

Clinical Policy: Naproxen and Esomeprazole (Vimovo)

Reference Number: CP.PMN.117

Effective Date: 06.01.18

Last Review Date: 05.18

Line of Business: Commercial, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

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 Centene Corporation[®] 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 \geq 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:

Medicaid - 12 months

Commercial - Length of Benefit

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
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:

Medicaid - 12 months

Commercial - Length of Benefit

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

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 – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid 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
<i>PPIs</i>		
lansoprazole (Prevacid [®])	NSAID-induced ulcer prophylaxis: 15 mg PO once daily NSAID-associated gastric ulcer (healing): 30 mg PO once daily	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 once daily	40 mg/day (for most GERD indications)
<i>NSAIDs</i>		
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 PO 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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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
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: 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 of esomeprazole; or 500 mg naproxen/20 mg of 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 of esomeprazole; or 500 mg naproxen/20 mg of esomeprazole	> 50 kg: 1000 mg naproxen/40mg esomeprazole per day 38 to 50 kg: 750 mg naproxen/40 mg esomeprazole per day

Indication	Dosing Regimen	Maximum Dose
	38 to < 50 kg: 375 mg naproxen/20 mg of esomeprazole PO BID	

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.; July 2017. www.vimovo.com. Accessed February 21, 2018.
2. Micromedex® Healthcare Series [Internet Database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed February 21, 2018.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed February 21, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: replaces CP.CPA.168 Vimovo; Medicaid line of business added.	02.27.18	05.18

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to

applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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