



Louisiana

CaroSpir[®] (spironolactone oral suspension)

Policy # 00609

Original Effective Date: 03/21/2018

Current Effective Date: 03/21/2018

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 CaroSpir[®] (spironolactone oral suspension) for the treatment of heart failure, hypertension, or edema secondary to cirrhosis to be **eligible for coverage** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for CaroSpir (spironolactone) will be considered when the following criteria are met:

- The patient meets ONE of the following:
 - Patient has a diagnosis of New York Heart Association (NYHA) Class III-IV heart failure and a reduced ejection fraction ($\leq 40\%$); OR
 - Patient has a diagnosis of hypertension and CaroSpir will be used in addition to at least one other drug for the treatment of hypertension; OR
 - Patient is an adult with edema secondary to cirrhosis that is not responsive to fluid and sodium restriction; AND
- The patient is unable to swallow generic spironolactone tablets; AND
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- The patient is not taking any other medications in tablet or capsule form.
*(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 Not Medically Necessary

Based on review of available data, the Company considers the use of CaroSpir (spironolactone) when the patient is able to swallow generic spironolactone tablets or is currently taking other medications in tablet or capsule form to be **not medically necessary.****

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 CaroSpir (spironolactone) for the treatment of any indication other than NYHA Class III-IV heart failure with reduced ejection fraction, hypertension

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uncontrolled with at least one other anti-hypertensive agent, or edema unresponsive to fluid and sodium restriction in adult cirrhotic patients to be **investigational**.*

Background/Overview

CaroSpir is a liquid formulation of spironolactone, which is also available as a generic tablet and as brand Aldactone[™] tablets. While spironolactone been approved by the Food and Drug Administration (FDA) for many indications including hyperaldosteronism, edematous conditions, and hypokalemia; CaroSpir is only approved to be used in the treatment of NYHA Class III-IV heart failure with reduced ejection fraction, as add-on therapy for the treatment of hypertension, and for the management of edema unresponsive to fluid and sodium restriction in adult cirrhotic patients. Pharmacokinetic studies have found that CaroSpir results in a 15-37% higher serum concentration of spironolactone compared to spironolactone tablets and is thus not therapeutically equivalent to Aldactone. In addition, patients requiring a CaroSpir dose greater than 100 mg should use a different formulation of spironolactone because doses of CaroSpir above 100 mg may result in higher concentrations than expected. Typical doses of CaroSpir are 20-75 mg per day and depend on the condition being treated and the patient's serum potassium level.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

CaroSpir was approved in August 2017 for the treatment of NYHA Class III-IV heart failure with reduced ejection fraction, as add-on therapy for the treatment of hypertension, and for the management of edema in adult cirrhotic patients when edema is not responsive to fluid and sodium restriction.

Rationale/Source

CaroSpir was approved by the FDA based on the same clinical studies used for the approval of the spironolactone tablets in 1960. The patient selection criteria presented in this policy take into consideration whether or not the patient can tolerate the generic tablet formulation of spironolactone. Based on a review of the data, if the above mentioned criteria are not met there is no advantage to the use of CaroSpir over the generic oral spironolactone tablets.

References

1. CaroSpir [package insert]. CMP Pharma, Inc. Farmville, NC. August 2017

Policy History

Original Effective Date: 03/21/2018

Current Effective Date: 03/21/2018

03/01/2018 Medical Policy Committee review

03/21/2018 Medical Policy Implementation Committee approval. New policy.

Next Scheduled Review Date: 03/2019

*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:

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- 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.

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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.

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