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, Etanercept (Enbrel®) 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 Etanercept (Enbrel®).

IV. SCOPE

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

Criteria for Etanercept

Enbrel® is indicated for the following:

- Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in members with moderately to severely active rheumatoid arthritis (RA)
- Reducing signs and symptoms of moderately to severely active polyarticular-course juvenile rheumatoid arthritis in members who have had an inadequate response to one or more disease-modifying drugs (DMARDs)
- Reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in members with psoriatic arthritis
- Reducing signs and symptoms of active ankylosing spondylitis
- Treatment of adult members with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy

Based upon diagnosis, the member must have a confirming diagnosis by a rheumatologist or a dermatologist, and the following criteria must be met:

1) Member must have a negative Tuberculin PPD (purified protein derivative) test.

2) For the diagnosis of rheumatoid arthritis, and juvenile rheumatoid arthritis:
   - Member must have a diagnosis of moderate to severe rheumatoid arthritis or juvenile rheumatoid arthritis
   - For 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,
   - Member has experienced significant side effects/toxicity of methotrexate.
   - Approvals will be granted only upon documented medical contraindications, by the prescribing provider, to methotrexate therapy.
   - Currently not using a Tumor Necrosis Factor (TNF) blocking agent or other biologic agent such as Kineret or Humira
   - Limited to 8-25mg vials or 4-50mg vials per month

3) For the diagnosis of psoriatic arthritis:
   - Member must have a diagnosis of moderate to severe psoriatic arthritis, defined as affecting at least five joints
   - Member must have tried methotrexate for at least 3-6 months with an inadequate response as reported by the prescribing provider; or,
   - Member has experienced significant side effects/toxicity of methotrexate.
   - Approvals will be granted only upon documented medical contraindications, by the prescribing provider, to methotrexate therapy.
   - Currently not using a TNF-blocking agent or other biologic agent such as Kineret or Humira
   - Limited to 8-25mg vials or 4-50mg vials per month
4) For the diagnosis of psoriasis:
   • Members with a diagnosis 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 tried methotrexate for at least 3-6 months with an inadequate response as reported by the prescribing provider; or,
   • Member has experienced significant side effects/toxicity of methotrexate.
   • Approvals will be granted only upon documented medical contraindications, by the prescribing provider, to methotrexate therapy.
   • Currently not using a TNF-blocking agent or other biologic agent such as Kineret or Humira
   • If Enbrel® is approved for the treatment of psoriasis, the following will be approved:
     ➢ a total quantity of 50mg twice a week for 3 months can be approved (16-25mg vials or 8-50mg vials), per the FDA approved manufacturer’s recommendations.
     ➢ Past 3 months, Enbrel® can be approved for a total of 50mg once a week (8-25mg vials or 4-50mg vials per month) for maintenance, per the FDA approved manufacturer’s recommendations.

5) For the diagnosis of ankylosing spondylitis:
   • Chart documentation must be submitted showing that the member has tried and failed intensive conservative treatment measures, including when indicated, a trial with a DMARD, such as methotrexate or sulfasalazine, for at least 3-6 months with an inadequate response as reported by the prescribing provider;
   • Member must currently not be using a TNF-blocking agent or other biologic agent such as Kineret or Humira
   • Limited to 8-25mg vials or 4-50mg vials per month
   • The medication will be approved based upon the above criteria for an initial period of one year.
   • 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.
   • If a member does not meet the above approval criteria, the request will be referred to a UPMC Health Plan Medical Director for review.

Bibliography


Proprietary and Confidential Information of UPMC Health Plan


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