

COX-II INHIBITORS UTILIZATION MANAGEMENT CRITERIA

DRUG CLASS: COX-2 Inhibitors

DRUG NAME: Celebrex (celecoxib) [100mg, 200mg, 400mg capsules]

PRIOR APPROVAL 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 antiplatelet, corticosteroid or DMARD (disease-modifying and anti-rheumatic drug) therapy (e.g., methotrexate)
 - d) Previous intolerance 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

Benefit Approval: Approve indefinitely

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 treatment of colon cancer and the prevention/treatment of Alzheimer's disease.

REFERENCES:

Lanza FL. A guideline for the treatment and prevention of NSAID-induced ulcers. Members of the Ad Hoc Committee on Practice Parameters of the American College of Gastroenterology. Am J Gastroenterology 1998 Nov; 93 (11): 2037-46.

Laine L. Approaches to nonsteroidal anti-inflammatory drug use in the high-risk patient. Gastroenterology 2001 Feb; 120 (3): 593-606.

Aalykke C, Lauritsen K. Epidemiology of NSAID-related gastroduodenal mucosal injury. Best Pract Res Clin Gastroenterol 2001 Oct;15 (5): 705-22.

The Medical Letter 2001 Nov; 43 (1118): 99-100.

Celebrex Prescribing Information. Pfizer, July 2005

FDA Alert for Practitioners. <http://www.fda.gov/cder/drug/infopage/celebrex>. 4/7/2005.

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