Pharmacy Policy Bulletin: J-1266 Furoscix (furosemide) – Commercial and Healthcare Reform	
Number: J-1266	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Injectable = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1266-004	**Original Date:** 12/07/2022
Effective Date: 04/25/2025	**Review Date:** 04/09/2025

Drugs Product(s):	• Furoscix (furosemide)
FDA-Approved Indication(s):	Treatment of edema in adult patients with chronic heart failure or chronic kidney disease, including the nephrotic syndrome.

Background:	• Furoscix is a novel on-body infusor to deliver furosemide for treatment of edema in adults with chronic heart failure or chronic kidney disease. Furoscix allows a patient to self-administer an injectable loop diuretic via the proprietary drug delivery system. It is the first and only FDA-approved subcutaneous loop diuretic for home use. • The on-body infusor delivers 30 mg of furosemide over the first hour, followed by 12.5 mg per hour for the subsequent 4 hours. While the furosemide is infusing, the patient should limit their activity until the administration is complete. • Furosemide, a loop diuretic, inhibits sodium and chloride resorption by competing with chloride for the Na+/K+/2CL- co-transporter in the ascending limb of the loop of Henle. It also inhibits the absorption of sodium and chloride in the proximal and distal tubules. • The subcutaneous infusion of Furoscix was shown to be equivalent to intravenous (IV) administration of furosemide. A clinical study showed that Furoscix demonstrated 99.6% bioavailability (90% confidence interval [CI]: 94.8%-104.8%). In addition, Furoscix resulted in an 8-hour urine output of 2.7 liters which was similar to those patients receiving IV furosemide. • Heart failure is a chronic, progressive condition in which the heart muscle is unable to pump enough blood to meet the body's needs for blood and oxygen. As a result, blood flow out of the heart slows and the blood returning to the heart through the veins backs up; this causes edema as fluid accumulates in the feet, arms, lungs, and other organs. In addition, the kidneys are less able to dispose of sodium and water, resulting in fluid retention in the tissues. The initial treatment for most patients with heart failure and volume overload is an oral loop

	diuretic in addition to a low sodium diet. IV loop diuretics, such as furosemide, are generally required for acute decompensated heart failure.
	• Chronic kidney disease (CKD) impairs the kidneys' ability to excrete sodium and water, leading to fluid overload. This, coupled with reduced albumin production resulting in decreased oncotic pressure, contributes to a shift of fluid from the intravascular space to the interstitial space. Edema develops as a consequence of both increased hydrostatic pressure and decreased oncotic pressure within the capillaries.
	• Furoscix may allow certain patients to receive treatment for edema outside of an acute hospital setting or an infusion center.
	• Prescribing Considerations:
	  ○ Furoscix is not for chronic use and should be replaced with oral diuretics as soon as possible.
	  ○ Furoscix is intended for use in a setting where the patient can limit their activity for the duration of administration.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Furoscix may be approved when all of the following criteria are met **(A. through F.)**:

A. The member is 18 years of age or older.

B. Furoscix is prescribed by or in consultation with a cardiologist.

C. The member meets one (1) of the following criteria **(1. or 2.)**:

1. The member has a diagnosis of heart failure (ICD-10: I50).

2. The member has a diagnosis of chronic kidney disease (ICD-10: N18) and/or nephrotic syndrome (ICD-10: N04).

D. The prescriber attests that the member has experienced a previous episode of edema and was treated with a parenteral loop diuretic.

E. The member has been receiving an oral loop diuretic (e.g., furosemide, bumetanide, torsemide) as part of their medication regimen.

F. The prescriber attests that treatment with oral diuretics will resume as soon as practical after discontinuation of Furoscix

.

II. Reauthorization

When a benefit, reauthorization of Furoscix may be approved when all of the following criteria is met **(A. through E.)**:

A. The prescriber attests that the member has used Furoscix for a previous episode of edema due to chronic heart failure or chronic kidney disease (including nephrotic syndrome), had a positive clinical result, and avoided hospitalization.

B. Furoscix is prescribed by or in consultation with a cardiologist.

C. The members meets one (1) of the following criteria **(1. or 2.)**:

1. The member continues to have a diagnosis of heart failure (ICD-10: I5).

2. The member has a diagnosis of chronic kidney disease (ICD-10: N18) and/or nephrotic syndrome (ICD-10: N04).

D. The member has been receiving an oral loop diuretic (e.g., furosemide, bumetanide, torsemide) as part of their medication regimen.

E. The provider attests that treatment with oral diuretics will be discontinued until transitioned back to oral diuretic maintenance therapy.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 6 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Furoscix [package insert]. Burlington, MA: scPharmaceuticals, Inc.; March 2025.
2. American Heart Association. What is Heart Failure? Available at: https://www.heart.org/en/health-topics/heart-failure/what-is-heart-failure#. Accessed November 6, 2023.
3. Furosemide [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; June 2023.
4. Clinical Pharmacology On-Line, Tampa, FL: Elsevier 2024. Accessed August 23, 2024.
5. scPharmaceuticals Inc. Update – scPharmaceuticals Announces FDA Approval of Furoscix (furosemide injection), the First and Only Self-Administered, Subcutaneous Loop Diuretic for the At-Home Treatment of Congestion in Chronic Heart Failure. Available at: https://scpharmaceuticalsinc.gcs-web.com/news-releases/news-release-details/scpharmaceuticals-announces-fda-approval-furoscixr-furosemide.. Accessed November 6, 2023.
6. scPharmaceuticals. News Release. scPharmaceuticals Announces FDA Approval of Supplemental New Drug Application Expanding the Furoscix Indication in Heart Failure. Available at: https://www.ir.scpharma.com/news-releases/news-release-details/scpharmaceuticals-announces-fda-approval-supplemental-new-drug. Accessed August 27, 2024.
7. Heidenreich PA, Bozkurt B, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure. *J Am Coll Cardiol.* 2022;79:e263-e421.