Clinical Policy: Furosemide (Furoscix)

Reference Number: LA.PHAR.608
Effective Date: 09.29.23
Last Review Date: 03.25.24 Revision Log
Line of Business: Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Please note: This policy is for medical benefit

Description
Furosemide (Furoscix®) is a loop diuretic administered via a wearable, single-use, pre-programmed On-Body Infusor for outpatient self-administration.

FDA Approved Indication(s)
Furoscix is indicated for the treatment of congestion due to fluid overload in adults with New York Heart Association (NYHA) Class II/III chronic heart failure.

Limitation(s) of use:
- Furoscix is not indicated for emergency situations or in patients with acute pulmonary edema.
- The On-Body Infusor will deliver only an 80-mg dose of Furoscix.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections® that Furoscix is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Heart Failure (must meet all)**:**

1. Diagnosis of chronic heart failure (CHF) of NYHA Class II or Class III;
2. Prescribed by or in consultation with a cardiologist;
3. Age ≥ 18 years;
4. Provider attestation that member is showing signs of extracellular volume expansion due to CHF;
5. Documentation that member is a candidate for parenteral diuresis outside of the hospital, as defined by all of the following (a, b, c, and d):
   a. Oxygen saturation ≥ 90% on exertion;
   b. Respiratory rate < 24 breaths per minute;
   c. Resting heart rate < 100 beats per minute;
   d. Systolic blood pressure > 100 mmHg;
6. Provider attestation that member will use Furoscix for short-term use only and will be transitioned to oral diuretics as soon as practical;

7. Member has been stable and is refractory (as defined by *Appendix D*) to at least one of the following loop diuretics, at up to maximally indicated doses (a, b, or c):
   a. Furosemide oral tablets;
   b. Torsemide oral tablets;
   c. Bumetanide oral tablets;
8. Dose does not exceed both of the following (a and b):
   a. 80 mg (1 cartridge) per day;
   b. Total of 8 kits over 30 days.

Approval duration: 4 weeks (up to 8 kits total)

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

II. Continued Therapy

A. Heart Failure (must meet all):

1. Re-authorization is not permitted. Members must meet the initial approval criteria for each request.

Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 2 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – LA.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
CHF: congestive heart failure
FDA: Food and Drug Administration
NYHA: New York Heart Association

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
bumetanide (Bumex®)	0.5 to 2 mg PO QD	10 mg/day
furosemide (Lasix®)	20 to 80 mg PO QD	600 mg/day
torsemide (Sooanz®)	10 to 20 mg PO QD	200 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s):
  - Anuria
  - Hepatic cirrhosis or ascites
  - Hypersensitivity to furosemide or medical adhesives
- Boxed warning(s): none reported

Appendix D: General Information
- Definition of disease refractory to loop diuretics
  - Failure to relieve volume overload, edema, or congestion despite a full dose of loop diuretic. Full dose of loop diuretic is defined by oral furosemide 80 mg daily or equivalent. The approximate dose conversion ratio for bumetanide: torsemide: furosemide is 1:20:40.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NYHA Class II/III CHF	80 mg SC once over 5 hours	80 mg/day

VI. Product Availability

Carton containing one prefilled cartridge co-packed with one On-body Infusor [i.e., one kit]: 80 mg/mL

VII. References

1. Furoscix Prescribing Information. Burlington, MA: scPharmaceuticals, Inc; October 2022. Available at www.furoscix.com. Accessed November 6, 2023.
2. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2022;145:e895–e1032. doi: 10.1161/CIR.0000000000001063.

3. Wilcox CS, Testani JM, Pitt B. Pathophysiology of Diuretic Resistance and Its Implications for the Management of Chronic Heart Failure. Hypertension. 2020 Oct;76(4):1045-1054. doi: 10.1161/HYPERTENSIONAHA.120.15205. Epub 2020 Aug 24. PMID: 32829662.
4. ClinicalTrials.gov. Furoscix Real-World Evaluation for Decreasing Hospital Admissions in Heart Failure (FREEDOM-HF). Last updated July 15, 2021. Available at: https://clinicaltrials.gov/ct2/show/NCT03458325. Accessed November 6, 2023.
5. Merative™ Micromedex® Alternative Medicine (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com.
6. Clinical Pharmacology [database online]. Tampa, FL: Elsevier; 2023. URL: www.clinicalkeys.com/pharmacology.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Code	Description
J1941	Injection, furosemide (furoscix), 20 mg

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Policy created	05.01.23	08.28.23
Annual review: no significant changes; in Appendix B, removed thiazide diuretics (metolazone and chlorothiazide) since there are no thiazide-related redirection in criteria and added commercially available brand names; references reviewed and updated.	03.25.24	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and

limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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