Commercial/Healthcare Exchange PA Criteria

Effective: September 2010

Prior Authorization: Duexis

Products Affected: Duexis (ibuprofen and famotidine) oral tablet

Medication Description:

NSAIDs exhibit antipyretic, analgesic, and anti-inflammatory activities. The major mechanism of therapeutic effects is believed to result from inhibition of prostaglandin synthesis. NSAIDs inhibit cyclooxygenase (COX), the enzyme that catalyzes the synthesis of cyclic endoperoxides from arachidonic acid to form prostaglandins. In the gastric mucosa, prostaglandins decrease gastric acid synthesis, stimulate the production of glutathione that scavenges superoxides, promote the generation of a protective barrier of mucus and bicarbonate, and promote adequate blood flow to the gastric mucosal cells. Prostaglandin in the kidneys modulates intrarenal plasma flow and electrolyte balance.

Duexis is a combination of the NSAID ibuprofen and the histamine H2-receptor antagonist famotidine, is indicated for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers, which in the clinical trials was defined as a gastric and/or duodenal ulcer, in patients who are taking ibuprofen for those indications. The clinical trials primarily enrolled patients less than 65 years of age without a prior history of gastrointestinal ulcer. Controlled trials do not extend beyond 6 months.

Covered Uses: The relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers.

Exclusion Criteria:

1. History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs
2. In the setting of coronary artery bypass graft (CABG) surgery

Required Medical Information:

1. Diagnosis of rheumatoid arthritis and/or osteoarthritis
2. Previous medications tried/failed
3. Previous medical history

Age Restrictions: 18 years of age and older

Prescriber Restrictions: N/A

Coverage Duration: 12 months

Other Criteria:

A. The patient has a diagnosis of osteoarthritis and/or rheumatoid arthritis; AND
B. The patient has a history or current diagnosis of peptic ulcer (gastric or duodenal), gastrointestinal (GI) bleed, GI obstruction, or GI perforation; AND
C. The patient has had an adequate trial and therapeutic failure of TWO generic NSAIDs defined as:
    a. Failure to control symptoms; OR
    b. Intolerance defined as (but not limited to):
        i. Allergic reaction
        ii. Adverse drug reactions; AND

D. The patient has had an adequate trial and therapeutic failure of TWO generic H2-receptor antagonists defined as:
    a. Failure to control symptoms; OR
    b. Intolerance defined as (but not limited to):
        i. Allergic reaction
        ii. Adverse drug reactions; AND
E. The patient has had an adequate trial and therapeutic failure of an NSAID taken WITH an H2-receptor antagonist**.**

References:

1. Product Information: DUEXIS(R) oral tablets, ibuprofen famotidine oral tablets. Horizon Pharma USA, Inc. (per FDA), Lake Forest, IL, 2016.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	September 2009
2	Update	Added criteria requiring trial of two NSAIDs and two H2 blockers Moved to updated template Updated exclusion criteria to include FDA labeled contraindications CCI Revision Record: 5/14, 9/15, 11/16, 5/17, 2/20	All	2/7/2020