

Novel Loop Diuretic Formulations

Policy # 00832

Original Effective Date: 03/13/2023

Current Effective Date: 04/01/2026

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Furoscix®

Based on review of available data, the Company may consider Furoscix®[†] (furosemide) to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Furoscix (furosemide) will be considered when the following criteria are met:

- Patient meets ONE of the following:
 - Patient has a diagnosis of chronic heart failure; OR
 - Patient has a diagnosis of chronic kidney disease; AND
 - Patient has edema; AND
 - Patient weighs greater than or equal to 43 kg; AND
 - Patient is on background oral diuretic therapy, which includes either furosemide, bumetanide, or torsemide; AND
- (Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient meets the following:
 - For adult patients:
 - Patient is stable and suitable for at-home treatment with parenteral diuresis as evidenced by ALL of the following:
 - ❖ Patient's oxygen saturation is greater than or equal to 90% on exertion; AND
 - ❖ Patient's respiratory rate is less than 24 breaths per minute; AND

Novel Loop Diuretic Formulations

Policy # 00832

Original Effective Date: 03/13/2023

Current Effective Date: 04/01/2026

- ❖ Patient's resting heart rate is less than 100 beats per minute; AND
- ❖ Patient's systolic blood pressure is greater than 100 mm Hg; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient has a creatinine clearance that is greater than or equal to 30 ml/min OR an estimated glomerular filtration rate of greater than 20 mL/min/1.73 m²; OR
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- For pediatric patients:
 - Patient's vital signs are within age-appropriate parameters, and the patient is clinically stable for home administration; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
 - Patient's kidney function is assessed using an age appropriate pediatric eGFR method (e.g., Schwartz based) and deemed adequate for safe administration; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient's fluid and electrolyte status will be assessed before therapy with Furoscix and monitored frequently for the duration of therapy and after treatment with Furoscix; AND
- Patient does not have any conditions such as acute pulmonary edema or hepatic cirrhosis that require immediate hospitalization or admission within 30 days; AND
- Treatment with oral diuretics will be discontinued during administration of Furoscix until patient is transitioned back to oral diuretic maintenance therapy; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient/caregiver has demonstrated understanding of how to properly use the device; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient has an adequate at home environment for at-home administration, such as in a setting where patient can limit their activity for the duration of administration.
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Furoscix (furosemide) when the following criteria are not met to be **not medically necessary**.**

- Patient is on background oral diuretic therapy, which includes either furosemide, bumetanide, or torsemide

Novel Loop Diuretic Formulations

Policy # 00832

Original Effective Date: 03/13/2023

Current Effective Date: 04/01/2026

- For adult patients: Patient is stable and suitable for at-home treatment with parenteral diuresis as evidenced by ALL of the following:
 - Patient's oxygen saturation is greater than or equal to 90% on exertion; AND
 - Patient's respiratory rate is less than 24 breaths per minute; AND
 - Patient's resting heart rate is less than 100 beats per minute; AND
 - Patient's systolic blood pressure is greater than 100 mm Hg
- For adult patients: Patient has a creatinine clearance that is greater than or equal to 30 ml/min OR an estimated glomerular filtration rate of greater than 20 mL/min/1.73 m²
- For pediatric patients: Patient's vital signs are within age-appropriate parameters, and the patient is clinically stable for home administration
- For pediatric patients: Patient's kidney function is assessed using an age appropriate pediatric eGFR method (e.g., Schwartz based) and deemed adequate for safe administration
- Treatment with oral diuretics will be discontinued during administration of Furoscix until patient is transitioned back to oral diuretic maintenance therapy
- Patient/caregiver has demonstrated understanding of how to properly use the device
- Patient has an adequate at home environment for at-home administration, such as in a setting where patient can limit their activity for the duration of administration

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers Furoscix (furosemide) for any indication other than edema secondary to chronic heart failure or chronic kidney disease to be **investigational**.*

Based on review of available data, the Company considers Furoscix (furosemide) when the patient selection criteria are not met (EXCEPT those denoted as **not medically necessary****) to be **investigational**.*

Enbumyst™

Based on review of available data, the Company may consider Enbumyst™[‡] (bumetanide spray) to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Enbumyst (bumetanide spray) will be considered when the following criteria are met:

- Patient has edema due to the following:
 - Congestive heart failure; OR
 - Hepatic disease; OR
 - Renal disease; AND
- Patient is 18 years of age or older; AND
- Requested drug will be for short-term and non-chronic use; AND

Novel Loop Diuretic Formulations

Policy # 00832

Original Effective Date: 03/13/2023

Current Effective Date: 04/01/2026

- Patient is stable and suitable for at-home treatment with Enbumyst; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient is on background oral diuretic therapy, which includes either furosemide, bumetanide, or torsemide; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Treatment with oral diuretics will be discontinued during administration of Enbumyst until patient is transitioned back to oral diuretic maintenance therapy; AND
- Patient's fluid and electrolyte status will be assessed before therapy with Enbumyst and monitored frequently for the duration of therapy and after treatment with Enbumyst; AND
- Patient does not have significant nasal mucosal or structural abnormalities, such as acute episodes of rhinitis or congestion due to any cause; AND
- Patient does not have anuria or evidence of hepatic coma.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Enbumyst (bumetanide spray) when the following criteria are not met to be **not medically necessary.****

- Patient is stable and suitable for at-home treatment with Enbumyst
- Patient is on background oral diuretic therapy, which includes either furosemide, bumetanide, or torsemide

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers Enbumyst (bumetanide spray) for any indication other than edema secondary to congestive heart failure, hepatic disease or renal disease to be **investigational.***

Based on review of available data, the Company considers Enbumyst (bumetanide spray) when the patient selection criteria are not met (EXCEPT those denoted as **not medically necessary****) to be **investigational.***

Lasix® ONYU

Based on review of available data, the Company may consider Lasix^{TM†} ONYU (furosemide) to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Lasix ONYU (furosemide) will be considered when the following criteria are met:

- Patient has a diagnosis of chronic heart failure; AND
- Patient has edema; AND

Novel Loop Diuretic Formulations

Policy # 00832

Original Effective Date: 03/13/2023

Current Effective Date: 04/01/2026

- Patient is 18 years of age or older; AND
- Requested drug will be for short-term and non-chronic use; AND
- Patient is on background oral diuretic therapy, which includes either furosemide, bumetanide, or torsemide; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Treatment with oral diuretics will be discontinued during administration of Lasix ONYU until patient is transitioned back to oral diuretic maintenance therapy; AND
- Patient is stable and suitable for at-home treatment with Lasix ONYU; AND
- Patient has an adequate at home environment for at-home administration, such as in a setting where patient can limit their activity for the duration of administration; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient's fluid and electrolyte status will be assessed before therapy with Lasix ONYU and monitored frequently for the duration of therapy and after treatment with Lasix ONYU; AND
- Patient does not have anuria, hepatic cirrhosis or ascites, or a hypersensitivity to medical adhesives; AND
- Patient has demonstrated understanding of how to properly use the device.
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Lasix ONYU (furosemide) when the following criteria are not met to be **not medically necessary**.**

- Patient is on background oral diuretic therapy, which includes either furosemide, bumetanide, or torsemide
- Patient has an adequate at home environment for at-home administration, such as in a setting where patient can limit their activity for the duration of administration
- Patient has demonstrated understanding of how to properly use the device.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers Lasix ONYU (furosemide) for any indication other than edema secondary to chronic heart failure to be **investigational**.*

Based on review of available data, the Company considers Lasix ONYU (furosemide) when the patient selection criteria are not met (EXCEPT those denoted as **not medically necessary****) to be **investigational**.*

Policy # 00832

Original Effective Date: 03/13/2023

Current Effective Date: 04/01/2026

Background/Overview

Furoscix is a loop diuretic that is indicated for the treatment of edema in pediatric patients weighing 43 kg and above and in adults with chronic heart failure or chronic kidney disease. It was the first loop diuretic to be approved in a subcutaneous (SC) formulation. It is available as a single use on-body infusor with a prefilled cartridge that is pre-programmed to deliver 30 mg of furosemide subcutaneously over one hour, followed by 12.5 mg per hour for four hours to deliver a total of 80 mg over 5 hours. Lasix ONYU is a second subcutaneous formulation of furosemide approved for the treatment of edema in adult patients with chronic heart failure. It's administered through an Infusor containing single-dose prefilled cartridges which deliver 30 mg of Lasix ONYU over the first hour followed by 12.5 mg per hour for the subsequent 4 hours. Lasix ONYU can be administered once or twice daily as needed for edema. The package inserts for both drugs state that they are intended for use in a setting where the patient can limit their activity for the duration of administration. A third loop diuretic with a novel delivery mechanism, Enbumyst, was approved for the treatment of edema associated with congestive heart failure, hepatic and renal disease, including nephrotic syndrome in adults. Enbumyst is a nasal spray containing 0.5 mg of bumetanide per unit dose. The usual total daily dosage of Enbumyst is 0.5 mg to 2 mg once daily. The number of nasal spray devices needed for a single dose depends upon the prescribed dose. Dosage is individualized based on patient response up to a maximum dose of 2 mg/day. These drugs are not indicated in emergency situations and should not be given in patients with acute pulmonary edema, anuria, or hepatic cirrhosis. Patients using Furoscix, Lasix ONYU, or Enbumyst should be transitioned back to oral loop diuretics as soon as feasible as they are not indicated for chronic use. Furoscix, Lasix ONYU, and Enbumyst are not specifically mentioned in guidelines at the time this policy was written, but the American College of Cardiology/American Heart Association (2022) states that loop diuretics (i.e., furosemide, bumetanide, and torsemide) are the preferred diuretic agents for use in most patients with heart failure. Furosemide is the most common loop diuretic to be used, but it is key to note that some patients may respond more favorably to other agents in this class and therapy is often individualized for patients with acutely decompensated heart failure. Furoscix and Lasix ONYU were approved via a 505(b)(2) pathway and relied upon existing data with furosemide injection. Although the trials involving these drugs were very small, they showed similar efficacy between intravenous (IV) and SC furosemide. Similarly, Enbumyst's approval was based on proven statistical bioequivalence to oral bumetanide. Though IV loop diuretics are the primary therapy for patients with acute decompensated heart failure, Furoscix and Lasix ONYU may find their place in therapy to prevent patients from having to be treated in an acute hospitalized setting, thus decreasing the number of heart failure related hospitalizations. In addition, Enbumyst offers a non-invasive alternative that bypasses gastrointestinal absorption and may serve as rescue therapy in ambulatory settings, although its effectiveness depends on proper intranasal administration.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Furoscix is indicated for the treatment of congestion due to fluid overload in adults with NYHA Class II/III chronic heart failure. In 2024, the FDA expanded the approval of Furoscix to include treatment of congestion due to fluid overload in adult patients with chronic heart failure, regardless of NYHA functional class. In August 2025, the approval was further expanded to include adult

Novel Loop Diuretic Formulations

Policy # 00832

Original Effective Date: 03/13/2023

Current Effective Date: 04/01/2026

patients with chronic kidney disease. Additionally, the wording of the indication was updated to the treatment of edema in adult patients with chronic heart failure or chronic kidney disease, including the nephrotic syndrome. In December 2025, the FDA granted additional approval for use in pediatric patients weighing 43 kg and above.

Enbumyst is indicated for the treatment of edema associated with congestive heart failure, hepatic and renal disease, including nephrotic syndrome in adults.

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

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

The purpose of this policy is to ensure that Furoscix, Enbumyst and Lasix ONYU are being used per their FDA approved indication given the limited data defining which patients may benefit most from therapy. It is also intended to ensure safe and appropriate use of Furoscix, Enbumyst and Lasix ONYU given the unique route of self-administration for these drugs.

References

1. Furoscix [package insert]. scPharmaceuticals, Inc. Burlington, Massachusetts. Updated August 2025.
2. Furoscix for the Treatment of Congestion in Chronic Heart Failure. Rx Insights: Cardiovascular IPD Analytics. Published November 2022.
3. Furoscix (furosemide subcutaneous injection by on-body infusor-scPharmaceuticals). Drug Evaluation. Express Scripts. November 2022.
4. Enbumyst [package insert]. Corstasis USA, LLC. Henderson, NV. Updated September 2025.
5. Lasix ONYU [package insert]. SQ Innovation, Inc. Burlington, Massachusetts. Updated October 2025.

Policy History

Original Effective Date: 03/13/2023

Current Effective Date: 04/01/2026

02/02/2023 Medical Policy Committee review

02/08/2023 Medical Policy Implementation Committee approval. New policy.

02/01/2024 Medical Policy Committee review

02/14/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

02/06/2025 Medical Policy Committee review

Novel Loop Diuretic Formulations

Policy # 00832

Original Effective Date: 03/13/2023

Current Effective Date: 04/01/2026

- 02/12/2025 Medical Policy Implementation Committee approval. Updated criteria to reflect expanded indication to include treatment of congestion due to fluid overload in adult patients with chronic heart failure, regardless of NYHA functional class per the updated FDA package insert. Also, removed ascites as a contraindicated condition.
- 11/06/2025 Medical Policy Committee review
- 11/12/2025 Medical Policy Implementation Committee approval. Updated criteria to reflect expanded indication to include adult patients with chronic kidney disease per the updated FDA package insert. In addition, the wording “congestion due to fluid overload” as part of the indication was replaced with “edema” as per the updated package insert.
- 03/05/2026 Medical Policy Committee review
- 03/11/2026 Medical Policy Implementation Committee approval. Updated Furoscix criteria to reflect expanded indication in pediatric patients weighing at least 43 kg. Added new drugs Enbumyst and Lasix ONYU to the policy with relevant criteria. Title changed from “Furoscix (furosemide)” to “Novel Loop Diuretic Formulations”.

Next Scheduled Review Date: 03/2027

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

Novel Loop Diuretic Formulations

Policy # 00832

Original Effective Date: 03/13/2023

Current Effective Date: 04/01/2026

- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan’s authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan’s pharmacy benefit.