

Pharmacy Policy Bulletin: J-0640 Yosprala (aspirin and omeprazole) – Commercial and Healthcare Reform	
Number: J-0640	Category: Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	Benefit(s): Commercial: Prior Authorization (1.): 1. Other Managed Prior Authorization = Yes w/ Prior Authorization Healthcare Reform: Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	Additional Restriction(s): None
Version: J-0640-010	Original Date: 12/07/2016
Effective Date: 10/28/2024	Review Date: 10/02/2024

Drugs Product(s):	Yosprala (aspirin and omeprazole)
FDA-Approved Indication(s):	Patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk of developing aspirin associated gastric ulcers.

Background:	- Aspirin is indicated for 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, reducing the combined risk of death and nonfatal myocardial infarction (MI) in patients with a previous MI or unstable angina pectoris, reducing the combined risk of MI and sudden death in patients with chronic stable angina pectoris, and in patients who have undergone revascularization procedures (Coronary Artery Bypass Graft [CABG] or Percutaneous Transluminal Coronary Angioplasty [PTCA]) when there is a pre-existing condition for which aspirin is already indicated. - Aspirin irreversibly inhibits cyclooxygenase-1 and 2 (COX-1 and COX-2), decreasing formulation of prostaglandin precursors and platelet aggregation. - Low-dose aspirin can be used for the primary or secondary prevention of Atherosclerotic Cardiovascular Disease (ASCVD), however current guidelines suggest that low-dose aspirin should not be administered on a routine basis in patients who are older than 60 years of age for primary prevention or have an increased risk of bleeding. - Secondary prevention of cardiovascular and cerebrovascular events focuses on reducing impact of the disease by early diagnosis prior to any critical or permanent damage. Deciding whether secondary prevention is needed requires identifying risk factors. Examples of when secondary prevention of cardiovascular and cerebrovascular events are appropriate may include modifiable factors such as obesity, blood lipids, and behavioral factors or non-modifiable risk factors such as age, gender, and genetic predisposition. - Omeprazole is used in combination with aspirin to decrease the risk of developing aspirin associated gastric ulcers in patients at risk for developing
-------------	---

	aspirin-associated gastric ulcers due to being ≥ 55 years of age or documented history of gastric ulcers. • Omeprazole suppresses gastric acid secretion by inhibiting the H⁺/K⁺ adenosine triphosphate (ATP) pump, which suppress basal and stimulated acid secretion. • Prescribing Considerations: ○ Yosprala contains a delayed-release formulation of aspirin and it is not for use as the initial dose of aspirin therapy during onset of acute coronary syndrome (ACS), acute MI or before percutaneous coronary intervention (PCI), for which immediate-release aspirin therapy is appropriate. ○ Yosprala has not been shown to reduce the risk of gastrointestinal bleeding due to aspirin. ○ Due to the increased risk of <i>Clostridium difficile</i>-associated diarrhea, bone fractures, and fundic gland polyps, use the lowest dose and shortest duration of proton pump inhibitor (PPI) treatment. ○ Yosprala is contraindicated in patients with a history of asthma, urticaria or other allergic reactions after taking NSAIDs, with a known hypersensitivity to any Yosprala ingredients or any of its excipients and in patients receiving rilpivirine-containing products. ○ Use of Yosprala in pregnancy and lactation is not recommended.
--	--

Approval Criteria

I. Initial Authorization

When a benefit, coverage for Yosprala (aspirin and omeprazole) will be approved when all the following criteria are met **(A. through D.)**:

- A.** The member is 18 years of age or older.
- B.** The member has an appropriate need for secondary prevention of cardiovascular and cerebrovascular events (no ICD-10 code).
- C.** The member meets one (1) of the following criteria **(1. or 2.)**:
 - 1.** The member has a risk of developing aspirin associated gastric ulcers due to being ≥ 55 years of age.
 - 2.** The member has a risk of developing aspirin associated gastric ulcers due to a history of gastric ulcers.
- D.** The member has experienced therapeutic failure or intolerance to all of the following, plan-preferred, generic agents, available separately and taken together **(1. and 2.)**:
 - 1.** aspirin in combination with omeprazole
 - 2.** aspirin in combination with pantoprazole

II. Reauthorization

When a benefit, reauthorization of Yosprala (aspirin and omeprazole) may be approved when all of the following criteria are met **(A. and B.)**:

- A.** The prescriber attests that the member has experienced positive clinical response to therapy.
- B.** The prescriber attests that the member requires additional courses of treatment.

- III.** An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

- I.** No exceptions will be made if the sole purpose of Yosprala (aspirin and omeprazole) use is to increase patient adherence or convenience.

- II. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
- III. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Yosprala [package insert]. Princeton, NJ: Aralez Pharmaceuticals, Inc.; July 2023.
2. Arnett DK, Blumenthal RS, Albert MA, et al. *Journal of the American College of Cardiology*. 2019;74(10):172-232.
3. Karunathilake SP, Ganegoda GU. Secondary Prevention of Cardiovascular Diseases and Application of Technology for Early Diagnosis. *BioMed Research International*. 2018; 5767864 (9).
4. American College of Cardiology. New USPSTF Recommendation on Aspirin in CVD: No For Primary Prevention, Yes For Secondary Prevention. Available at: <https://www.acc.org/Latest-in-Cardiology/Articles/2022/04/27/20/41/New-USPSTF-Recommendation-on-Aspirin-in-CVD>. Accessed October 2, 2024.

Pharmacy policies do not constitute medical advice, nor are they intended to govern physicians' prescribing or the practice of medicine. They are intended to reflect the plan's coverage and reimbursement guidelines. Coverage may vary for individual members, based on the terms of the benefit contract.

The plan retains the right to review and update its pharmacy policy at its sole discretion. These guidelines are the proprietary information of the plan. Any sale, copying or dissemination of the pharmacy policies is prohibited; however, limited copying of pharmacy policies is permitted for individual use.