09-J4000-43

Original Effective Date: 03/15/23

Reviewed: 09/11/24

Revised: 10/15/24

Subject: Furosemide (Furoscix) subcutaneous infusion

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DESCRIPTION:

Heart failure is a chronic, progressive cardiac dysfunction resulting in reduced ejection fraction and cardiac output. Causes of heart failure include, but are not limited to, myocardial infarction, valvular heart disease, chronic systemic hypertension, and dilated cardiomyopathy, which can be idiopathic or the result of medications, alcohol use, infections, and/or genetics. Classical symptoms include dyspnea, fatigue, decreased exercise tolerance, orthopnea, paroxysmal nocturnal dyspnea, edema and weight gain with volume overload, and gastrointestinal symptoms including poor appetite, nausea, and bloating. It is estimated that the 30-day readmission rate for heart failure is approximately 25%. Additionally, the 5-year mortality rate is about 24.4% at age 60 years and 54.4% at age 80 years.

Management of heart failure typically includes a combination of a variety of pharmacologic agents such as an angiotensin receptor-neprilysin inhibitor (ARNI), angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARB), beta blockers, mineralocorticoid receptor antagonists, sodium-glucose cotransporter 2 (SGLT2) inhibitors, and diuretics. Diuretic administration is utilized for cases of fluid retention to alleviate congestion, improve symptoms, and prevent worsening heart failure. In acute situations, a non-oral route (i.e., intravenous, subcutaneous) for diuretics is preferred, as patient's gastrointestinal tract may become edematous resulting in poor absorption and reduced efficacy, necessitating a hospital admission for diuretic administration.

On October 10, 2022, the FDA approved furosemide (Furoscix) subcutaneous infusion for outpatient administration for congestion due to fluid overload in adults with NYHA Class II/III chronic heart failure. The approval was based on a bioavailability study compared with intravenous furosemide. Furosemide (Furoscix) 30 mg subcutaneously infused over 1 hour, followed by 12.5 mg/hour for the next 4 hours was 99.6% relative to intravenous furosemide (two 40-mg bolus doses separated by 2 hours) and produced a similar therapeutic diuresis. The most common adverse reactions associated with the furosemide (Furoscix) subcutaneous infusion were administration site and skin reactions such as erythema, bruising, edema, and infusion site pain.

POSITION STATEMENT:

Comparative Effectiveness

The FDA has deemed the drug(s) or biological product(s) in this coverage policy to be appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional). Therefore, coverage (i.e., administration) in a provider-administered setting such as an outpatient hospital, ambulatory surgical suite, physician office, or emergency facility is not considered medically necessary.

Initiation of furosemide (Furoscix) subcutaneous infusion **meets the definition of medical necessity** when **ALL** of the following are met:

1. The member has a diagnosis of chronic heart failure with congestion due to fluid overload
2. The member currently or previously received oral loop diuretic therapy (e.g., furosemide, bumetanide, torsemide) equivalent to a total daily oral furosemide dose of at least 40 to 160 mg for 4 weeks- medical record documentation must be submitted
3. The member does not have anuria, acute pulmonary edema, hepatic cirrhosis or ascites, or other conditions that require immediate hospitalization, or anticipated admission within 30 days
4. The medication is prescribed by or in consultation with a cardiologist
5. The member has been educated on safe administration and use with guidance on action steps for various parameters (e.g., blood pressure)
6. The dose does not exceed 160 mg subcutaneous in 24 hours (2 kits) and 8 kits per 30 days

Approval duration: 6 months

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved

- Furosemide (Furoscix) subcutaneous infusion is indicated for the treatment of congestion due to fluid overload in adults with chronic heart failure.
- The subcutaneous single-use, on-body infusor is pre-programed to deliver 30 mg of furosemide over the first hour then 12.5 mg per hour for the subsequent 4 hours.
- For administration load the prefilled cartridge into the on-body infusor and close the cartridge holder. Peel away the adhesive liner on the on-body infusor and apply onto a clean, dry area of the abdomen between the top of the beltline and the bottom of the ribcage that is not tender, bruised, red or indurated. The distance from the top of the beltline to the bottom of the ribcage should be at least 2 ½ inches. Start the injection by firmly pressing and releasing the blue start button. Do not remove until the injection is complete (signaled by the solid green status light, beeping sound, and the white plunger rod filling the cartridge window).
- The site of each subcutaneous administration should be rotated.

- Furosemide (Furoscix) subcutaneous infusion should be replaced with oral diuretics as soon as practical.
- Furosemide (Furoscix) subcutaneous infusion is not indicated for emergency situations, in patients with acute pulmonary edema, or for chronic use.

Dose Adjustments

- None

Drug Availability

- Injection: 80 mg per 10 mL in a single-dose prefilled cartridge co-packaged with a single-use on-body infusor.

PRECAUTIONS:

Boxed Warning

- None

Contraindications

- Anuria
- Hypersensitivity to furosemide or medical adhesives.
- Hepatic cirrhosis or ascites.

Precautions/Warnings

- **Fluid, Electrolyte, and Metabolic Abnormalities:** Monitor serum electrolytes, CO2, BUN, creatinine, glucose, and uric acid.
- **Worsening Renal Function:** Monitor for dehydration and azotemia.
- **Ototoxicity:** Avoid higher than recommended doses.
- **Acute Urinary Retention:** Monitor patients with symptoms of urinary retention.
- Incomplete Dosing: Fluid contact and certain patient movements during treatment may cause the On-body Infusor to prematurely terminate infusion. Ensure patients can detect and respond to alarms.

BILLING/CODING INFORMATION:

The following codes may be used to describe:

HCPCS Coding

J1941	Injection, furosemide (furoscix), 20 mg

ICD-10 Diagnosis Codes That Support Medical Necessity

I50.1-I50.9	Heart failure

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

DEFINITIONS:

None

RELATED GUIDELINES:

None

OTHER:

None

REFERENCES:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2023. URL www.clinicalpharmacilogy-ip.com Accessed 8/29/24.
2. DynaMed [database online]. Ipswich, MA: EBSCO Information Services.; 2023. URL http://www.dynamed.com. Accessed 1/27/23.
3. Furoscix (furosemide) subcutaneous infusion [package insert]. scPharmaceuticals, Inc., Burlington (MA): August 2024.
4. Micromedex Healthcare Series [Internet Database]. Greenwood Village, CO: Thomson Healthcare. Updated periodically. Accessed 8/29/24.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 09/11/24.

GUIDELINE UPDATE INFORMATION:

03/15/23	New Medical Coverage Guideline – Furosemide (Furoscix) subcutaneous infusion for the outpatient treatment of congestion due to fluid overload in patients with NYHA Class II/III chronic heart failure.

07/01/23	Revision: Added HCPCS code J1941 and deleted code J3490.
10/15/23	Review and revision to guideline consisting of updating the billing/coding and references.
10/15/24	Review and revision to the guideline consisting of revising the position statement to specify oral loop diuretic doses prior to subcutaneous furosemide and submission of medical documentation, removing the continuation criteria and updating the FDA indication to remove the NYHA Class II/III classification.