Clinical Policy: Furosemide (Furoscix)

Reference Number: PA.CP.PHAR.608
Effective Date: 01/2023
Last Review Date: 05/2025

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 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 PA Health & Wellness® 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. 160 mg (2 cartridge) per day;
   b. Total of 8 kits over 30 days*.
   **more than 8 kits in 30 days will be reviewed on a case-by-case basis.*

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

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Heart Failure of 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. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

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 – PA.CP.PMN.53.

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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
bumetanide (Bumex®)	0.5 to 2 mg orally per day	10 mg/day
Furosemide (Lasix®)	20 to 80 mg orally per day	600 mg/day
torsemide (Sooanz®)	10 to 20 mg orally per day	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; 2024. 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
Policy created	01/2023
1Q 2024 annual review: added HCPCS code [J1941]; 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.	01/2023
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.	09/2024
1Q 2025 annual review: no significant changes; added examples of extracellular volume expansion due to CHF; references reviewed and updated.	01/2025
RT4: updated FDA indication and criteria to include CKD including nephrotic syndrome; added nephrologist as an option for the prescriber specialty requirement.	05/2025