GEMTESA® (vibegron) 75 mg tablets

THE ROAD TO GEMTESA
Navigating Prior Authorizations, Tier and Medical Exceptions

THERE IS ONLY ONE GEMTESA– NO GENERIC SUBSTITUTE

Once a healthcare professional (HCP) writes a GEMTESA prescription for an appropriate adult patient, additional steps may be necessary before the patient can begin taking the medication.

If GEMTESA is

COVERED/PREFERRED — Prior Authorization (PA) (may be required)

A PA is a request from an HCP to a health plan to approve care.[1] Health plans use PAs to assess medical necessity and ensure compliance with clinical best practices.[1,2]

COVERED/NONPREFERRED — Tier Exception (TE)

A TE is a request to obtain a nonpreferred drug at the lower out-of-pocket cost of preferred-tier drugs. This formal request cites the patient's circumstances and why lower-tier alternatives are not clinically appropriate.[3]

***NOT* COVERED** — Medical Exception (ME)

An ME is a request from an HCP to a health plan for a nonformulary medication, explaining the patient's circumstances and why the medication is medically necessary.[3]

Many health plans provide PA, TE, and ME forms on their website. Medicare or Medicaid standard forms can be found at https://www.cms.gov/medicare/appeals-and-grievances/medprescriptdrugapplgriev/downloads/modcovdetreqform-and-instrctns-feb-2019-508-.zip.

Sumitomo Pharma Is Committed to Supporting Your Patients With Obtaining Access to GEMTESA

Additional support is available for providers submitting GEMTESA PA requests. CoverMyMeds® streamlines the PA process by electronically connecting providers, pharmacists, and health plans.

STEP 1

If a claim is rejected at the pharmacy, enter your key, as well as your patient's last name and date of birth, as indicated on the fax. You'll see that some of the request has been auto-populated based on pharmacy claim information.

STEP 2

If the initial PA is denied and the denial can be appealed, CoverMyMeds will initiate an appeal and communicate instructions to the HCP for submitting it.

STEP 3

Once coverage is approved, both the pharmacy and the HCP are notified, and GEMTESA can be dispensed.

covermymeds®

Live support:
- Via chat box at CoverMyMeds.Health
- By phone at 1-866-452-5017, Monday through Friday, 8:00 AM – 8:00 PM ET

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.
- overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency in adult males on pharmacological therapy for benign prostatic hyperplasia (BPH).

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.

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

PRESCRIBE GEMTESA FOR OVERACTIVE BLADDER (OAB) SYMPTOM RELIEF

GEMTESA Is the First and Only β_3-Agonist With[4]:

Clinically significant reductions in all 3 key OAB symptoms* vs placebo at 12 weeks[4,5†]:
- urgency, frequency, urge urinary incontinence (UUI)

An indication for men with OAB who are being pharmacologically treated for BPH[4]

No blood pressure warning in its label[4]
- In a 24-week study of OAB in men being treated for BPH, rates of hypertension were 9.0% with GEMTESA (n=553) vs 8.3% with placebo (n=551).[4,6]

No drug interactions with CYP2D6 substrates[4]
- Concomitant use of GEMTESA increases digoxin maximal concentrations (C_{max}) and systemic exposure as assessed by area under the concentration-time curve (AUC). Serum digoxin concentrations should be monitored before initiating and during therapy with GEMTESA and used for titration of the digoxin dose to obtain the desired clinical effect. Continue monitoring digoxin concentrations upon discontinuation of GEMTESA and adjust digoxin dose as needed.

*The 3 key symptoms of OAB are UUI/leakage, micturition frequency, and urgency.[5]

†The efficacy of GEMTESA was evaluated in a 12-week, double-blind, randomized, placebo- and active-controlled trial in patients with OAB (UUI, urgency, and urinary frequency). For study entry, patients had to have symptoms of OAB for at least 3 months with an average of 8 or more micturitions per day and at least 1 UUI per day, or an average of 8 or more micturitions per day and an average of at least 3 urgency episodes per day. A total of 1,515 patients received at least 1 daily dose of placebo (n=540), GEMTESA 75 mg (n=545), or an active-control treatment (n=430). The majority of patients were Caucasian (78%) and female (85%), with a mean age of 60 (range 18 to 93) years.[4,7]

IMPORTANT SAFETY INFORMATION (cont'd)

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 or patients taking muscarinic antagonist medications for the treatment of OAB. Discontinue GEMTESA in patients who develop urinary retention.

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 accompanying full Prescribing Information.

References: 1. Turner A, Miller G, Clark S. Impacts of prior authorization on health care costs and quality: a review of the evidence. November 2019. Accessed November 10, 2025. https://www.nihcr.org/wp-content/uploads/Altarum-Prior-Authorization-Review-November-2019.pdf **2.** Preauthorization. Healthcare.gov website. Accessed November 10, 2025. https://www.healthcare.gov/glossary/preauthorization/ **3.** Exceptions. Centers for Medicare & Medicaid Services website. Updated November 10, 2025. Accessed November 10, 2025. https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Exceptions **4.** GEMTESA. Prescribing Information. Marlborough, MA; Sumitomo Pharma America; 2025. **5.** Edmondson SD, Zhu C, Kar NF, et al. Discovery of vibegron: a potent and selective β3 adrenergic receptor agonist for the treatment of overactive bladder. *J Med Chem.* 2016;59(2):609-623. doi:10.1021/acs.jmedchem.5b01372 **6.** Weber MA, Haag-Molkenteller C, King J, Walker A, Mudd PN Jr, White WB. Effects of vibegron on ambulatory blood pressure in patients with overactive bladder: results from a double-blind, placebo-controlled trial. *Blood Press Monit.* 2022;27(2):128-134. doi:10.1097/MBP.0000000000000572 **7.** Data on File. Sumitomo Pharma America, Inc.

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