



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

ASPIRIN ER

Generic	Brand	HICL	GCN	Exception/Other
ASPIRIN ER	DURLAZA		17988	

**GUIDELINES FOR USE**

1. Does the patient have a diagnosis of chronic coronary artery disease, (e.g., a history of MI or unstable angina), or a history of an ischemic stroke or transient ischemic attack (TIA)?

If yes, continue to #2.

If no, do not approve.

**DENIAL TEXT:** See the denial text at the end of guideline.

2. Does the patient meet the following criteria?

- Patient has previously tried aspirin over-the-counter (OTC)
- Durlaza is NOT being used for acute treatment of myocardial infarction or before percutaneous coronary intervention

If yes, **approve for 12 months by GPID for a quantity limit of #30 tablets per 30 days.**

If no, do not approve.

**DENIAL TEXT:** See the denial text at the end of guideline.

**DENIAL TEXT:** Our guideline for **ASPIRIN ER** requires a diagnosis of chronic coronary artery disease, (e.g., a history of MI or unstable angina), or a history of an ischemic stroke or transient ischemic attack (TIA). Additional guideline requirements apply.

- Patient has previously tried aspirin over-the-counter (OTC)
- Durlaza is not being used for acute treatment of myocardial infarction or before percutaneous coronary intervention

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**RATIONALE**

Promote appropriate utilization of Durlaza based on FDA approved indication and cost-effectiveness.

DURLAZA is a nonsteroidal anti-inflammatory drug 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.

Limitation 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).

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ASPIRIN ER

**RATIONALE (CONTINUED)**

Durlaza is a 162.5mg extended release formulation of aspirin. Aspirin is available in multiple strengths as an over the counter (OTC) product. There were no new studies on the safety and efficacy of Durlaza performed. The platelet inhibitory effects of aspirin last for the life of the circulating platelets, which is ~10 days, thus an extended release formulation of aspirin has not been demonstrated to be superior to previously available OTC aspirin.

**DOSAGE**

The recommended dose is 162.5 mg per day with a full glass of water at the same time each day.

**FDA APPROVED INDICATION**

DURLAZA is a nonsteroidal anti-inflammatory drug 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.

Limitation 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).

**REFERENCES**

- New haven Pharmaceuticals, Inc. Durlaza Package Insert. North Haven, CT. September 2015.
- Awtry, Eric H., Loscalzo, Joseph. Cardiology Drugs: Aspirin. Journal Circulation: 2000; 101: 1206-1218. Accessed online October 12, 2015 at: <http://circ.ahajournals.org/content/101/10/1206.full>

Library	Commercial	NSA
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