Clinical Policy: Furosemide (Furoscix)

Reference Number: CP.PHAR.608
Effective Date: 03.01.23
Last Review Date: 02.25
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

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

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 edema in adult patients with chronic heart failure (CHF) or chronic kidney disease (CKD), including the nephrotic syndrome.

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® that Furoscix is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Heart Failure or Chronic Kidney Disease (must meet all)**:**

1. Diagnosis of CHF or CKD;
2. Prescribed by or in consultation with a cardiologist or nephrologist;
3. Age ≥ 18 years;
4. Provider attestation that member is showing signs of extracellular volume expansion due to CHF or CKD (e.g., jugular venous distension, pitting edema [≥ 1+], abdominal distension, pulmonary congestion on chest x-ray, pulmonary rales);
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 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 or Chronic Kidney Disease

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 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.

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
CKD: chronic kidney disease
FDA: Food and Drug Administration

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; hypersensitivity to furosemide, components of Furoscix formulation, 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
CHF, CKD	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/10 mL

VII. References

1. Furoscix Prescribing Information. Burlington, MA: scPharmaceuticals, Inc; March 2025. Available at www.furoscix.com. Accessed March 14, 2025.
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. Maddox TM, Januzzi JL, Allen LA, et al. 2024 ACC Expert Consensus Decision Pathway for treatment of heart failure with reduced ejection fraction: A report of the American College of Cardiology Solution Set Oversight Committee. *JACC*. 2024; 83(15): 1444-1488.
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. Bensimhon D, Weintraub WS, Peacock WF, et al. Reduced heart failure-related healthcare costs with Furoscix versus in-hospital intravenous diuresis in heart failure patients: The FREEDOM-HF study. *Future Cardiol.* 2023 Jun;19(8):385-396. doi: 10.2217/fca-2023-0071.
6. Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. KDIGO 2024 Clinical practice guideline for the evaluation and management of chronic kidney disease. *Kidney Int.* 2024;105(4S): S117–S314.
7. Kidney Disease Outcomes Quality Initiative (K/DOQI). K/DOQI clinical practice guidelines on hypertension and antihypertensive agents in chronic kidney disease. *Am J Kidney Dis.* 2004 May;43(5 Suppl 1):S1-290.
8. Clinical Pharmacology [database online]. Tampa, FL: Elsevier; 2025. URL: www.clinicalkey.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	P&T Approval Date
Policy created	12.14.22	02.23
Added HCPCS code [J1941]	05.24.23	
1Q 2024 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.	11.06.23	02.24

Reviews, Revisions, and Approvals	Date	P&T Approval Date
RT4: removed specification of NYHA Class II or Class III from criteria per expanded FDA-approved indication; removed ascites from contraindications and revised dosage strength from 80 mg/mL to 80 mg/10 mL per PI.	08.22.24	
1Q 2025 annual review: no significant changes; added examples of extracellular volume expansion due to CHF; references reviewed and updated.	11.04.24	02.25
RT4: updated FDA indication and criteria to include CKD including nephrotic syndrome; added nephrologist as an option for the prescriber specialty requirement.	04.15.25	

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.