Clinical Policy: Naproxen and Esomeprazole (Vimovo)

Reference Number: PA.CP.PMN.117
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Revision Log

Description
Naproxen and esomeprazole magnesium (Vimovo®) is a combination of a nonsteroidal anti-inflammatory drug (NSAID) and a proton pump inhibitor (PPI).

FDA Approved Indication(s)
Vimovo is indicated in adult and adolescent patients 12 years of age and older weighing at least 38 kg, requiring naproxen for symptomatic relief of arthritis and esomeprazole magnesium to decrease the risk for developing naproxen-associated gastric ulcers.

The naproxen component of Vimovo is indicated for relief of signs and symptoms of:
- Osteoarthritis, rheumatoid arthritis and ankylosing spondylitis in adults.
- Juvenile idiopathic arthritis (JIA) in adolescent patients.

The esomeprazole magnesium component of Vimovo is indicated to decrease the risk of developing naproxen-associated gastric ulcers.

Limitation(s) of use:
- Do not substitute Vimovo with the single-ingredient products of naproxen and esomeprazole magnesium.
- 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.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health and Wellness® that Vimovo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria
A. All FDA Approved Indications (must meet all)**:**
1. Prescribed to decrease the risk of developing NSAID-induced gastric ulcers in patients with rheumatoid arthritis, JIA, osteoarthritis, or ankylosing spondylitis;
2. Age ≥ 12 years;
3. Failure of three PPIs (e.g., omeprazole, pantoprazole, lansoprazole) in combination with three different NSAIDs, unless contraindicated or clinically significant adverse effects are experienced;

4. Medical justification supports inability to use the individual components (i.e., esomeprazole* and naproxen) concurrently (e.g., contraindications to the excipients of all brand and generic products);
   **Prior authorization may be required for esomeprazole.*
5. Dose does not exceed 1000 mg naproxen/40mg esomeprazole per day (2 tablets per day).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

A. All FDA Approved Indications (must meet all)**:**

1. Currently receiving medication via PA Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1000 mg naproxen/40mg esomeprazole per day (2 tablets per day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
GI: gastrointestinal
JIA: juvenile idiopathic arthritis
NSAID: nonsteroidal anti-inflammatory drug
PPI: proton pump inhibitor

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
PPIs		
lansoprazole (Prevacid®)	NSAID-induced ulcer prophylaxis: 15 mg PO QD NSAID-associated gastric ulcer (healing): 30 mg PO QD	30 mg/day (for most indications)
omeprazole (Prilosec®)	NSAID-induced ulcer prophylaxis†: 20 mg PO QD	40 mg/day (for most indications)
pantoprazole (Protonix®)	NSAID-induced ulcer prophylaxis†: 40 mg PO QD	40 mg/day (for most GERD indications)
NSAIDs		
diclofenac (Voltaren®)	Osteoarthritis: 50 mg PO BID-TID or 75 mg PO BID Rheumatoid arthritis: 50 mg PO TID-QID, or 75 mg PO BID Ankylosing spondylitis: 25 mg PO QID with an additional 25 mg dose at bedtime	Osteoarthritis: 150 mg/day Rheumatoid arthritis: 200 mg/day Ankylosing spondylitis 125 mg/day
etodolac (Lodine®)	Osteoarthritis or rheumatoid arthritis: 400 – 500 mg PO BID	1200 mg/day
fenoprofen (Nalfon®)	400 - 600 mg PO TID-QID	3200 mg/day
ibuprofen (Motrin®)	400 – 800 mg PO TID-QID	3200 mg/day
indomethacin (Indocin®)	25 PO BID-TID	200 mg/day
indomethacin SR (Indocin SR®)	75 mg PO QD-BID	150 mg/day
ketoprofen (Orudis®)	50 mg PO QID or 75 mg PO TID	300 mg/day
meloxicam (Mobic®)	7.5 mg – 15 mg PO QD	15 mg/day
naproxen (Naprosyn®)	250 – 500 mg PO BID	1500 mg/day
naproxen sodium (Anaprox®, Anaprox DS®)	275 – 550 mg PO BID	1650 mg/day
oxaprozin (Daypro®)	600 – 1200 mg PO QD	1800 mg/day
piroxicam (Feldene®)	10 – 20 mg PO QD	20 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
salsalate (Disalcid®)	1,500 mg PO BID or 1,000 mg PO TID	3000 mg/day
sulindac (Clinoril®)	150 mg – 200 mg PO BID	400 mg/day
tolmetin	400 – 600 mg PO TID	1800 mg/day
meclofenamate	50 – 100 mg PO Q4-6hr	400 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
†Off-label indication

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity to naproxen, esomeprazole magnesium, substituted benzimidazoles, or to any components of the drug product including omeprazole; history of asthma, urticaria, or other allergic-type reactions to aspirin or other NSAIDs; in the setting of coronary artery bypass graft (CABG) surgery; concurrent use of rilpivirine-containing products.
- Boxed warning(s): NSAIDs cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal; NSAIDs, including naproxen, cause an increased risk of serious GI adverse events including bleeding, ulceration, and perforation of the stomach or intestines.

Appendix D: General Information

- Black Box Warning: NSAIDs, a component of Vimovo, may cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction, and stroke, which can be fatal. This risk may occur early in treatment and may increase with duration of use. Vimovo is contraindicated in the setting of coronary artery bypass graft surgery. NSAIDS, including naproxen, a component of Vimovo, cause an increased risk of serious gastrointestinal (GI) 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 and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis	One tablet PO BID of either 375 mg naproxen/20 mg esomeprazole or 500 mg naproxen/20 mg esomeprazole	1000 mg naproxen/40mg esomeprazole per day
Juvenile idiopathic arthritis in adolescent patients 12 years of age and older and weighing at least 38 kg	> 50 kg: One tablet PO BID of either 375 mg naproxen/20 mg esomeprazole or 500 mg naproxen/20 mg esomeprazole	> 50 kg: 1000 mg naproxen/40mg esomeprazole per day

Indication	Dosing Regimen	Maximum Dose
	38 to < 50 kg: 375 mg naproxen/20 mg esomeprazole PO BID	38 to 50 kg: 750 mg naproxen/40 mg esomeprazole per day

VI. Product Availability

Delayed-release tablets (enteric-coated naproxen/immediate-release esomeprazole): 375 mg/20 mg and 500 mg/20 mg

VII. References

1. Vimovo Prescribing Information. Lake Forest, IL: Horizon Pharma USA, Inc.; June 2018. www.vimovo.com. Accessed February 23, 2019.
2. Micromedex® Healthcare Series [Internet Database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed February 23, 2019.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/. Accessed February 23, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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