



## NAPROXEN/ESOMEPRAZOLE (VIMOVO) UTILIZATION MANAGEMENT CRITERIA

**DRUG CLASS:** Combination Non-Steroidal Anti-Inflammatory Drug (NSAID) and Proton Pump Inhibitor

**BRAND (generic) NAMES:** Naproxen/esomeprazole magnesium (Vimovo<sup>®</sup>) delayed-release tablets 500/20, 375/20 mg

### FDA-APPROVED INDICATIONS

Vimovo 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.

### COVERAGE AUTHORIZATION CRITERIA for naproxen/esomeprazole magnesium

- 1) Patient must be treated for osteoarthritis, rheumatoid arthritis or ankylosing spondylitis.
- 2) Patient must be 18 years of age or older.
- 3) Patient must 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 NSAIDs;
  - c) Current regimen includes anticoagulant, prescription antiplatelet drug, corticosteroid or DMARD (disease-modifying and anti-rheumatic drug) therapy (e.g., methotrexate);
  - d) Hereditary or acquired coagulation defect (e.g., hemophilia, Von Willebrand's disease, protein C or S deficiency, thrombocytopenia or chronic renal failure).

### BLACK BOX WARNINGS

#### Cardiovascular Risk

NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk. Vimovo is contraindicated for the treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery.

#### Gastrointestinal Risk

NSAIDs, including naproxen, 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. Vimovo is only indicated for treatment of the chronic conditions osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis, AND in patients who are at risk of developing NSAID-associated gastric ulcers.

**DOSAGE AND ADMINISTRATION:**

One tablet twice daily. Use the lowest effective dose.  
Not recommended in moderate/severe renal insufficiency or in severe hepatic insufficiency. Consider dose reduction in mild/moderate hepatic insufficiency.

**REFERENCES:**

Vimovo (naproxen/esomeprazole). Product Information. AstraZeneca, LP. 2010.

Lanza FL, et al. Members of the Practice Parameters Committee of the American College of Gastroenterology. Am J Gastroenterol 2009; 104:728 – 738; doi: 10.1038/ajg.2009.115; published online 24 February 2009.