MEDICAL PAYMENT and PRIOR-AUTHORIZATION POLICY	
Policy Name:	**Clinical Pharmacy Prior Authorization: Remicade (infliximab)**
Policy Number:	
Approved By:	Medical Management
Provider Notice Date:	September 1, 2015
Original Effective Date:	November 1, 2015
Annual Approval Date:	
Revision Date:	
Products:	Pennsylvania Medicaid and Pennsylvania Medicare Advantage
Application:	All participating providers
Page Number(s):	1 of 4

Disclaimer

Gateway Health℠'s (Gateway) medical payment and prior-authorization policy is intended to serve only as a general reference resource regarding payment and coverage for the services described. This policy does not constitute medical advice and is not intended to govern and/or otherwise influence medical decisions.

POLICY STATEMENT:

To describe the criteria in place to determine if a request for Remicade (infliximab) is medically necessary and appropriate.

DEFINITIONS:

Medical necessity: A service or benefit is medically necessary if it is compensable under the MA program and if it meets any one of the following standards:

- The service or benefit will, or is reasonably expected to prevent the onset of an illness, condition, or disability
- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental, or developmental effects of an illness, condition, injury, or disability.
- The service or benefit will assist the member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the member and those functional capacities that are appropriate for members of the same age.

Prior Authorization: A medication benefit that is approved once established criteria are met. The criteria are medication specific and may be based on FDA and manufacturer guidelines, medical literature, safety, appropriate use, and benefit design. A prior authorization may be established to address appropriate utilization due to patient safety concerns, limited indications, and potential for misuse/abuse.

PROCEDURES

All requests for Remicade (infliximab) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below. These criteria were developed by Gateway Health℠ (Gateway) Pharmacy and Therapeutics Subcommittee for approval by the Quality Improvement/Utilization Management Committee.

Remicade (infliximab) Prior Authorization Criteria

- For all indications, the patient, if less than 21 years old, must be up to date with immunizations in accordance with The Early and Period Screening Diagnostic, and Treatment (EPSDT) guidelines.
- Prior to treatment, the patient must have been evaluated and where warranted, screened for the presence of latent TB infection and for the presence of Hepatitis B (antibody and/or surface antigen). The date and results of these tests must be provided.
- The prescribing physician must be a Rheumatologist, Gastroenterologist, or Dermatologist.
- Coverage for Remicade (infliximab) is considered for the treatment of patients with:
    - Moderate to severe active Rheumatoid or Psoriatic Arthritis within recommended dosing guidelines.
        - If the patient has tried methotrexate for 3 months with an inadequate response
        - If the patient has a contraindication to methotrexate
        - If the patient has tried/failed a DMARD other than methotrexate (eg: sulfasalazine, Plaquenil)
    - Moderate to severe Crohn's Disease, including pediatric Crohn's Disease (down to age 6), within recommended dosing guidelines.
        - If the patient has tried/failed two or more of the following medications:
            - Aminosalicylates, 5-ASAs (*i.e.,* Sulfasalazine, Pentasa®, Asacol®, Colazal®).
            - Antibiotics (*i.e.,* Metronidazole, Ciprofloxacin).
            - Steroids (*i.e.,* prednisone, Entocort®).
            - Immunomodulators (*i.e.,* Azothioprine®, 6-Mercaptopurine, Methrotrexate®)
    - Fistulizing Crohn's Disease within recommended dosing guidelines.
    - Ulcerative Colitis, including pediatric ulcerative colitis (down to age 6) within recommended dosing guidelines.
    - Ankylosing Spondylitis within recommended dosing guidelines.
        - The patient must have active disease for at least four weeks as defined by both a sustained Bath AS Disease Activity Index (BASDAI) $\geq$ 4cm and a Physician Global Assessment of 2 or greater on the Likert Scale.
        - If the patient has peripheral arthritis and has had an inadequate response or intolerability to at least two NSAIDs for at least a 3 month trial and had a lack of response or intolerability to one or more DMARDs (*i.e.*, sulfasalazine, methotrexate) for at least a 3 month trial
        - If the patient has axial or enthesitis and has had an inadequate response or intolerability to at least two NSAIDs for at least a 3 month trial.

- Coverage is provided for a diagnosis of moderate to severe plaque psoriasis defined as 10% or more body surface area (BSA) affected or BSA involvement of < 10% in critical areas (palms, soles, or face) that interferes with daily activities
    - Patients must have therapeutic failure of a three or more month trial of psoralens with UVA light (PUVA) or UVB light with coal tar or dithranol.
    - Must have tried/failed or have a contraindication to systemic treatments including:
        - Immunomodulators *(i.e*. Methotrexate, Cyclosporine, - Enbrel, Humira)
        - Retinoids (*i.e.* Soriatane)
- Requests for the continued use of Remicade will be approved if the patient has documented significant improvement with prior courses of treatment and the requested regimen remains within the recommended dosing parameters as listed in the dosing table. Renewal requests falling outside recommend dosing for the patient's indication will be forwarded to the Medical Director for review
- When criteria are not met for dispensing through specialty pharmacy, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

Dosing Table

- *Requests for dosages outside the recommended parameters below will be forwarded to the medical director for review.*

INDICATION	DOSING & BENEFIT APPROVAL
Crohn's Disease, adult	Initial: 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks thereafter Initial authorization: 60 days Renewal: may approve x 6 months *Dose escalation to 10 mg /kg is permissible for ADULTS ONLY in the event of loss of response to above dosing. However, interval is to remain at q 8 weeks
Crohn's Disease, pediatric	5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks thereafter. Initial authorization: 60 days Renewal: may approve x 6 months
Ulcerative Colitis, adult or pediatric	Initial: 5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks thereafter Initial authorization: 60 days Renewal: may approve x 6 months
Rheumatoid Arthritis	3 mg/kg at 0, 2, and 6 weeks, then every 8 weeks thereafter. Dose escalation per manufacturer insert to 10 mg/kg or increasing interval to q 4 weeks. Initial: approve x 60 days Renewal: approve x 6 months
Ankylosing Spondylitis	5 mg/kg at 0, 2, and 6 weeks, then every 6 weeks thereafter Initial, approve x 60 days Renewal, approve x 6 months
Psoriatic Arthritis Plaque Psoriasis	5 mg/kg at 0, 2, and 6 weeks, then every 8 weeks thereafter Initial – approve x 60 days Renewal- approve x 6 months