

## Commercial/Healthcare Exchange PA Criteria

*Effective: May 2016*

**Prior Authorization:** Aspirin Products

**Products Affected:** Durlaza (acetylsalicylic acid) extended release oral capsule, Yosprala (aspirin/omeprazole) oral tablet

**Medication Description:** Aspirins irreversibly inhibits cyclooxygenase-1 and 2 (COX-1 and 2) enzymes, via acetylation, which results in decreased formation of prostaglandin precursors; irreversibly inhibits formation of prostaglandin derivative, thromboxane A<sub>2</sub>, via acetylation of platelet cyclooxygenase, thus inhibiting platelet aggregation; has antipyretic, analgesic, and anti-inflammatory properties.

**Covered Uses:**

**DURLAZA**

1. Reduce the risk of death and myocardial infarction (MI) in patients with chronic coronary artery disease, such as patients with a history of MI or unstable angina pectoris or with chronic stable angina
2. Reduce the risk of death and recurrent stroke in patients who have had an ischemic stroke or transient ischemic attack

YOSPRALA is 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.

The aspirin component of YOSPRALA is indicated for:

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 (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 ( $\geq 55$ ) or documented history of gastric ulcers.

**Exclusion Criteria:**

1. Situations where a rapid onset of action is required (such as acute treatment of myocardial infarction or before percutaneous coronary intervention).
2. Patients with a hypersensitivity to nonsteroidal anti-inflammatory drugs (NSAIDs).
3. Patients with the syndrome of asthma, rhinitis, and nasal polyps.
4. Yosprala when used to reduce the risk of gastrointestinal bleeding due to aspirin.
5. Yosprala: known hypersensitivity to aspirin, omeprazole, substituted benzimidazoles

**Required Medical Information:**

1. Diagnosis
2. Previous medications tried/failed

**Age Restrictions:** N/A

**Prescriber Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:**

1. Patient has had an intolerance to, or treatment failure of, generic aspirin; **OR**
2. Patient has had an intolerance to, or treatment failure of, any of the following: Plavix or Brilinta

**References:**

1. Durlaza package insert, New Haven pharmaceuticals, North Haven, CT
2. Facts and Comparisons Online

**Policy Revision history**

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	May 2016
2	Policy Update	Moved to updated template Updated exclusion criteria and covered uses to mirror FDA label/package insert Removed Effient from other criteria section	All	2/4/2020