SUBJECT: Infliximab (Remicade®)
INDEX TITLE: Clinical Pharmacy Services
ORIGINAL DATE: 11/15/01

This policy applies to the following lines of business: (Check those that apply.)

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I. POLICY

It is the policy of UPMC Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drug, Infliximab (Remicade) is subject to the prior authorization process.

II. DEFINITIONS

N/A

III. PURPOSE

The purpose of this policy is to define the prior authorization process for Infliximab (Remicade).

IV. SCOPE

This policy applies to the Pharmacy Services Department.
V. PROCEDURE

Criteria for Infliximab

Remicade® is indicated for the reduction of signs and symptoms and inhibiting progression of structural damage of moderate-to-severe active rheumatoid arthritis, psoriatic arthritis, moderate-to-severe active Crohn’s disease in adults and pediatrics, active ankylosing spondylitis, ulcerative colitis, and plaque psoriasis.

Initial Authorization Criteria:

- Member must have a negative Tuberculin PPD (purified protein derivative) test and the following criteria must be met:

1) In the treatment of rheumatoid arthritis, clinical studies have demonstrated comparable efficacy to the gold standard, methotrexate therapy. Therefore, the following criteria must be met for approval of these agents:
   - Member must have a confirming diagnosis by a rheumatologist
   - Member must be at least 18 years of age.
   - Member must have a diagnosis of moderate to severe rheumatoid arthritis
   - If appropriate, member must have:
     - Tried methotrexate for at least 3-6 months with an inadequate response as reported by the prescribing provider; or,
     - Experienced significant side effects/toxicity of methotrexate; or,
     - Documented medical contraindications, by the prescribing provider, to methotrexate therapy.
   - Member must not currently be using another Tumor Necrosis Factor (TNF) blocking agent, such as Enbrel® or Humira® or other biologic agent such as Kineret®, Orencia®, or Rituxan®.
   - Dose: 3mg/kg IV at week 0, 2 and 6, then every 6 to 8 weeks thereafter. Typically given in combination with methotrexate. For incomplete response the dose may be increased to 10mg/kg or treatment may be as often as every 4 weeks.

2) Remicade® is indicated for reducing signs and symptoms and inducing and maintaining clinical remission in adult and pediatric members with moderate to severe active Crohn’s disease who have had an inadequate response to conventional therapy. Therefore, all of the following criteria must be met for approval of these agents:
   - Member must have a confirming diagnosis by a gastroenterologist
   - Member must be at least 6 years of age.
   - Member must have tried conventional therapy including corticosteroids, or 5-ASA (i.e., Sulfasalazine, Mesalamine)
   - Member must currently not be using a TNF-blocking agent, such as Enbrel® or Humira® or other biologic agent, such as Kineret®
   - Dosage:
     - Crohn's disease induction: 5mg/kg IV at week 0, 2 and 6 weeks
Crohn's disease maintenance: 5mg/kg IV Q 8 wks

- For adult members who respond but then lose their response, a dose increase to 10mg/kg should be considered.
- Response must be shown by week 14 in order to continue Remicade® therapy

### 3) Remicade®

- Remicade® is indicated for reducing the signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in members with psoriatic arthritis. All of the following criteria must be met:
  - Member must have a confirming diagnosis by a rheumatologist or a dermatologist
  - Member must be at least 18 years of age.
  - Member must have active psoriatic arthritis, defined as affecting at least five joints.
  - If appropriate, member must have:
    - Tried methotrexate for at least 3-6 months with an inadequate response as reported by the prescribing provider; or,
    - Experienced significant side effects/toxicity of methotrexate; or,
    - Documented medical contraindications, by the prescribing provider, to methotrexate therapy.

- Members with dominant axial disease – sulfasalazine or methotrexate trial not required
- Member must currently not be using a TNF-blocking agent, such as Enbrel® or Humira® or other biologic agent, such as Kineret
- Dosage: 5 mg/kg IV given at weeks 0, 2, 6, and every 8 weeks thereafter; with or without methotrexate

### 4) Remicade®

- Remicade® is indicated for reducing signs and symptoms in members with active ankylosing spondylitis. All of the following criteria must be met:
  - Member must have a confirming diagnosis by a rheumatologist
  - Member must be at least 18 years of age.
  - Members must have:
    - Tried at least two NSAIDs for at least 3 months at maximum recommended or tolerated dose with an inadequate response, or
    - Experienced intolerability or toxicity of NSAIDs, or
    - Documented medical contraindications, by the prescribing provider, to NSAID therapy
  - Members with peripheral arthritis must have:
    - Tried sulfasalazine or methotrexate for at least 3-6 months with an inadequate response as reported by the prescribing provider, or
    - Experienced significant side effects/toxicity to sulfasalazine or methotrexate, or
    - Documented medical contraindications, by the prescribing provider, to sulfasalazine or methotrexate therapy
  - Members with axial disease – sulfasalazine or methotrexate trial not required
  - Currently not using a TNF blocking agent, such as Enbrel® or other biologic agent, such as Kineret®
- **Induction dosage:** 5 mg/kg IV over 2 hr given at week 0, 2 and 6
- **Maintenance dosage:** 5 mg/kg IV over 2 hr every 6 weeks

5) Remicade® is indicated for reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing and eliminating corticosteroid use in members with moderately to severely active ulcerative colitis who have had an inadequate response to traditional therapy. Therefore, all of the following criteria must be met:

- Member must have a confirming diagnosis of moderate to severe refractory ulcerative colitis by a gastroenterologist
- Member must be at least 18 years of age.
- Member must have tried conventional therapy including corticosteroids, or 5-ASA (i.e., Sulfasalazine, Mesalamine) for at least 3-6 months with inadequate response;
- Member must currently not be using a TNF-blocking agent or other biologic agent, such as Enbrel, Kineret, or Humira
- **Dosage:**
  - Ulcerative colitis induction: 5 mg/kg IV at 0, 2, and 6 weeks
  - Ulcerative colitis maintenance: 5 mg/kg IV every 8 weeks

6) Remicade® is indicated for the treatment of adult members 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. Remicade® should only be administered to members who will be closely monitored and have regular follow-up visits with a physician. All of the following criteria must be met:

- Members must have a diagnosis of severe plaque psoriasis (>10% BSA involvement), who are candidates for systemic therapy (members with plaque psoriasis of the palms, soles, head and neck, or genitalia are not required to have a minimum body surface area involvement)
- Member must have a confirming diagnosis by a dermatologist
- Member must be at least 18 years of age.
- Member must have tried topical treatments (calcipotriene [Dovonex], corticosteroids, or tazarotene [Tazorac]) OR have tried phototherapy (UVB) or photochemotherapy (psoralens with UVA [PUVA])
- Member must have:
  - Tried methotrexate, cyclosporine, or soriatane for at least 3-6 months with an inadequate response as reported by the prescribing provider; or,
  - Experienced significant side effects/toxicity of methotrexate, cyclosporine, and soriatane; or,
  - Documented medical contraindications, by the prescribing provider, to methotrexate, cyclosporine, and soriatane therapy.
- Member must currently not be using a TNF-blocking agent, such as Enbrel® or Humira® or other biologic agent, such as Kineret®, Amevive®, or Raptiva®
- **Dosage:** 5 mg/kg IV given at weeks 0, 2, 6, and every 8 weeks thereafter; dose to be increased to up to 7 mg/kg IV with a frequency of up to every 6 wks if the patient initially responds but then relapses
The medication will be approved based upon the above criteria for an initial period of one year.

Reauthorization Criteria:
All prior authorization renewals will be reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at one-year intervals based upon chart documentation from the provider that the member’s disease has improved based upon the prescriber’s assessment while on therapy.

Limitations:
If a member does not meet the above approval criteria, the prior authorization request will be sent for review by a UPMC Health Plan Medical Director.

Bibliography