GEMTESA® (vibegron) 75 mg tablets

PRIOR AUTHORIZATION (PA) PREPARATION TIPS AND CHECKLIST

THERE IS ONLY ONE GEMTESA–NO GENERIC SUBSTITUTE

A PA MAY BE NECESSARY WHEN AN APPROPRIATE ADULT PATIENT WITH OAB HAS RESTRICTED ACCESS TO TREATMENT WITH GEMTESA

Note: This resource provides information commonly used by payor plans to determine PA. It is intended for reference only and does not guarantee approval. Please be sure to check payor policies for the most up-to-date information.

✓ Gather details beforehand to inform the PA

- Find out the PA requirements from the patient's health plan, including specific forms
- Determine if the health plan necessitates a step edit
- Collect relevant medical records, including chart notes

✓ Provide personal/professional information

- Include patient information, such as full name, address, date of birth, gender, and member ID
- Include provider information, such as full name, specialty, address, National Provider Identifier, and office/fax numbers

✓ Detail diagnosis, medical history, and treatment

- Provide the OAB-related diagnosis and include the appropriate ICD-10-CM code(s) related to OAB (eg, N32.81 Overactive Bladder)[1,*]
- Add historical patient symptoms and tests undertaken, including physical exam and urinalysis[1]
- Document previous and current medication use/failure and rationale for new treatment
- Include recommended treatment dosage and directions
  - One 75-mg GEMTESA tablet taken once daily with or without food. Swallow GEMTESA tablets whole with a glass of water[2]
  - In adults, GEMTESA tablets also may be crushed, mixed with a tablespoon (approximately 15 mL) of applesauce and taken immediately with a glass of water[2]

*Nothing in this document is intended to serve as reimbursement advice. The decision about which code to report must be made by the provider/physician considering the clinical facts, circumstances, and applicable coding rules.

ICD-10-CM, *International Classification of Diseases, Tenth Revision, Clinical Modification*; ICS, International Continence Society; OAB, overactive bladder.

INDICATIONS AND USAGE

GEMTESA® is a beta-3 adrenergic agonist indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency in adults.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

GEMTESA is contraindicated in patients with known hypersensitivity to vibegron or any components of GEMTESA. Hypersensitivity reactions, such as angioedema, have occurred.

WARNINGS AND PRECAUTIONS

Urinary Retention

Urinary retention has been reported in patients taking GEMTESA. The risk of urinary retention may be increased in patients with bladder outlet obstruction and also in patients taking muscarinic antagonist medications for the treatment of OAB. Monitor patients for signs and symptoms of urinary retention, particularly in patients with bladder outlet obstruction and patients taking muscarinic antagonist medications for the treatment of OAB. Discontinue GEMTESA in patients who develop urinary retention.

Please see next page for additional Important Safety Information and accompanying full Prescribing Information.

EXAMPLE PA CHECKLIST FOR GEMTESA

Patient Information

First Name_____ Middle Name_____ Last Name_____ Suffix_____

Address_____ City_____ State_____ ZIP_____

Date of Birth_____/_____/_____ Gender_____ Member ID_____

Is the patient on Medicare? ◯ Yes ◯ No Is the patient in long-term care? ◯ Yes ◯ No

◯ Initiation of therapy ◯ Continuation of therapy

Diagnosis

◯ Urge urinary incontinence ◯ Urgency ◯ Urinary frequency ◯ Other _____

ICD-10-CM Code(s)			

Treatment History

Has the patient tried and failed any over-the-counter incontinence products? ◯ Yes ◯ No

Has the patient tried and failed any behavioral interventions, such as pelvic floor muscle training or bladder training? ◯ Yes ◯ No

Has the patient tried and failed a first-line urinary antispasmodic? ◯ Yes ◯ No

Treatment or Medication & Dosage	Date Started	Date Ended	Notes

Additional Medical Information

Include any necessary supporting documentation for other medical conditions the patient may have that influenced your prescribing decision (eg, high blood pressure, prolonged QT interval, dysphagia, cognitive impairment, etc).

Personalized Support for the GEMTESA Treatment Journey

CONNECT

The Patient Connect Support Program can help appropriate patients access GEMTESA with tools such as prior authorization support.

CoverMyMeds® provides support throughout the PA process and electronically connects providers, pharmacists, and health plans. Additional support is available for providers when submitting GEMTESA PA requests.

covermymeds®

Live support:

- Via chat box at **CoverMyMeds.com**
- By phone at 1-866-452-5017, 8 A.M. to 11 P.M. ET Monday-Friday and 8 A.M. to 6 P.M. ET Saturday

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Angioedema

Angioedema of the face and/or larynx has been reported with GEMTESA. Angioedema has been reported to occur hours after the first dose or after multiple doses. Angioedema, associated with upper airway swelling, may be life-threatening. If involvement of the tongue, hypopharynx, or larynx occurs, immediately discontinue GEMTESA and provide appropriate therapy and/or measures necessary to ensure a patent airway.

ADVERSE REACTIONS

Most common adverse reactions (≥2%) reported with GEMTESA were headache, urinary tract infection, nasopharyngitis, diarrhea, nausea, and upper respiratory tract infection.

Please see full Prescribing Information.

Reference: 1. Cameron AP, Chung DE, Dielubanza EJ, et al. The AUA/SUFU Guideline on the Diagnosis and Treatment of Idiopathic Overactive Bladder. *J Urol.* 2024;212(1):11-20. doi:10.1097/JU.0000000000003985 **2.** GEMTESA. Prescribing Information. Marlborough, MA; Sumitomo Pharma America; 2024.

Sumitomo Pharma

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