

## **Clinical Policy: Furosemide (Furoscix)**

Reference Number: CP.PHAR.608

Effective Date: 03.01.23

Last Review Date: 02.23

Line of Business: Commercial, HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **Description**

Furosemide (Furoscix<sup>®</sup>) 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 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 health plans affiliated with Centene Corporation<sup>®</sup> 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  $\geq$  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  $\geq$  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 one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
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: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.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 one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

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: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.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.*

<b>Drug Name</b>	<b>Dosing Regimen</b>	<b>Dose Limit/ Maximum Dose</b>
bumetanide	0.5 to 2 mg orally per day	10 mg/day
furosemide	20 to 80 mg orally per day	600 mg/day
torseamide	10 to 20 mg orally per day	200 mg/day
metolazone	2.5 mg orally per day	20 mg/day
chlorothiazide	250 to 500 mg orally per day	1,000/day

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) 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: torseamide: 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](http://www.furoscix.com). Accessed October 26, 2022.
2. Heidenreich PA, Bozkurt B, Aguilar D, Allen LA, Byun JJ, Colvin MM, Deswal A, Drazner MH, Dunlay SM, Evers LR, Fang JC, Fedson SE, Fonarow GC, Hayek SS, Hernandez AF, Khazanie P, Kittleson MM, Lee CS, Link MS, Milano CA, Nwacheta LC, Sandhu AT, Stevenson LW, Vardeny O, Vest AR, Yancy CW. 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. Micromedex<sup>®</sup> Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed October 26, 2022.
4. 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.
5. 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 December 14, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	12.14.22	02.23

**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. The Health Plan 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. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. 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. The Health Plan 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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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