Vimovo

Description

Vimovo (delayed-release enteric-coated naproxen with esomeprazole)

Background

Vimovo is a combination product of naproxen and esomeprazole for use in osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis for patients that are at moderate to high risk of developing NSAID-associated gastric ulcers. It consists of an immediate-release esomeprazole magnesium layer and an enteric-coated naproxen core. As a result, esomeprazole is released first in the stomach, prior to the dissolution of naproxen in the small intestine. Naproxen is an NSAID with analgesic, antipyretic, and anti-inflammatory properties. Esomeprazole is a proton pump inhibitor (PPI) that suppresses gastric acid secretion. By acting specifically on the proton pump, esomeprazole blocks the final step in acid production, thus reducing gastric acidity (1).

Regulatory Status

FDA-approved indication: Vimovo is a combination product of naproxen and esomeprazole indicated for the relief of signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis in patients with moderate to high risk of developing NSAID-associated gastric ulcers (1).

Vimovo carries boxed warnings of both a cardiovascular and gastrointestinal risk. The non-steroidal anti-inflammatory ingredient, naproxen, may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction (MI), 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 a greater risk (1).
Naproxen/esomeprazole is contraindicated for the treatment of perioperative pain in the setting of coronary artery bypass graft surgery (CABG) (1).

Vimovo should be avoided in patients with severe hepatic impairment or advanced renal disease because naproxen may increase the risk of renal failure or bleeding. When active and clinically significant bleeding from any source occurs in patients receiving Vimovo, the treatment should be withdrawn (1).

Nonsteroidal anti-inflammatory drugs (NSAIDs), including naproxen, cause an increased risk of serious GI adverse events, including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. Patients receiving Vimovo who may be adversely affected by alterations in platelet function, such as those with coagulation disorders or patients receiving anticoagulants or antiplatelets, should be carefully monitored. Avoid concomitant use of esomeprazole with clopidogrel (1).

The safety and efficacy of Vimovo has not been established in children younger than 18 years (1).

Related policies

Policy
*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Vimovo may be considered **medically necessary** in patients 18 years and older for treatment of 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, and inadequate treatment response, intolerance, or contraindication to a prescription strength NSAID and proton pump inhibitor and inadequate treatment response, intolerance, or contraindication to use naproxen and esomeprazole separately.

Vimovo may be considered **investigational** in patients under the age of 18 years, for acute pain or for patients not at risk of NSAID-associated gastric ulcer.
Prior-Approval Requirements

Age  18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Osteoarthritis
2. Rheumatoid arthritis
3. Ankylosing spondylitis

AND **ALL** of the following:

1. Moderate to high risk of NSAID-associated gastric ulcers
2. Inadequate treatment response, intolerance, or contraindication to use naproxen and esomeprazole separately

**OR**

3. Inadequate treatment response, intolerance, or contraindication to a prescription strength NSAID and proton pump inhibitor

Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Osteoarthritis
2. Rheumatoid arthritis
3. Ankylosing spondylitis

AND the following:

1. Moderate to high risk of NSAID-associated gastric ulcers

**Policy Guidelines**

**Pre - PA Allowance**

None

**Prior - Approval Limits**

<table>
<thead>
<tr>
<th>Quantity</th>
<th>180 quantity every 90 days</th>
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<tbody>
<tr>
<td>Duration</td>
<td>12 months</td>
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Prior – Approval Renewal Limits

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Rationale

Summary

Vimovo is a combination product of naproxen and esomeprazole for use in osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis for patients that are at moderate to high risk of developing NSAID-associated gastric ulcers. Vimovo carries boxed warnings of both a cardiovascular and gastrointestinal risk (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Vimovo while maintaining optimal therapeutic outcomes.

References


Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Reason</th>
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</thead>
<tbody>
<tr>
<td>June 2010</td>
<td>Addition of Vimovo, a FDA approved fixed-dose combination of delayed-release enteric-coated naproxen, a non-steroidal anti-inflammatory drug (NSAID), and immediate-release esomeprazole, a stomach acid-reducing proton pump inhibitor (PPI), approved 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.</td>
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<tr>
<td>August 2012</td>
<td>Revision of criteria to reflect the current FDA approved indications</td>
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<tr>
<td>May 2013</td>
<td>Separation of Vimovo from PPIs.</td>
</tr>
<tr>
<td>September 2014</td>
<td>Annual criteria review and reference update</td>
</tr>
<tr>
<td>March 2015</td>
<td>Annual criteria review and reference update</td>
</tr>
<tr>
<td>June 2015</td>
<td>Addition of inadequate treatment response, intolerance, or contraindication to a prescription strength NSAID and proton pump inhibitor and inadequate treatment response, intolerance, or contraindication to use naproxen and esomeprazole separately</td>
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</table>
This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 18, 2015 and effective October 1, 2015.

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