aspirin extended release capsules (Durlaza™)

Policy # 00500
Original Effective Date: 02/17/2016
Current Effective Date: 03/09/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider aspirin extended release capsules (Durlaza™)‡ to reduce the risk of death and myocardial infarction (MI) in patients with chronic coronary artery disease and/or to reduce the risk of death and recurrent stroke in patients who have had an ischemic stroke or transient ischemic attack to be **eligible for coverage.** **

Patient Selection Criteria

Coverage eligibility for aspirin extended release capsules (Durlaza) to reduce the risk of death and MI in patients with chronic coronary artery disease and/or to reduce the risk of death and recurrent stroke in patients who have had an ischemic stroke or transient ischemic attack will be considered when the following criteria are met:

- Durlaza is being used to reduce the risk of death and myocardial infarction in patients with chronic coronary artery disease (e.g. those that HAVE experienced myocardial infarction, unstable angina pectoris, or chronic stable angina) AND/OR to reduce the risk of death and recurrent stroke in patients who have had an ischemic stroke or transient ischemic attack; AND
- Patient has tried and failed (e.g. intolerability) at least TWO other antiplatelet agents for their condition [examples of antiplatelet agents include: aspirin, clopidogrel (Plavix®)‡, extended release aspirin/dipyridamole (Aggrenox®)‡] unless there is clinical evidence or patient history that suggests the use of two other antiplatelet agents will be ineffective or cause an adverse reaction to the patient.

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*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of aspirin extended release capsules (Durlaza) for any indication other than 1) reducing the risk of death and myocardial infarction in patients with chronic coronary artery disease OR 2) reducing the risk of death and recurrent stroke in patients who have had an ischemic stroke or transient ischemic attack to be **investigational.***

When Services Are Considered Not Medically Necessary
Based on review of available data, the Company considers the use of aspirin extended release capsules (Durlaza) when the patient has NOT tried and failed at least TWO other antiplatelet agents to be **not medically necessary.****

Background/Overview

Durlaza is aspirin extended release in a capsule form available as 162.5 mg. Durlaza is approved to 1) reduce the risk of death and 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 2) reduce the risk of death and recurrent stroke in patients who have had an ischemic stroke or transient ischemic attack. The FDA approved dose is 162.5 mg taken once daily at the same time each day.

Aspirin in Cardiovascular Events and Strokes
Aspirin has been used for the prevention and management of cardiovascular disease, as well as for the prevention of ischemic stroke and transient ischemic attack for several decades. Aspirin is available in various dosages and dosage forms as over the counter (OTC) products. At this point, no guidelines have specifically addressed Durlaza. However, various national guidelines have detailed the benefits of aspirin and have also recommended aspirin in a variety of situations. It should be noted (as mentioned later in the rationale/source) that this version of aspirin (extended release capsule form) offers no therapeutic advantage over "older" versions of aspirin.

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For the secondary prevention of cardiovascular disease, aspirin has shown to reduce the risk of subsequent myocardial infarction and vascular death. An option for those that aren't able to tolerate aspirin (about 5% of the population) is clopidogrel. For secondary prevention of strokes, other options include aspirin, clopidogrel, or the combination of aspirin/dipyridamole.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Durlaza was approved in September of 2015 to 1) reduce the risk of death and 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 2) reduce the risk of death and recurrent stroke in patients who have had an ischemic stroke or transient ischemic attack.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Durlaza was assessed in one pivotal trial that evaluated its pharmacokinetic and pharmacodynamic properties. The efficacy and safety of Durlaza were not evaluated in separate trials, but the data used was from other trials studying aspirin. The pivotal study enrolled 50 subjects and was an open label, 4-way, crossover, single-center, single-dose, dose response study that assessed Durlaza versus immediate release 81 mg aspirin. The study showed that in order to obtain similar pharmacodynamic effects, a two-fold greater dose of Durlaza is needed (e.g. 162.5 mg of Durlaza vs. 81 mg of immediate release aspirin). Durlaza did have prolonged concentrations vs. immediate release aspirin.

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Policy History

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02/04/2016 Medical Policy Committee review
02/17/2016 Medical Policy Implementation Committee approval. New Policy.
02/02/2017 Medical Policy Committee review
02/15/2017 Medical Policy Implementation Committee approval. No change to coverage.
02/01/2018 Medical Policy Committee review
02/21/2018 Medical Policy Implementation Committee approval. No change to coverage.
02/07/2019 Medical Policy Committee review
02/20/2019 Medical Policy Implementation Committee approval. No change to coverage.
02/06/2020 Medical Policy Committee review
02/12/2020 Medical Policy Implementation Committee approval. No change to coverage.
Next Scheduled Review Date: 02/2021

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

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1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.