Daxbia™ (cephalexin)

Policy # 00565
Original Effective Date: 06/21/2017
Current Effective Date: 07/13/2020

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 Daxbia™‡ (cephalexin) to be **eligible for coverage**** when the patient selection criterion is met.

Patient Selection Criterion

Coverage eligibility for Daxbia (cephalexin) will be considered when the following criterion is met:

- The patient has tried and failed at least THREE generic cephalexin containing products/strengths FOR THE CURRENT INFECTION prior to requesting this drug unless there is clinical evidence or patient history that suggests the use of THREE generic cephalexin containing products/strengths FOR THE CURRENT INFECTION will be ineffective or cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Daxbia (cephalexin) when the patient selection criterion is not met to be **not medically necessary.****

Background/Overview

Daxbia is a capsule containing cephalexin 333 mg. It carries the exact same indications as generic cephalexin, which is available in 250 mg, 500 mg, and 750 mg capsules. The indications include infections caused by susceptible isolates of designated bacteria including respiratory tract infections, otitis media, skin and skin structure infections, bone infections, and genitourinary tract infections. There are no clinical trials listed in the package insert to gain any knowledge of the manner in which

this cephalexin product was studied. Given the lack of any clinical or safety advantage with this product, generic cephalexin capsules are a clinically and economically sensible option.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Daxbia is indicated for the treatment of infections caused by susceptible isolates of designated bacteria including respiratory tract infections, otitis media, skin and skin structure infections, bone infections, and genitourinary tract infections. Daxbia carries the same indications as generic cephalexin 250 mg, 500 mg, and 750 mg capsules.

Rationale/Source

Daxbia is simply a cephalexin 333 mg containing product. Daxbia has the same exact indications as generic cephalexin 250 mg, 500 mg, and 750 mg capsules. There are also no clinical studies in the package insert to give insight into any advantages of this product. There have been no head to head studies of this product versus generic cephalexin in a clinical setting. Based on a review of the available data, there is no advantage of using Daxbia over generic cephalexin.

References

1. Daxbia [package insert]. Crown Laboratories, Inc. Johnson City, Tennessee.

Policy History

Original Effective Date: 06/21/2017
Current Effective Date: 07/13/2020

06/01/2017	Medical Policy Committee review
06/21/2017	Medical Policy Implementation Committee approval. New policy.
06/07/2018	Medical Policy Committee review
06/20/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/06/2019	Medical Policy Committee review
06/19/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/04/2020	Medical Policy Committee review

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06/10/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 06/2021

**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: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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.