LOUISIANA BLUE

Furoscix® (furosemide)

Policy # 00832
Original Effective Date: 03/13/2023
Current Effective Date: 03/10/2025

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 Furoscix®‡ (furosemide) to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Furoscix (furosemide) will be considered when the following criteria are met:

- Patient has a diagnosis of chronic heart failure; AND
- Patient has congestion due to fluid overload; AND
- Patient is 18 years of age or older; AND
- Patient is on background oral diuretic therapy, which includes either furosemide, bumetanide, or torsemide; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient is stable and suitable for at-home treatment with parenteral diuresis as evidenced by ALL of the following:
  - Patient's oxygen saturation is greater than or equal to 90% on exertion; AND
  - Patient's respiratory rate is less than 24 breaths per minute; AND
  - Patient's resting heart rate is less than 100 beats per minute; AND
  - Patient's systolic blood pressure is greater than 100 mm Hg; AND

  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient has a creatinine clearance that is greater than or equal to 30 ml/min OR an estimated glomerular filtration rate of greater than 20 mL/min/1.73 m^2; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient's fluid and electrolyte status will be assessed before therapy with Furoscix and monitored frequently for the duration of therapy and after treatment with Furoscix; AND

- Patient does not have any conditions such as acute pulmonary edema or hepatic cirrhosis that require immediate hospitalization or admission within 30 days; AND
- Treatment with oral diuretics will be discontinued during administration of Furoscix until patient is transitioned back to oral diuretic maintenance therapy; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient has demonstrated understanding of how to properly use the device; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient has an adequate at home environment for at-home administration, such as in a setting where patient can limit their activity for the duration of administration.
  *(Note: This specific patient selection 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 Furoscix (furosemide) when the following criteria are not met to be **not medically necessary.****

- Patient is on background oral diuretic therapy, which includes either furosemide, bumetanide, or torsemide
- Patient is stable and suitable for at-home treatment with parenteral diuresis as evidenced by ALL of the following:
  - Patient's oxygen saturation is greater than or equal to 90% on exertion; AND
  - Patient's respiratory rate is less than 24 breaths per minute; AND
  - Patient's resting heart rate is less than 100 beats per minute; AND
  - Patient's systolic blood pressure is greater than 100 mm Hg
- Patient has a creatinine clearance that is greater than or equal to 30 ml/min OR an estimated glomerular filtration rate of greater than 20 mL/min/1.73 m^2
- Treatment with oral diuretics will be discontinued during administration of Furoscix until patient is transitioned back to oral diuretic maintenance therapy
- Patient has demonstrated understanding of how to properly use the device
- Patient has an adequate at home environment for at-home administration, such as in a setting where patient can limit their activity for the duration of administration

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 Furoscix (furosemide) for any indication other than congestion due to fluid overload secondary to chronic heart failure to be **investigational.***

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Based on review of available data, the Company considers Furoscix (furosemide) when the patient selection criteria are not met (EXCEPT those denoted as **not medically necessary****) to be **investigational.***

Background/Overview

Furoscix is a loop diuretic that is indicated for the treatment of congestion due to fluid overload in adults with chronic heart failure. It is the first loop diuretic to be approved in a subcutaneous (SC) formulation. It is available as a single use on-body infusor with a prefilled cartridge that is pre-programmed to deliver 30 mg of furosemide subcutaneously over one hour, followed by 12.5 mg per hour for four hours to deliver a total of 80 mg over 5 hours. The package insert states that Furoscix is intended for use in a setting where the patient can limit their activity for the duration of administration. It is not indicated in emergency situations and should not be given in patients with acute pulmonary edema, anuria, or hepatic cirrhosis. Patients using Furoscix should be transitioned back to oral loop diuretics as soon as feasible as it is not indicated for chronic use. Furoscix is not specifically mentioned in guidelines at the time this policy was written, but the American College of Cardiology/American Heart Association (2022) states that loop diuretics (i.e., furosemide, bumetanide, and torsemide) are the preferred diuretic agents for use in most patients with heart failure. Furosemide is the most common loop diuretic to be used, but it is key to note that some patients may respond more favorably to other agents in this class and therapy is often individualized for patients with acutely decompensated heart failure. Furoscix was approved via a 505(b)(2) pathway and relied upon existing data with furosemide injection. Although the trials involving this drug were very small, they showed similar efficacy between intravenous (IV) and SC furosemide. Though IV loop diuretics are the primary therapy for patients with acute decompensated heart failure, Furoscix may find its place in therapy to prevent patients from having to be treated in an acute hospitalized setting, thus decreasing the number of heart failure related hospitalizations.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Furoscix is indicated for the treatment of congestion due to fluid overload in adults with NYHA Class II/III chronic heart failure. In 2024, the FDA expanded the approval of Furoscix to include treatment of congestion due to fluid overload in adult patients with chronic heart failure, regardless of NYHA functional class.

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, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

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The purpose of this policy is to ensure that Furoscix is being used per its FDA approved indication given the limited data defining which patients may benefit most from therapy. It is also intended to ensure safe and appropriate use of Furoscix given that this is a unique route of self-administration for this drug.

References

1. Furoscix [package insert]. scPharmaceuticals, Inc. Burlington, Massachusetts. Updated August 2024.
2. Furoscix for the Treatment of Congestion in Chronic Heart Failure. Rx Insights: Cardiovascular IPD Analytics. Published November 2022.
3. Furoscix (furosemide subcutaneous injection by on-body infusor-scPharmaceuticals). Drug Evaluation. Express Scripts. November 2022.

Policy History

Original Effective Date: 03/13/2023
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02/02/2023	Medical Policy Committee review
02/08/2023	Medical Policy Implementation Committee approval. New policy.
02/01/2024	Medical Policy Committee review
02/14/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/06/2025	Medical Policy Committee review
02/12/2025	Medical Policy Implementation Committee approval. Updated criteria to reflect expanded indication to include treatment of congestion due to fluid overload in adult patients with chronic heart failure, regardless of NYHA functional class per the updated FDA package insert. Also, removed ascites as a contraindicated condition.

Next Scheduled Review Date: 02/2026

*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 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.

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.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.