



# Drug Coverage Policy

Effective Date.....3/15/2026

Coverage Policy Number.....IP0784

Policy Title.....Enbumyst

## Diuretic – Enbumyst

- Enbumyst™ (bumetanide nasal spray – Corstasis)

### INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see “Coding Information” below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

### 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.<sup>1</sup>

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

### **Pharmacokinetic Data**

There are no clinical efficacy data with Enbumyst.<sup>1</sup> Enbumyst was evaluated in one Phase I, pharmacokinetic/pharmacodynamic, open-label, randomized, controlled crossover study of healthy adults.<sup>2</sup> 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.<sup>3</sup> 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.<sup>4</sup> 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.<sup>5</sup>

## **Coverage Policy**

### **POLICY STATEMENT**

Prior Authorization is required for 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.

**Documentation:** Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, laboratory tests, claims records, and/or other information. All documentation must include patient-specific identifying information.

**Enbumyst is considered medically necessary when ONE of the following are met:**

### **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)** Medication is prescribed by or in consultation with a cardiologist; AND
  - D)** Preferred product criteria is met for the product as listed in the below tables
- 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) Medication is prescribed by or in consultation with a gastroenterologist; AND
- D) Preferred product criteria is met for the product as listed in the below tables

**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) Medication is prescribed by or in consultation with a nephrologist; AND
- D) Preferred product criteria is met for the product as listed in the below tables

**Employer Plans:**

Product	Criteria
<b>Enbumyst</b> (bumetanide nasal spray)	Patient has tried [ <b>documentation required</b> ] and cannot take at least one oral loop diuretic. <u>Note:</u> Examples of loop diuretics include furosemide, bumetanide, torsemide, ethacrynic acid.

**Individual and Family Plans:**

Product	Criteria
<b>Enbumyst</b> (bumetanide nasal spray)	Patient has tried [ <b>documentation required</b> ] and cannot take at least one oral loop diuretic. <u>Note:</u> Examples of loop diuretics include furosemide, bumetanide, torsemide, ethacrynic acid.

**Conditions Not Covered**

**Enbumyst for any other use is considered not medically necessary. 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.

**Revision Details**

Type of Revision	Summary of Changes	Date
New	New policy	3/15/2026

The policy effective date is in force until updated or retired.

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