Clinical Policy: Naproxen/Esomeprazole (Vimovo)

Reference Number: CP.PMN.117
Effective Date: 06.01.18
Last Review Date: 05.22
Line of Business: Commercial, HIM, Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Naproxen/esomeprazole magnesium (Vimovo®) is a fixed combination of naproxen, a non-steroidal anti-inflammatory drug (NSAID), and esomeprazole, 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 ≥ 12 years and weight ≥ 38 kg ;

3. Failure of three PPIs (e.g., omeprazole, pantoprazole, lansoprazole) in combination with three different NSAIDs, unless clinically significant adverse effects are experienced or all are contraindicated;
4. Member must instead use the individual components (i.e., esomeprazole* and naproxen) concurrently, unless contraindicated or clinically significant adverse effects are experienced;
   **Prior authorization may be required for esomeprazole.*
5. Member has at least one of the following risk factors for developing NSAID-induced gastric ulcers (a, b, or c);
   a. Age > 65 years;
   b. Member has a history of peptic ulcer disease;
   c. Concurrent use of antiplatelets, corticosteroids, or anticoagulants;
6. If request is for brand Vimovo, member must use generic naproxen/esomeprazole, unless contraindicated or clinically significant adverse effects are experienced;
7. Dose does not exceed 1,000 mg naproxen/40 mg esomeprazole (2 tablets) per day.

Approval duration:
Medicaid/HIM – 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, HIM.PA.154 for health insurance marketplace, 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. Member has at least one of the following risk factors for developing NSAID-induced gastric ulcers (a, b, or c);
   a. Age > 65 years;
   b. Member has a history of peptic ulcer disease;
   c. Concurrent use of antiplatelets, corticosteroids, or anticoagulants;
4. If request is for a dose increase, new dose does not exceed 1,000 mg naproxen/40 mg esomeprazole (2 tablets) per day.

Approval duration:
Medicaid/HIM – 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, HIM.PA.154 for health insurance marketplace, 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, HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CABG: coronary artery bypass graft
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:	Osteoarthritis: 150 mg/day Rheumatoid arthritis: 200 mg/day Ankylosing spondylitis 125 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	25 mg PO QID with an additional 25 mg dose at bedtime	
etodolac (Lodine®)	Osteoarthritis or rheumatoid arthritis: 400 – 500 mg PO BID	1200 mg/day
fenoprofen (Nalfon®)	400 – 600 mg PO TID-QID	3,200 mg/day
ibuprofen (Motrin®)	400 – 800 mg PO TID-QID	3,200 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	1,500 mg/day
naproxen sodium (Anaprox®, Anaprox DS®)	275 – 550 mg PO BID	1,650 mg/day
oxaprozin (Daypro®)	600 – 1,200 mg PO QD	1,800 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	3,000 mg/day
sulindac (Clinoril®)	150 mg – 200 mg PO BID	400 mg/day
tolmetin	400 – 600 mg PO TID	1,800 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; Vimovo is contraindicated in the setting of CABG surgery

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	1,000 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 38 to < 50 kg: 375 mg naproxen/20 mg esomeprazole PO BID	> 50 kg: 1,000 mg naproxen/40mg esomeprazole per day 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, 500 mg/20 mg

VII. References

1. Vimovo Prescribing Information. Lake Forest, IL: Horizon Pharma USA, Inc.; April 2021. www.vimovo.com. Accessed January 18, 2022.
2. Micromedex® Healthcare Series [Internet Database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. January 18, 2022.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: http://www.clinicalpharmacology-ip.com/. January 18, 2022.

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
2Q 2019 annual review: no significant changes. References reviewed and updated.	02.23.19	05.19
2Q 2020 annual review: no significant changes; added HIM line of business; references reviewed and updated.	02.04.20	05.20
2Q 2021 annual review: added weight requirement per PI; revised medical justification to member "must use" individual components; added that request is for generic formulation; updated reference for HIM off-label use to HIM.PA.154 (replaces HIM.PHAR.21); references reviewed and updated.	02.15.21	05.21
2Q 2022 annual review: no significant changes; added risk factors for developing NSAID-induced gastric ulcers to criteria; references reviewed and updated.	01.18.22	05.22

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.