written by a rheumatologist AND
3. The member is 18 years of age or older AND
4. The member has tried and failed treatment with, or the member has a contraindication to at least one NSAID AND
5. The member has tried and failed treatment with, or the provider has indicated clinical inappropriateness of Humira and Enbrel OR
6. The member is new to Tufts Health Plan – Network Health and has been stable on Remicade prior to enrollment.

For Crohn’s Disease (except fistulizing Crohn’s Disease) or Ulcerative Colitis / Pediatric Ulcerative Colitis
1. The member has a documented diagnosis of Crohn’s disease or ulcerative colitis by a gastroenterologist AND
2. The member is at least 6 years of age or older AND
3. The member has demonstrated an inadequate response to, or the member has a contraindication to an appropriate trial with two or more of the following agents:
   - Corticosteroids (i.e., prednisone, prednisolone, methylprednisolone)
   - 5-Aminosalicylates (i.e., Sulfasalazine, Azulfidine, Apriso, Delzicol, Pentasa, Rowasa, Dipentum, Colazal)
   - 6-mercaptopurine (6-MP, Purinethol), azathioprine (Imuran), and/or cyclosporine (Gengraf, Neoral, Sandimmune)
   - Methotrexate (MTX) AND
4. The member has tried and failed treatment with, or the provider has indicated clinical inappropriateness of Humira OR
5. The member is new to Tufts Health Plan – Network Health and has been stable on Remicade prior to enrollment.

For fistulizing Crohn’s Disease
1. The member has a documented diagnosis of fistulizing Crohn’s disease by a gastroenterologist AND
2. The member is at least 6 years of age or older AND
3. The member has demonstrated an inadequate response to, or the member has a contraindication to an appropriate trial with two or more of the following agents:
   - Corticosteroids (i.e., prednisone, prednisolone, methylprednisolone)
   - 5-Aminosalicylates (i.e., Sulfasalazine, Azulfidine, Apriso, Delzicol, Pentasa, Rowasa, Dipentum, Colazal)
   - 6-mercaptopurine (6-MP, Purinethol), azathioprine (Imuran), and/or cyclosporine (Gengraf, Neoral, Sandimmune)
   - Methotrexate (MTX) OR
4. The member is new to Tufts Health Plan – Network Health and has been stable on Remicade prior to enrollment.

For Plaque Psoriasis
1. The member has a documented definitive diagnosis from a dermatologist of severe chronic plaque psoriasis AND
2. The member is 18 years of age or older AND
3. The member has tried and failed treatment with, or the member has a contraindication to, at least 2 of the preferred therapies, such as PUVA or UVB phototherapy, acitretin, cyclosporine or methotrexate AND
4. The member has tried and failed treatment with, or the provider has indicated clinical inappropriateness of Humira and Enbrel OR
5. The member is new to Tufts Health Plan – Network Health and has been stable on Remicade prior to enrollment.

For Psoriatic Arthritis
1. The member has a documented diagnosis of psoriatic arthritis AND
2. The prescription is written by a rheumatologist AND
3. The member is 18 years of age or older AND
4. The member tried and failed treatment with, or does the patient have a contraindication to methotrexate and one other DMARD’s (Disease Modifying Anti-rheumatic Drugs), such as azathioprine, gold therapy, hydroxychloroquine, penicillamine, sulfasalazine, cyclosporine or leflunomide AND
5. The member has tried and failed treatment with, or the provider has indicated clinical inappropriateness of Humira and Enbrel OR
6. The member is new to Tufts Health Plan – Network Health and has been stable on Remicade prior to enrollment.

For Rheumatoid Arthritis
1. The member has a documented diagnosis of rheumatoid arthritis AND
2. The prescription is written by a rheumatologist AND
3. The member is 18 years of age or older AND
4. The member is currently taking methotrexate or has a contraindication to methotrexate and one other DMARD’s (Disease Modifying Anti-rheumatic Drugs), such as azathioprine, gold therapy, hydroxychloroquine, penicillamine, sulfasalazine, cyclosporine or leflunomide AND
5. The member has tried and failed treatment with, or the provider has indicated clinical inappropriateness of Humira and Enbrel OR
6. The member is new to Tufts Health Plan – Network Health and has been stable on Remicade prior to enrollment.
REFERENCES


APPROVAL HISTORY

- March 11, 2004: Reviewed by the Pharmacy and Therapeutics Committee
- October 7, 2014: Reviewed by the Pharmacy and Therapeutics Committee
- June 9, 2015: Added pharmacy coverage guidelines for fistulizing Crohn’s Disease.

BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION

Pharmacy Medication Request Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). Pharmacy Medication Request Guidelines are developed for selected therapeutic classes or drugs found to be safe but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medication Request Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medication Request Guidelines apply to all insured offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the applicable Preferred Drug List (formulary) in the pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to the Tufts Health Unify Prior Authorization Medical Necessity Guidelines.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines, when applicable, and adherence to plan policies and procedures and claims editing logic.