

## Lasix ONYU (furosemide injection)

### 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.*

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### 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 New York Heart Association (NYHA) Class II-IV 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 oxygen demand on the heart, reduce fluid overload and improve symptoms. In addition, aldosterone antagonists may also be used if other measures are inadequate.

Lasix ONYU is a loop diuretic indicated for the treatment of edema in adult patients with chronic heart failure.

- Lasix ONYU is intended for outpatient treatment as an on-body "infusor" (patch pump).
- Each single-use on-body infusor contains 80 mg of Furoscix (furosemide) per 2.67 mL single-dose prefilled cartridge. It is designed to deliver a pre-programmed dose of 30 mg of Lasix ONYU over the first hour followed by 12.5 mg per hour for the subsequent 4 hours (for a total of 80 mg per day). Administer Lasix ONYU once or twice daily as needed for edema.
- Lasix ONYU is not for chronic use and should be replaced with oral diuretics as soon as practical.
- The On-body Infusor should not be allowed to get wet from water or any other fluids (blood or drug product). Fluid contact with the circuit board can lead to device errors and premature termination of infusion. The On-body Infusor is intended for use in a setting where the individual can limit their activity for the duration of administration. Certain movements may cause interruption of device adherence to skin and premature termination of infusion.
- The On-body Infusor for Lasix ONYU should only be used in those who can detect and respond to alarms to ensure a complete dose is administered.
- The Infusor consists of a custom Reusable Unit which can be used for close to 50 treatments. The Reusable Unit is used with a Disposable Unit and single-dose prefilled cartridge which are provided together for the user as a Lasix ONYU Kit. The Disposable Unit must be discarded after use.
- Monitor serum electrolytes, CO<sub>2</sub>, BUN, creatinine, glucose, and uric acid.

### Definitions

"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, kidney disease, 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 demands. It occurs when the heart muscle is weakened or damaged or if the heart

does not relax and fill properly, 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 resulting from different etiologies including infection.

“Diuretic” is a medication that promotes the excretion of salt and excess water from the body through the kidneys, thereby increasing urine output. Diuretics are commonly used to treat conditions such as volume overload, ascites, anasarca, heart disease, and high blood pressure. 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.

“Documentation” refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

“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.

“No evidence of” indicates that the reviewer has not identified any records of the specified item or condition within the submitted materials or claims history. In the absence of such evidence, the member is considered eligible. If any evidence of the item or condition is present upon review of the request, the member does not qualify.

“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.

“[s]” indicates state mandates may apply.

## Clinical Indications

### Medical Necessity Criteria for Clinical Review

General Medical Necessity Criteria

General Indication-Specific Criteria

#### Edema in those with Chronic Heart Failure

The Plan considers Lasix ONYU (furosemide injection) medically necessary when ALL of the following criteria are met for the applicable indication listed below:

1. The member is 18 years of age or older; *AND*
2. The member has 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 meets ALL of the following:
    - i. No evidence of anuria (urine output  $< 50$  mL/day); *or*
    - ii. No evidence of a history of hypersensitivity to furosemide or medical adhesives; *or*
    - iii. No evidence 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. 1 starter kit per 12 months; *or*
  - b. 5 kits per 3 months; *or*

- c. 10 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 up to 3 months.<sup>[s]</sup>

**Experimental or Investigational / Not Medically Necessary**<sup>[s]</sup>

Lasix ONYU (furosemide injection) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- For chronic use. Lasix ONYU is not approved for chronic use and should be replaced with oral diuretics as soon as practical.
- Use for the management of hypertension.
- Use for the management of hepatic cirrhosis.
- Use for the treatment of acute pulmonary edema.
- Use for the treatment of hypertensive crises.
- Use for the treatment of hypercalcemia.

**Applicable Billing Codes**

Table 1	
CPT/HCPCS codes considered medically necessary if criteria are met:	
<i>Code</i>	<i>Description</i>
C9399	Lasix Onyu Unclassified drugs or biologicals
J3490	Lasix Onyu Unclassified drugs

Table 2	
ICD-10 diagnosis codes considered medically necessary with Table 1 (CPT/HCPCS) codes if criteria are met:	
<i>Code</i>	<i>Description</i>
I50.1	Left ventricular failure, unspecified

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ICD-10 diagnosis codes considered medically necessary with Table 1 (CPT/HCPCS) codes if criteria are met:	
<i>Code</i>	<i>Description</i>
I50.20	Unspecified systolic (congestive) heart failure
I50.21	Acute 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
I50.31	Acute 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
I50.41	Acute 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
I50.810	Right heart failure, unspecified
I50.811	Acute right heart failure
I50.812	Chronic right heart failure
I50.813	Acute on chronic right heart failure
I50.814	Right heart failure due to left heart failure
I50.82	Biventricular heart failure
I50.83	High output heart failure
I50.84	End stage heart failure
I50.89	Other heart failure
I50.9	Heart failure, unspecified

Table 2	
ICD-10 diagnosis codes considered medically necessary with Table 1 (CPT/HCPCS) codes if criteria are met:	
<i>Code</i>	<i>Description</i>
N18.9	Chronic kidney disease, unspecified
R60.9	Edema, unspecified

## References

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Clinical Guideline Revision / History Information

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