

## Furoscix (furosemide) 8mg/1mL Solution for injection [On-Body Infusor]

### Disclaimer

*Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.*

*Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.*

### Summary

Chronic heart failure (CHF) is a common yet complex clinical syndrome. It affects millions of people every year and can be a debilitating condition. CHF is a progressive disorder of the heart characterized by an inability of the heart to pump enough blood to meet the needs of the body. This results in symptoms such as shortness of breath, fatigue, and edema. Treatment of CHF is multifactorial and includes lifestyle modifications, pharmacologic interventions, and device therapy.

Fluid overload is a common problem in patients with NYHA Class II and III chronic heart failure and can lead to increased morbidity and mortality if not properly managed. Treatment of fluid overload in these patients involve a combination of non-pharmacological and pharmacological measures. Pharmacological measures include the use of Angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor neprilysin inhibitor (ARNIs), beta-blockers, loop diuretics, and thiazide diuretics. These medications can help reduce fluid overload and improve symptoms. In addition, aldosterone antagonists may also be used if other measures are inadequate.

Furoscix (furosemide) is indicated for the treatment of congestion due to fluid overload in adult patients with New York Heart Association (NYHA) Class II and Class III chronic heart failure.

- Furoscix is not indicated for use in emergency situations or in patients with acute pulmonary edema.

- The product is supplied in a single-dose prefilled cartridge for subcutaneous infusion co-packaged with the On-body Infusor. Each single-use on-body infusor with a prefilled cartridge is designed to deliver 80 mg of Furoscix in 10 mL solution over 5-hours.

## Definitions

“Anuria” is a medical term used to describe a condition in which a person's kidneys stop producing urine, or produce very little urine. Specifically, anuria is defined as the production of less than 50 milliliters of urine per day in adults.

“Ascites” is a medical condition in which fluid accumulates in the abdominal cavity, causing abdominal swelling and discomfort. Ascites can be a complication of a variety of underlying health problems, including liver disease, heart failure, and certain types of cancer.

“Chronic heart failure (CHF)” is a medical condition in which the heart is unable to pump enough blood to meet the body's needs. It occurs when the heart muscle is weakened or damaged, resulting in decreased blood flow to the organs and tissues. CHF can be caused by a variety of factors, including coronary artery disease, hypertension, heart valve disease, and cardiomyopathy.

“Cirrhosis” is a chronic liver disease that results from damage to liver cells and the formation of scar tissue in the liver. This can lead to a variety of symptoms and complications, including jaundice, fatigue, fluid retention, and an increased risk of liver cancer.

“Diuretic” is a medication that promotes the excretion of excess water and salt from the body through the kidneys, thereby increasing urine output. Diuretics are commonly used to treat conditions such as high blood pressure, heart failure, and edema. Diuretics can be classified into several categories based on their mechanism of action, such as loop diuretics, thiazide diuretics, potassium-sparing diuretics, and osmotic diuretics.

“Edema” refers to the swelling of the body's tissues, typically due to the accumulation of excess fluid. In the context of heart failure, edema often occurs in the legs, ankles, and feet, but it can also affect the abdomen, lungs, and other parts of the body. Edema is caused by an imbalance in the body's fluid levels, which can result from the heart's inability to pump blood effectively.

“Parenteral” is a term used to describe medications or nutrients that are delivered into the body through non-oral routes, such as injection or infusion. This is in contrast to enteral administration, which involves delivering medications or nutrients through the digestive system, such as by mouth or through a feeding tube.

“The New York Heart Association (NYHA) classification system” is used to assess the severity of heart failure symptoms. It is based on a patient's ability to carry out physical activity without experiencing symptoms such as shortness of breath or fatigue. The NYHA classification system has four stages:

- NYHA class I: No limitation of physical activity. Ordinary physical activity does not cause symptoms of heart failure.
- NYHA class II: Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in symptoms of heart failure.
- NYHA class III: Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes symptoms of heart failure.
- NYHA class IV: Unable to carry out any physical activity without symptoms of heart failure, or symptoms of heart failure at rest.

### Medical Necessity Criteria for Authorization

The Plan considers Furoscix (furosemide injection) medically necessary when ALL of the following criteria are met:

1. The member is 18 years of age or older; *AND*
2. The member has New York Heart Association (NYHA) Class II or Class III chronic heart failure; *AND*
3. The medication is being used for the treatment of congestion due to fluid overload; *AND*
4. The member has been taking an oral loop diuretic (i.e., furosemide, torsemide, bumetanide) at an optimized dose; *AND*
5. The medication is being used for the short-term management of acute episodes of edema and NOT for long-term management; *AND*
6. The member is an appropriate candidate for parenteral diuresis outside of the hospital, defined as all the following:
  - a. Documentation of ALL of the following:
    - i. Oxygen saturation  $\geq$  90% on exertion; *and*
    - ii. Respiratory Rate  $<$  24 breaths per minute; *and*
    - iii. Resting Heart Rate  $<$  100 beats per minute; *and*
    - iv. Systolic Blood Pressure  $>$  100 mmHg; *and*
  - b. The member does NOT have documentation of ANY of the following:
    - i. Anuria (urine output  $<$ 50 mL/day); *or*
    - ii. History of hypersensitivity to furosemide or medical adhesives; *or*
    - iii. Hepatic cirrhosis or ascites; *or*
    - iv. Presence of a complicating condition that requires immediate hospitalization or anticipated hospitalization in the next 30 days; *AND*
7. The medication is being prescribed for use within ONE of the following Plan's Quantity Limit:
  - a. 5 kits per 3 months; *or*

- b. 10 Furoscix kits per 3 months AND a valid clinical rationale is provided demonstrating medical necessity; AND
- 8. Recent (within the last 3 months) clinical chart documentation is provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met, the requested medication will be approved for 3 months.

#### Experimental or Investigational / Not Medically Necessary

Furoscix (furosemide injection) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. This includes but are not limited to:

- 1. for chronic use. Furoscix is not for chronic use and should be replaced with oral diuretics as soon as practical.
- 2. for the management of hypertension.
- 3. for use in emergency situations.
- 4. in patients with hepatic cirrhosis.
- 5. in the management of edema associated with nephrotic syndrome.
- 6. in the treatment of acute pulmonary edema.
- 7. in the treatment of hypertensive crises.
- 8. to increase renal excretion of calcium in patients with hypercalcemia.

#### Applicable Billing Codes (HCPCS/CPT Codes)

CPT/HCPCS Codes considered medically necessary if criteria are met:	
<i>Code</i>	<i>Description</i>
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
J1941	Injection, furosemide (furoscix), 20 mg
ICD-10 codes considered medically necessary if criteria are met:	
<i>Code</i>	<i>Description</i>
I50.1	Left ventricular failure
I50.20	Unspecified systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.30	Unspecified diastolic (congestive) heart failure

I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.9	Heart failure, unspecified
ICD-10 codes that are not covered for indications specified in the Clinical Guideline	
I50.21	Acute systolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure

## References

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[Clinical Guideline Revision / History Information](#)

Original Date: 3/23/2023

Reviewed/Revised: 10/27/2023, 3/21/2024