Yosprala

Description

Yosprala (aspirin with omeprazole)

Background

Yosprala is a combination product of aspirin and omeprazole for use in patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk of developing aspirin-associated gastric ulcers. It consists of an immediate-release omeprazole layer and an enteric-coated aspirin core. Aspirin is an NSAID with antiplatelet, analgesic, antipyretic, and anti-inflammatory properties. Omeprazole is a proton pump inhibitor (PPI) that blocks the final step in acid production, thus reducing gastric acidity (1).

Regulatory Status

FDA-approved indication: Yosprala is a combination product of aspirin and omeprazole indicated for patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk of developing aspirin associated gastric ulcers (1).

The aspirin component of Yosprala in indicated for (1):

1. Reducing the combined risk of death and nonfatal stroke in patients who have had ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli
2. Reducing the combined risk of death and nonfatal MI in patients with a previous MI or unstable angina pectoris
3. Reducing the combined risk of MI and sudden death in patients with chronic stable angina pectoris
4. Use in patients who have undergone revascularization procedures, such as Coronary Artery Bypass Graft (CABG) or Percutaneous Transluminal Coronary Angioplasty (PTCA), when there is a pre-existing condition for which aspirin is already indicated.

The omeprazole component of Yosprala is indicated for decreasing the risk of developing aspirin-associated gastric ulcers in patients at risk for developing aspirin-associated gastric ulcers due to age (≥55) or documented history of gastric ulcers (1).

Yosprala is contraindicated in pediatric patients with suspected viral infections, with or without fever, because of the risk of Reye’s Syndrome, and in patients receiving rilpivirine-containing products (1).

Safety and effectiveness of Yosprala in pediatric patients less than 18 years of age have not been established (1).

Related policies
Durlaza, Duexis, Vimovo

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

Yosprala may be considered medically necessary in patients 18 years and older who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at moderate to high risk of developing aspirin-associated gastric ulcers due to ONE of the following: age greater than or equal to 55, or documented history of gastric ulcers; and have experienced inadequate treatment response, or intolerance to use aspirin and omeprazole separately.

Yosprala may be considered investigational in patients under the age of 18 years and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older
Diagnoses

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

1. Ischemic stroke
2. Transient ischemia of the brain
3. Previous myocardial infarction
4. Unstable angina pectoris
5. Chronic stable angina pectoris
6. Undergone **ONE** of following revascularization procedures:
   a. Coronary Artery Bypass Graft (CABG)
   b. Percutaneous Transluminal Coronary Angioplasty (PTCA)

**AND ALL** of the following:
1. Moderate to high risk of aspirin-associated gastric ulcers due to **ONE** of the following:
   a. Age ≥55
   b. Documented history of gastric ulcers
2. Inadequate treatment response, or intolerance to use aspirin and omeprazole separately

Prior – Approval **Renewal** Requirements

**Age**
18 years of age or older

**Diagnoses**

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

1. Ischemic stroke
2. Transient ischemia of the brain
3. Previous myocardial infarction
4. Unstable angina pectoris
5. Chronic stable angina pectoris
6. Undergone **ONE** of following revascularization procedures:
   a. Coronary Artery Bypass Graft (CABG)
b. Percutaneous Transluminal Coronary Angioplasty (PTCA)

**Policy Guidelines**

**Pre - PA Allowance**
None

**Prior - Approval Limits**

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**Prior – Approval Renewal Limits**

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**Rationale**

**Summary**

Yosprala is a combination product of aspirin and omeprazole indicated for use in patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk of developing aspirin-associated gastric ulcers. Yosprala is contraindicated in pediatric patients and in patients receiving rilpivirine-containing agents (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**

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**Keywords**
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<td><strong>Original Policy Date:</strong></td>
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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 2, 2016 and is effective on January 1, 2017.

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