Commercial/Healthcare Exchange PA Criteria

Effective: September 2010

Prior Authorization: Vimovo

Products Affected: Vimovo (naproxen and esomeprazole magnesium) delayed release 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.

VIMOVO is a combination product that contains naproxen and esomeprazole. It is indicated for the relief of signs and symptoms of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers. VIMOVO is not recommended for initial treatment of acute pain because the absorption of naproxen is delayed compared to absorption from other naproxen-containing products. Controlled studies do not extend beyond 6 months.

Covered Uses: The relief of signs and symptoms of ankylosing spondylitis, osteoarthritis, juvenile idiopathic arthritis and rheumatoid arthritis, and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID associated gastric ulcers.

Exclusion Criteria:

A. The treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery
B. Initial treatment of acute pain
C. Known hypersensitivity (e.g., anaphylactic reactions and serious skin reactions) to naproxen, esomeprazole magnesium, substituted benzimidazoles, and omeprazole.
D. History of asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs.
E. Concomitant use with rilpivirine-containing products

Required Medical Information:

1. Diagnosis
2. Previous medications tried/failed
3. Previous medical history

Age Restrictions: 12 years of age and older

Prescriber Restrictions: N/A

Coverage Duration: 12 months

Other Criteria:

A. The patient has a diagnosis of osteoarthritis, juvenile idiopathic arthritis, rheumatoid arthritis and/or ankylosing spondylitis; 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 PPIs defined as:
    a. Failure to control symptoms; OR
    b. Intolerance defined as (but not limited to):
        i. Allergic reaction
        ii. Adverse drug reactions
E. The patient has had an adequate trial and therapeutic failure of an NSAID taken WITH an PPI.

References:

1. Product Information: VIMOVO(R) oral delayed release tablets, naproxen esomeprazole magnesium oral delayed release 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 2010
2	Update	Moved to updated template Added juvenile idiopathic arthritis to match FDA indication Added criteria requiring trial of two NSAIDs and two H2 blockers Updated exclusion criteria CCI Revision Record: 5/14, 9/15, 11/16, 5/17, 2/20	All	2/7/2020