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 and Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drug Celecoxib (Celebrex) 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 Celecoxib (Celebrex).

IV. SCOPE

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

- Celebrex (celecoxib) is a COX-2 (cyclooxygenase-2) selective inhibitor indicated for the treatment of osteoarthritis, rheumatoid arthritis, the management of acute pain, the treatment of primary dysmenorrhea, ankylosing spondylitis, and adenomatous colorectal polyps in familial adenomatous polyposis, and juvenile rheumatoid arthritis (JRA) in patients two years of age and older.

- In April 2005, the FDA added a black box warning to Nonsteroidal Anti-inflammatory Drugs (NSAIDs) describing possible cardiovascular and gastrointestinal risks associated with its use.

**Criteria:**
- The criteria for automatic coverage of Celebrex are as follows:
  - Member must be at least 65 years of age, or
  - The member must have a documented pharmacy claim history of the following:
    - Anticoagulant (coumadin/warfarin)
    - 2 prescription strength NSAIDs

- For members who do not meet the automatic coverage criteria, a Medical Necessity review will be completed, and the following criteria must be met:
  - Member must have a diagnosis of osteoarthritis, rheumatoid arthritis, or an acceptable diagnosis based on other indications as determined by UPMC Health Plan.
  - Member must meet one of these requirements to be considered for coverage of Celebrex:
    - History of GI bleed, or
    - Documented ulcer (peptic, duodenal or gastric), or
    - Anticoagulant (coumadin/warfarin) use, or
    - Coagulopathy, active bleed, or bleeding disorder, or
    - Chronic steroid use, or
    - Documented trial and failure of 2 prescription strength NSAIDs

- If the member does have a risk factor listed above, the prescribing physician must verify that the member is aware of possible gastrointestinal and cardiovascular risks associated with the use of Celebrex and the authorization will be granted.

- Celebrex will not be approved if being used for the treatment of peri-operative pain in setting of coronary artery bypass graft (CABG) surgery.

- Celebrex 100mg and 200mg has quantity limits of 60 capsules per 30 days to allow for the recommended maximum daily dose. Exception will
be made for a diagnosis of familial multiple polyposis syndrome, which is dosed 400 mg twice a daily.

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