Enbumyst™
(bumetanide nasal spray) 0.5 mg

Prior Authorization Checklist

Use this checklist when completing a prior authorization (PA) for ENBUMYST to prevent incomplete submissions and help avoid delays or denials.

When submitting ENBUMYST prior authorizations, remember these 2 things

- ✓ **Prior oral loop diuretic history is often required**
- ✓ **Clear documentation of active edema or fluid overload may help reduce delays**

Step 1 Diagnosis Details:

Find the patient's diagnosis the prescriber has documented in the chart notes and include it on the PA.

Edema AND **Congestive heart failure** OR **Hepatic disease** OR **Renal disease, including nephrotic syndrome**

Document the related ICD-10 codes with the patient's diagnosis. See some example codes* below.[1] (ICD-10 codes are recommended but not required for edema; documentation must otherwise clearly support active edema or fluid overload through clinical notes, exam findings, diagnostics, etc.)

Edema

- ○ **R60.0** – Localized edema
- ○ **R60.1** – Generalized edema
- ○ **R60.9** – Edema, unspecified
- ○ **E87.70** - Fluid overload, unspecified
- ○ **E87.79** - Other fluid overload

Congestive heart failure

- ○ **I50.20** – Systolic (congestive) heart failure
- ○ **I50.30** – Diastolic (congestive) heart failure
- ○ **I50.40** – Combined systolic (congestive) and diastolic (congestive) heart failure
- ○ **I50.9** – Heart failure, unspecified

Hepatic disease

- ○ **K72.10 –** Chronic hepatic failure without coma
- ○ **K74.60** – Unspecified cirrhosis of liver
- ○ **K76.6** – Portal hypertension
- ○ **R18.8** – Other ascites

Renal disease

- ○ **N18.4** – Chronic kidney disease, stage 4 (severe)
- ○ **N18.5** – Chronic kidney disease, stage 5
- ○ **N18.9 –** Chronic kidney disease, unspecified
- ○ **E11.22** – Type 2 diabetes mellitus with diabetic chronic kidney disease

*The diagnosis codes above are provided as examples only and not intended to be directive or a guarantee of reimbursement. For a full list of ICD-10 codes, please refer to the current ICD-10.

INDICATION

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

IMPORTANT SAFETY INFORMATION

- ENBUMYST is contraindicated in patients with anuria, hepatic coma, or a history of hypersensitivity to bumetanide, including anaphylaxis and anaphylactoid reactions.

Please see continued Important Safety Information on reverse side and accompanying full Prescribing Information.

Step 2 Treatment History

Document prior oral loop diuretic use (eg: bumetanide, furosemide, torsemide, ethacrynic acid).
List the following details for each therapy:

Drug Name: _____ **Reason for discontinuation, failure, or inappropriateness:**

Dose and Duration: _____ _____

Response/Outcome: _____ _____

_____ _____

NOTE: ***If oral loop diuretics were not trialed or are not appropriate, consider including a Letter of Medical Necessity.***

Step 3 Supporting documentation

Make sure you read the PA criteria carefully and include all required documentation. Examples may include:

- ○ Recent chart notes supporting edema/fluid retention
- ○ Relevant progress notes documenting persistent symptoms, despite oral diuretic use
- ○ Medication list
- ○ Relevant labs, as appropriate (eg, renal function, electrolytes, BNP)
- ○ Relevant imaging or test results, when available and appropriate:
  - echocardiogram for heart failure
  - imaging or other documentation relevant to hepatic or renal disease
- ○ Letter of medical necessity

This checklist is provided as a courtesy only and is not comprehensive, directive, or a guarantee of coverage. Specific plan requirements may vary. Healthcare providers are responsible for all clinical decisions, including diagnosis, and treatment.

IMPORTANT SAFETY INFORMATION (Continued)

- ENBUMYST is a diuretic that may cause fluid, electrolyte, and metabolic abnormalities, particularly in patients receiving higher doses, those with inadequate electrolyte intake, and the elderly. Abnormalities may include changes in blood electrolytes, BUN, glucose, and uric acid. Monitor serum electrolytes, CO_2, BUN, creatinine, glucose, and uric acid frequently during therapy.
- Bumetanide can cause dehydration and azotemia. Discontinue bumetanide if azotemia worsens and oliguria occurs during treatment of severe progressive renal disease.
- Tinnitus and hearing loss (usually reversible) have been reported with loop diuretics, including bumetanide. Reports indicate that ototoxicity is associated with rapid injection, severe renal impairment, use of higher than recommended doses, hypoproteinemia or concomitant therapy with aminoglycoside antibiotics, ethacrynic acid, or other ototoxic drugs.
- Due to potential altered absorption, avoid use in patients with significant nasal mucosal or structural abnormalities, such as acute episodes of rhinitis or congestion due to any cause.
- Advise lactating women treated with ENBUMYST to monitor their breastfed infants for excessive urine output, dehydration, and lethargy.
- Most common adverse reactions reported in ENBUMYST studies were hypovolemia and headaches. Common adverse reactions reported with the use of oral bumetanide include muscle cramps, dizziness, hypotension, nausea and encephalopathy (in patients with pre-existing liver disease).

Please see accompanying full Prescribing Information for ENBUMYST.

Reference: 1. Centers for Medicare & Medicaid Services. ICD-10 Codes. Accessed May 1, 2025. https://www.cms.gov/medicare/coding-billing/icd-10-codes

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