

## THE ROAD TO GEMTESA

# Navigating Prior Authorizations 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	Not covered by the health plan
	Prior authorization (PA)	Medical exception (ME)
<b>Definition</b>	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 (in this case, treatment with GEMTESA). <sup>1</sup> Health plans often use PAs as a way to determine that the treatment is medically necessary and that its use complies with clinical best practices. <sup>1,2</sup>	An ME is a request made by an HCP to a health plan for the use of a nonpreferred or nonformulary medication. This formal request for a prescription drug cites the patient's individual circumstances and explains why treatment with the medication is medically necessary. <sup>3</sup>
<b>Form</b>	Many health plans provide PA forms on their website.	Many health plans provide ME forms on their website.  For patients on Medicare or Medicaid, standard forms can be found at <a href="http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrug/AppGriev/Downloads/ModCovDetReqForm-and-Instrctns-Feb-2019-508-.zip">www.cms.gov/Medicare/ Appeals-and-Grievances/MedPrescriptDrug/AppGriev/Downloads/ModCovDetReqForm-and-Instrctns-Feb-2019-508-.zip</a> .

### 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).<sup>4</sup>

For more information about the appeal process, please visit [www.healthcare.gov/appeal-insurance-company-decision/appeals/](http://www.healthcare.gov/appeal-insurance-company-decision/appeals/).

### INDICATIONS AND USAGE

GEMTESA<sup>®</sup> 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 next page for additional Important Safety Information and [click here](#) for full Prescribing Information.



# 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](https://www.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

## 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 ( $\geq 2\%$ ) reported with GEMTESA were headache, urinary tract infection, nasopharyngitis, diarrhea, nausea, and upper respiratory tract infection.

Please [click here](#) for 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. <https://www.nihcr.org/wp-content/uploads/Altarum-Prior-Authorization-Review-November-2019.pdf>. Published November 2019. Accessed February 18, 2021. **2.** Preauthorization. Healthcare.gov website. <https://www.healthcare.gov/glossary/preauthorization/>. Accessed February 18, 2021. **3.** Exceptions. Centers for Medicare & Medicaid Services website. <https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Exceptions>. Updated September 24, 2019. Accessed February 18, 2021. **4.** Internal appeals. Healthcare.gov website. <https://www.healthcare.gov/appeal-insurance-company-decision/internal-appeals/>. Accessed February 18, 2021.

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SCIENCES

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 GEMTESA®  
(vibegron) 75 mg  
tablets