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Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Hematological Agents	**Original Policy Date:**	June 3, 2016
Subject:	Durlaza	**Page:**	1 of 4

Last Review Date: March 12, 2021

Durlaza

Description

Durlaza (aspirin)

Background
Durlaza is an extended release aspirin formulation indicated to reduce the impact (secondary prevention) of high-risk cardiovascular disease (CVD). The aspirin delivery technology in Durlaza provides stable inhibition of platelets (antiplatelet effect) throughout the day. Patients with high-risk CVD generate new platelets all day long making this property important. This antiplatelet effect decreases the formation of blood clots reducing the risk of death and myocardial infarction (MI) or stroke. Durlaza provides an alternative dosing option for patients who need aspirin for CVD (1).

Regulatory Status
FDA-approved indication: Durlaza is a nonsteroidal anti-inflammatory drug (NSAID) indicated to 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 and to reduce the risk of death and recurrent stroke in patients who have had an ischemic stroke or transient ischemic attack (1).

Limitations of use:
Use immediate-release aspirin, not Durlaza in situations where a rapid onset of action is required (such as acute treatment of myocardial infarction or before percutaneous coronary intervention) (1).

The use of Durlaza is contraindicated in patients with asthma, rhinitis, and nasal polyps. Durlaza may cause severe urticaria, angioedema, or bronchospasm (1).

Durlaza increases the risk of bleeding. Risk factors include the use of other drugs that increase the risk of bleeding (such as anticoagulants, antiplatelet agents and chronic use of NSAIDS). Durlaza may cause gastric ulceration and bleeding. Avoid Durlaza in patients with active peptic ulcer disease. Durlaza can cause fetal harm when administered to a pregnant woman. Maternal aspirin use during later stages of pregnancy may cause low birth weight, increased incidence for intracranial hemorrhage in premature infants, stillbirths and neonatal death. Avoid Durlaza in the third trimester of pregnancy because NSAIDs may cause premature closure of the fetal ductus arteriosus (1).

Safety and effectiveness in pediatric patients have not been established (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.

Durlaza may be considered **medically necessary** in patients 18 years of age and older with a history of MI, unstable angina pectoris, chronic stable angina, ischemic stroke, or transient ischemic attack and if the conditions indicated below are met.

Durlaza is considered **investigational** in patients under 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have the following:

1. History of **ONE** of the following:
    a. Myocardial infarction (MI)
    b. Unstable angina pectoris
    c. Chronic stable angina
    d. Ischemic Stroke

e. Transient ischemic attack (TIA)

AND ALL of the following:
1. Inadequate response to prior therapy with generic aspirin therapy
2. **NO** severe renal failure (GFR rate less than 10 mL/min/1.73 m^2)
3. **NO** severe hepatic insufficiency
4. **NOT** used for acute treatment of myocardial infarction or before percutaneous coronary intervention

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have the following:

1. **NO** history of the following while on Durlaza therapy:
   a. Myocardial infarction, transient ischemic attack (TIA) or increase in angina
   b. Has **NOT** experienced GI related side effects
2. **NO** severe renal failure (GFR rate less than 10 mL/min/1.73 m^2)
3. **NO** severe hepatic insufficiency

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits
Duration 12 months

Prior – Approval *Renewal* Limits
Same as above

Rationale

Summary

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Durlaza is an extended release aspirin formulation indicated to reduce the impact (secondary prevention) of high-risk cardiovascular disease (CVD). The aspirin delivery technology in Durlaza provides stable inhibition of platelets (antiplatelet effect) throughout the day. Patients with high-risk CVD generate new platelets all day long making this property important. This antiplatelet effect decreases the formation of blood clots reducing the risk of death and myocardial infarction (MI) or stroke. Durlaza is contraindicated in patients with active peptic ulcer disease, asthma, rhinitis, nasal polyps, severe hepatic insufficiency and severe renal failure. Durlaza can increase risk of bleeding. Risk factors for bleeding include the use of other drugs that increase the risk of bleeding (such as anticoagulants, antiplatelet agents and chronic use of nonsteroidal anti-inflammatory drugs) (1).

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

References

1. Durlaza [package insert]. North Haven, CT: New Haven Pharmaceuticals Inc; September 2015.

Policy History

Date	Action
May 2016	Addition to PA
December 2016	Annual editorial review and reference update
September 2017	Annual editorial review and reference update
September 2018	Annual review and reference update
September 2019	Annual review
September 2020	Annual review
March 2021	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.