COX-2 INHIBITORS UTILIZATION MANAGEMENT CRITERIA

<table>
<thead>
<tr>
<th>DRUG CLASS:</th>
<th>COX-2 Inhibitors</th>
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<tr>
<td>DRUG NAME:</td>
<td>Celebrex (celecoxib) 50 mg, 100 mg, 200 mg, 400 mg strength capsules</td>
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PRIOR REVIEW CRITERIA:
COX-II Inhibitors are considered medically necessary in the following situations:

1. Treatment of pain and inflammation in patients who meet at least one of the following criteria:
   a. Age 60 years or greater
   b. History of peptic ulcer disease or ulcer/GI bleeding related to non-steroidal anti
      inflammatory drugs (NSAIDs)
   c. Current regimen includes anticoagulant, prescription antiplatelets, corticosteroid
      or DMARD (disease modifying and anti-rheumatic drug) therapy (e.g.,
      methotrexate)
   d. Previous intolerance or inadequate response to at least two non-COX-2
      unique/different NSAIDs at therapeutic doses
   e. Hereditary or acquired coagulation defect (e.g., hemophilia, Von Willebrand’s
      disease, protein C or S deficiency, thrombocytopenia or chronic renal failure.

2. Treatment of Familial Adenomatous Polyposis (FAP) with celecoxib (Celebrex) as an adjunct
to usual care.

BLACK BOX WARNING:
Cardiovascular Risk:
• Celebrex may cause an increased risk of serious cardiovascular thrombotic events, myocardial
infarction, and stroke, which can be fatal. All NSAIDs may have a similar risk. This risk may
increase with duration of use. Patients with cardiovascular disease or risk factors for
cardiovascular disease may be at great risk.
• Celebrex is contraindicated for the treatment of peri-operative pain in the setting of coronary
artery bypass graft (CABG) surgery.

Gastrointestinal Risk:
• NSAIDs, including Celebrex, cause an increased risk of serious gastrointestinal adverse
events including bleeding, ulceration, and perforation of the stomach or intestines, which can be
fatal. These events can occur at any time during use and without warning symptoms. Elderly
patients are at greater risk for serious gastrointestinal events.

RATIONALE:
• Traditional NSAIDs are considered safe, effective and appropriate for short-term therapy in
patients with low risk of developing gastrointestinal ulcers or bleeding.
• COX-2 Inhibitors are considered investigational for a number of conditions including the
REFERENCES: