Original Effective Date: 02/25/2023
Current Effective Date: 01/31/2024
Last P&T Approval/Version: 01/31/2024
Next Review Due By: 01/2025
Policy Number: C24669-A

Furoscix (furosemide injection)

PRODUCTS AFFECTED

Furoscix (furosemide injection)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Congestion due to fluid overload

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. CONGESTION DUE TO FLUID OVERLOAD:
   1. Documentation of diagnosis for NYHA Class II or III chronic heart failure with history of congestion due to fluid overload (acute decompensation)
      AND
   2. Documentation member is currently on loop diuretic therapy
      AND

3. Provider attestation member has been evaluated for the following metrics and the member is suitable for at-home treatment: stable oxygen saturation, respiratory rate, resting heart rate, systolic blood pressure, estimated creatinine clearance of >30 mL/min and no evidence of renal failure
   AND
4. Prescriber attestation that member is or will be enrolled with a care or case management program for at-home monitoring by a health care professional
   AND
5. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Furoscix (furosemide injection) include: anuria, a history of hypersensitivity to furosemide or medical adhesives, hepatic cirrhosis or ascites]
   AND
6. Prescriber attests member and/or member's caregiver has been provided counseling and education on preparation, use and disposal of the on-body infusor device.

CONTINUATION OF THERAPY:

A. CONGESTION DUE TO FLUID OVERLOAD:

1. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
2. Documentation of medical record of response and number of doses utilized from last acute decompensation episode [DOCUMENTATION REQUIRED]
   AND
3. Provider attestation member has been evaluated (within last 30 days) for the following metrics and the member is suitable for continued at-home treatment: stable oxygen saturation, respiratory rate, resting heart rate, systolic blood pressure, estimated creatinine clearance of >30 mL/min and no evidence of renal failure
   AND
4. Prescriber attestation that member is or will continue to be enrolled with a care or case management program for at-home monitoring by a health care professional

DURATION OF APPROVAL:

Initial authorization: 1 month, Continuation of Therapy: 1 month

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified cardiologist or provider trained in managing acute decompensated heart failure [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

Up to 10 single use kits per dispense
NOTE: the number of Furoscix doses required to meet desired diuresis requirements will vary on a patient-by-patient basis per acute decompensation episode

PLACE OF ADMINISTRATION:

The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous

DRUG CLASS:
Loop Diuretics

FDA-APPROVED USES:
Indicated for the treatment of congestion due to fluid overload in adults with NYHA Class II/III chronic heart failure.
Limitations 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.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Furoscix is a pH-neutral formulation of furosemide designed for SC injection via a wearable, single-use, preprogrammed on-body infusor (OBI), for outpatient self-administration.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Furoscix (furosemide injection) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Furoscix (furosemide injection) include: anuria, hypersensitivity to furosemide or medical adhesives, hepatic cirrhosis or ascites.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J1941	Injection, furosemide (Furoscix), 20 mg

AVAILABLE DOSAGE FORMS:
Furoscix CTKT 80MG/10ML

REFERENCES

1. Furoscix (furosemide injection), for subcutaneous use [prescribing information]. Burlington, MA: scPharmaceuticals, Inc.; October 2023.
2. Buckley LF, et al. Intravenous diuretic therapy for the management of heart failure and volume overload in a multidisciplinary outpatient unit. JACC Heart Fail. 2016;4(1):1–8.

doi:10.1016/j.jchf.2015.06.017
3. Eapen ZJ, et al. Back to the future with intravenous diuretics: reinvigorating an old treatment through new care settings. JACC Heart Fail. 2016;4(1):9–11. doi:10.1016/j.jchf.2015.07.016
4. Farless LB, et al. Intermittent subcutaneous furosemide: parenteral diuretic rescue for hospice patients with congestive heart failure resistant to oral diuretic. Am J Hosp Palliat Care. 2013;30(8):791–792. doi:10.1177/1049909112465795
5. Felker GM, et al; Heart Failure Clinical Research Network Investigators. Loop diuretics in acute decompensated heart failure: necessary? Evil? A necessary evil? Circ Heart Fail. 2009;2(1):56–62. doi:10.1161/CIRCHEARTFAILURE.108.821785
6. Francis GS, et al. Furosemide reimagined: novel subcutaneous formulation for a 50-year-old loop diuretic agent for the treatment of acute decompensated heart failure. JACC Heart Fail. 2018;6(1):71–72. doi:10.1016/j.jchf.2017.10.005
7. Gheorghiade M, et al. Acute heart failure syndromes: current state and framework for future research. Circulation. 2005;112(25):3958–3968. doi:10.1161/CIRCULATIONAHA.105.59009120
8. Joseph SM, et al. Acute decompensated heart failure: contemporary medical management [published correction appears in Tex Heart Inst J. 2010;37(1):135. Dosage error in article text]. Tex Heart Inst J. 2009;36(6):510–520. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2801958/
9. Ng KT, et al. Continuous infusion vs. intermittent bolus injection of furosemide in acute decompensated heart failure: systematic review and meta-analysis of randomised controlled trials. Anaesthesia. 2018;73(2):238–247. doi:10.1111/anae.14038
10. Njoroge JN, et al. Pathophysiology and therapeutic approaches to acute decompensated heart failure. Circ Res. 2021;128(10):1468–1486. doi:10.1161/CIRCRESAHA.121.318186
11. Sica DA, et al. Subcutaneous furosemide in heart failure: pharmacokinetic characteristics of a newly buffered solution. JACC Basic Transl Sci. 2018;3(1):25–34. doi:10.1016/j.jacbts.2017.10.001
12. Smith SC Jr, et al. Measuring and improving the quality of heart failure care globally. JAMA Netw Open. 2020;3(1):e1918642. doi:10.1001/jamanetworkopen.2019.18642
13. Tashtish N, et al. Length of stay and hospital charges for heart failure admissions in the United States: analysis of the national inpatient sample. J Cardiac Failure. 2017;23(8):S59. doi:10.1016/j.cardfail.2017.07.166
14. Urbich, M, et al. A systematic review of medical costs associated with heart failure in the USA (2014–2020). Pharmacoeconomics. 2020;38(11):1219–1236. doi:10.1007/s40273-020-00952-0

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Contraindications/Exclusions/ Discontinuation References	Q1 2024
NEW CRITERIA	Q1 2023