GEMTESA® (vibegron) 75 mg tablets

Now Available on Most Cigna and Express Scripts Medicare Part D Without Restrictions[1]

Effective February 1, 2022

GEMTESA Is Available for ~2.7 Million Cigna and Express Scripts Medicare Lives Without Restrictions[1,*]

UTILIZATION MANAGEMENT DETAILS:

- No Step Edits
- No Prior Authorization
- Unrestricted

Product images are not actual size.

PACKAGE CONFIGURATION

GEMTESA 75-mg tablets are available in a 30-count, 90-count, and 60-cc high-density polyethylene bottle with a child-resistant cap.[2]

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 accompanying full Prescribing Information.

*All formulary data and access criteria are provided by Managed Markets Insight & Technology, LLC database as of February 2022. Nothing in this document is intended to serve as a guarantee of coverage or a guarantee of payment. For verification of coverage, please visit https://www.cigna.com or https://www.cigna.com/medicare/part-d.

MEDICARE

If GEMTESA has a higher formulary tier co-pay than other lower-tier alternatives that are not clinically appropriate for a patient, a tier exception may be granted.[3]

- In those cases, a supporting statement from the patient's prescriber will need to be submitted to the Medicare Part D plan[3]
- A Model Coverage Determination Request Form can be used for documenting the rationale for formulary exception[3]; it can be found at https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/CoverageDeterminations-
  - Patients can also use this form, or work with their health plan, to appeal if their request is denied[4]
- Medicare Part D plans must review both standard tier exception requests and appeals within 72 hours[3,4]

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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.

References: 1. Data on File, Gemtesa Access. MMIT. Urovant Sciences GmbH. February 2022. **2.** GEMTESA [Prescribing Information]. Irvine, CA: Urovant Sciences, Inc. **3.** Exceptions. Centers for Medicare & Medicaid Services website. https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Exceptions. Updated December 1, 2021. Accessed January 13, 2022. **4.** How do I file an appeal? Medicare.gov website. https://www.medicare.gov/claims-appeals/how-do-i-file-an-appeal. Accessed January 13, 2022.

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