Conjupri™ (levamlodipine)

Policy # 00732
Original Effective Date: 03/08/2021
Current Effective Date: 03/08/2021

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 Conjupri™‡ (levamlodipine) to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Conjupri (levamlodipine) will be considered when the following criteria are met:

- Patient has a diagnosis of hypertension; AND
- Patient has tried and failed (e.g., intolerance or inadequate response) at least TWO other GENERIC formulary dihydropyridine calcium channel blockers (one of which MUST be amlodipine) unless there is clinical evidence or patient history that suggests the use of the generic formulary agents will be ineffective or cause an adverse reaction to the patient. Examples of generic formulary dihydropyridine calcium channel blockers include amlodipine, nifedipine, nifedipine ER, felodipine ER, and afeditab CR.
  *(Note: This criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Conjupri (levamlodipine) when the patient has not tried and failed at least TWO generic formulary dihydropyridine calcium channel blockers (one of which MUST be amlodipine) to be **not medically necessary.****

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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 Conjupri (levamlodipine) when the patient selection criteria are not met (except the criterion denoted above as **not medically necessary**)** to be **investigational.***

Background/Overview

Conjupri is the pharmacologically active isomer of amlodipine, a dihydropyridine calcium channel blocker that is used for the treatment of hypertension. Because Conjupri was approved based on studies done with amlodipine, no comparisons of efficacy between the two agents can be made. Generic amlodipine is widely available and may provide a more cost-effective treatment option than Conjupri. Additionally, there are many other dihydropyridine calcium channel blockers that are available as generics. These include nifedipine, nifedipine ER, felodipine ER, and afeditab CR.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Conjupri is indicated for the treatment of hypertension in adults and pediatric patients 6 years and older, to lower blood pressure.

Rationale/Source

Conjupri was approved based on clinical studies with amlodipine and pharmacokinetic studies demonstrating similar exposure of levamlodipine between Conjupri 5 mg and amlodipine besylate 10 mg. Because Conjupri has not been directly compared to any other antihypertensive agent, statements of superiority cannot be made. This policy takes into consideration the above as well as the numerous generically available antihypertensive agents with demonstrated efficacy and safety. Based on the review of the data, if the patient is able to tolerate the generic options, there is no advantage to the use of Conjupri over the generic dihydropyridine calcium channel blockers.

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References

1. Conjupri [package insert]. Burke Therapeutics, LLC. Hot Springs, AR. Updated September 2020.

Policy History

Original Effective Date: 03/08/2021
Current Effective Date: 03/08/2021
02/04/2021 Medical Policy Committee review
02/10/2021 Medical Policy Implementation Committee approval. New policy.
Next Scheduled Review Date: 02/2022

*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:
    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: 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.