GEMTESA® (vibegron) 75 mg tablets

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

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 by the health plan	**Covered on a non-preferred tier**	***Not* covered by the health plan**
	Prior authorization (PA)	**Tier exception (TE)**	**Medical exception (ME)**
Definition	A PA, also known as prior approval or precertification, is a common request made by an HCP to a health plan for approval to provide care.[1] Health plans use PAs to determine the medical necessity of a treatment and whether its use complies with clinical best practices.[1,2]	A TE is a request to obtain a non-preferred drug at the lower patient out-of-pocket costs applicable to drugs in the preferred tier. This formal request for a prescription drug cites the patient's individual circumstances and explains why a lower-tier alternative is not clinically appropriate for the patient.[3]	An ME is a request made by an HCP to a health plan for the use of a nonformulary medication. This formal request for a prescription drug cites the patient's individual circumstances and explains why treatment with the specified medication is medically necessary.[3]

Many health plans provide PA, TE, and ME forms on their website. Forms can also be found on the CoverMyMeds portal. Medicare or Medicaid standard forms can be found here.

In the Event of a Denial

Sometimes coverage may be denied and an appeal may be needed. Timing is critical in this period. Health plans are required to provide notification within a specific time period, and patients or their HCPs are required to provide answers within a set time by sending certain documentation (such as Explanation of Benefits forms or letters originally sent to the health plan).[4]

For more information about the appeal process, please click here.

Urovant Sciences Is Committed to Supporting Your Patients With Obtaining Access to GEMTESA

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.

STEP 1 If a claim is rejected at the pharmacy, the appropriate PA form is prepopulated with patient, payor, and pharmacy information and forwarded to the HCP to initiate a PA.

STEP 2 If the initial PA is denied, CoverMyMeds will contact the office with specific information about the denial and confirm with the HCP if he or she would like CoverMyMeds to support their effort to pursue an appeal.

STEP 3 Once coverage is approved, both the pharmacy and the provider are informed that GEMTESA can be distributed.

covermymeds®

Live support:

- Via chat box at **CoverMyMeds.com**
- By phone at 1-866-452-5017, Monday through Friday, 8:00 AM – 11:00 PM ET; Saturday, 8:00 AM – 6:00 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.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

GEMTESA is contraindicated in patients with known hypersensitivity to vibegron or any components of the product.

Please see reverse for additional Important Safety Information and full Prescribing Information or visit https://gemtesa.com/sites/default/files/gemtesa-prescribing-information.pdf.

PRESCRIBE GEMTESA 1st* FOR OAB SYMPTOM RELIEF[5,6]

Proven Efficacy Data

- **Statistically significant reduction** of all 3 key OAB symptoms† vs placebo at 12 weeks[5,6‡]:

URGE URINARY INCONTINENCE (UUI) EPISODES

MICTURITION FREQUENCY

URGENCY EPISODES

The first & only β_3-agonist with proven urgency reduction data in its label[1]

*First pharmacologic medication after behavioral therapy.[7]

†The 3 key symptoms of OAB are UUI/leakage, micturition frequency, and urgency.[6]

‡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 1515 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.[5,8]

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

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 or visit https://gemtesa.com/sites/default/files/gemtesa-prescribing-information.pdf.

References: 1. Turner A, Miller G, Clark S. Impacts of prior authorization on health care costs and quality: a review of the evidence. Published November 2019. Accessed October 24, 2022. https://www.nihcr.org/wp-content/uploads/Altarum-Prior-Authorization-Review-November-2019.pdf **2.** Preauthorization. Healthcare.gov website. Accessed October 24, 2022. https://www.healthcare.gov/glossary/preauthorization/ **3.** Exceptions. Centers for Medicare & Medicaid Services website. Updated December 1, 2021. Accessed October 24, 2022. https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Exceptions **4.** Internal appeals. Healthcare.gov website. Accessed October 24, 2022. https://www.healthcare.gov/appeal-insurance-company-decision/internal-appeals/ **5.** GEMTESA [prescribing information]. Irvine, CA: Urovant Sciences; 2020. **6.** 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 **7.** Gormley EA, Lightner DJ, Burgio KL, et al. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU guideline. American Urological Association/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction; 2019. Accessed November 11, 2022. https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwjMsMWsu6b7AhVKEEQIHYm3APoQFnoECA8QAQ&url=https%3A%2F%2Fwww.auanet.org%2Fdocuments%2FGuidelines%2FPDF%2FOveractive-Bladder.pdf&usg=AOvVaw2W-poY97ZmPRdwfT72Ol92 **8.** Data on file. Urovant Sciences.

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