

PRIOR AUTHORIZATION POLICY

POLICY: Diuretic – Enbumyst Prior Authorization with Step Therapy Policy

- Enbumyst™ (bumetanide nasal spray – Corstasis)

REVIEW DATE: 01/14/2026

OVERVIEW

Enbumyst, a loop diuretic, indicated for the **treatment of edema** associated with congestive heart failure, hepatic disease, and renal disease, including the nephrotic syndrome, in adults.¹

Enbumyst is not intended for chronic use and should be replaced with oral diuretics as soon as practical.¹ There is no information provided in the Enbumyst prescribing information regarding repeat use.

Pharmacokinetic Data

There are no clinical efficacy data with Enbumyst.¹ Enbumyst was evaluated in one Phase I, pharmacokinetic/pharmacodynamic, open-label, randomized, controlled crossover study of healthy adults.² The primary endpoint was statistical bioequivalence. In this published study (n = 68), Enbumyst met statistical bioequivalence to oral bumetanide for key measures including maximum concentration and area under the concentration-time curve. Enbumyst had a median time to maximum concentration of 1 hour compared with a median of 1.5 hours for the oral formulation.

Guidelines

Enbumyst as a nasal spray is not yet addressed in any guideline. There are no dedicated guidelines for the management of edema; treatment depends on the underlying cause. For conditions such as heart failure, cirrhosis, and renal disease, guidelines recommend a multifaceted approach that includes loop diuretics. The American Heart Association/American College of Cardiology/Heart Failure Society of America heart failure guideline (2022) supports diuretic use as needed for heart failure with preserved and reduced ejection fraction, without preference for a specific agent.³ The American College of Gastroenterology recommends diuretics for edema associated with hepatic disease, typically furosemide and spironolactone, although bumetanide is also listed as an alternative.⁴ Similarly, the Kidney Disease Improving Global Outcomes guideline for glomerular diseases (2021) lists loop diuretics as first-line for treatment, noting that torsemide and bumetanide may offer more consistent bioavailability compared with furosemide in patients with heart failure.⁵

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Enbumyst. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Enbumyst as well as the monitoring required for adverse events and long-term efficacy, approval requires Enbumyst to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Enbumyst is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Heart Failure.** Approve for 1 month if the patient meets ALL of the following (A, B, C and D):
 - A) Patient is \geq 18 years of age; AND
 - B) According to the prescriber, patient has edema; AND
 - C) Patient has tried an oral loop diuretic; AND
Note: Examples of oral loop diuretics include oral bumetanide, oral torsemide, and oral furosemide.
 - D) Medication is prescribed by or in consultation with a cardiologist.

2. **Hepatic Disease.** Approve for 1 month if the patient meets ALL of the following (A, B, C and D):
 - A) Patient is \geq 18 years of age; AND
 - B) According to the prescriber, patient has edema; AND
 - C) Patient has tried an oral loop diuretic; AND
Note: Examples of oral loop diuretics include oral bumetanide, oral torsemide, and oral furosemide.
 - D) Medication is prescribed by or in consultation with a gastroenterologist.

3. **Renal Disease.** Approve for 1 month if the patient meets ALL of the following (A, B, C and D):
Note: Renal disease includes nephrotic syndrome.
 - A) Patient is \geq 18 years of age; AND
 - B) According to the prescriber, patient has edema; AND
 - C) Patient has tried an oral loop diuretic; AND
Note: Examples of oral loop diuretics include oral bumetanide, oral torsemide, and oral furosemide.
 - D) Medication is prescribed by or in consultation with a nephrologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Enbumyst is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Enbumyst™ nasal spray [prescribing information]. Henderson, NV: Corstasis; September 2025.
2. Ambrosy AP, Bensihon D, Bernstein G, et al. Randomized study comparing a novel intranasal formulation of bumetanide with oral and intravenous formulations. *Circulation*. 2025;151(10):737-740.
3. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA guideline for the management of heart failure: executive summary: a report of the American College of Cardiology/American Heart Association joint committee on clinical practice guidelines. *Circulation*. 2022;145:e876-e894.
4. American College of Gastroenterology. Ascites: a common problem in people with cirrhosis. Available at: <https://gi.org/topics/ascites/>. Accessed on September 18, 2025.
5. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 clinical practice guideline for the management of glomerular diseases. *Kidney Int*. 2021;100(4):S1-S276.

HISTORY

Type of Revision	Summary of Changes	Review Date
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New Policy	--	01/14/2026
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