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 drugs, Leflunomide (Arava) and Anakinra (Kineret) are 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 Leflunomide and Anakinra.

IV. SCOPE

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

Criteria for Leflunomide and Anakinra

- These agents are indicated for the reduction of signs and symptoms and inhibiting progression of structural damage of moderate-to-severe, active 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:
  - A rheumatologist must be prescribing, and the following criteria must be met:
    - Member must have moderate to severe rheumatoid arthritis
    - 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.
    - Member must currently not be using another Tumor Necrosis Factor (TNF) blocking agent or biologic agent, such as Enbrel®, Kineret®, Humira®, or Arava®
  - **Arava®** dose: option load 100 mg PO qd x 3d; then 10-20 mg PO qd
  - **Kineret®** dose: 100mg SC q24h

- 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


