This is a sample letter of medical necessity for Enbumyst™ (bumetanide nasal spray). This sample is provided for your guidance only. Use of information in this letter does not guarantee that the health plan will provide reimbursement for ENBUMYST, and is not intended to substitute for or influence your independent medical judgement as a Prescriber.

Based on your clinical judgement, you may use this letter as an example of the type of information that may be helpful when submitting a prior authorization or appealing a denial of coverage for ENBUMYST from a patient's health plan.

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.
- 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 full Prescribing Information for additional information.

US-ENBU-2600016

Enbumyst™ (bumetanide nasal spray) Letter of Medical Necessity

[Sample letter: You may want to consider printing this letter on your Practice's Letterhead]

[Health Plan Name]
Attn: [Department]
[Health Plan Contact]
[Health Plan Address]
[Health Plan City, State Zip]

Patient: [Patient's First and Last Name]

Date of Birth: [Patient's Date of Birth]

Policy ID & Group: [Patient's Member ID & Group #]

Claim: [Claim #]

Date: [Insert Date Form Populated]

Dosing: [example: 1 spray (0.5mg) in each nostril 2 times per day as needed]

Duration: [6 days (increments of 3)]

Refills: [# of annual refills]

Prescribing Provider: [Prescriber Name]

EXPEDITED REQUEST (Decision needed within 24 hours):
Authorization for treatment with Enbumyst™ (bumetanide nasal spray) 0.5 mg

Dear [Example: Medical Director_____] :

I am writing this on behalf of my patient, [Patient Name_____] as I believe that treatment with ENBUMYST is medically necessary. ENBUMYST is approved by the FDA for the treatment of edema associated with congestive heart failure, hepatic disease, and renal disease, including nephrotic syndrome, in adults.

The patient has a diagnosis of [Diagnosis] ([ICD-10 code(s)]), resulting in persistent edema and related symptoms that have not been adequately controlled with standard therapies.

ENBUMYST is a short-term nasal option for diuretic management when oral therapy is inadequate, before escalation to IV therapy. The nasal route offers a path to systemic absorption without relying on the GI tract. This route of administration is intended for patients who have experienced inadequate diuretic response, variable absorption, or diuretic resistance with conventional oral loop diuretic therapy.

[Optional: Describe why you are prescribing ENBUMYST for this patient]

Prior Therapy Trial and Failure

The patient has previously tried the following oral diuretic therapies without adequate clinical benefit:

Oral Diuretic Name	Dosage	Duration (or currently taking)
[Medication Dose]	[Medication Dose]	[Medication Duration]
[Medication Dose]	[Medication Dose]	[Medication Duration]
[Medication Dose]	[Medication Dose]	[Medication Duration]

In summary, based on my clinical opinion, delaying initiation of ENBUMYST or requiring further step therapy with additional oral diuretics is not clinically appropriate for this patient. The patient has already demonstrated insufficient symptom control and/or diuretic resistance with oral loop diuretics. Further delay in adequate diuresis increases the risk of worsening symptoms.

ENBUMYST is not intended for chronic use and will be replaced with oral diuretics as soon as practical.

Approval is respectfully requested to ensure timely and effective patient care.

Prescribing Provider Signature: _____

[Prescriber Name]
[NPI Number]
[Prescriber address]
[Prescriber phone number]

Enclosures: [Include supporting evidence, such as relevant medical records, clinical notes/diagnostic report, medication records, ENBUMYST Prescribing Information, and relevant peer-reviewed journal articles]