BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

Fesoterodine fumarate ER oral
GEMTESA® (vibegron) oral
TOVIAZ® (fesoterodine fumarate ER) oral
Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

Fesoterodine
TOVIAZ (fesoterodine)

- **Criteria for initial therapy:** Toviaz (fesoterodine) and generic fesoterodine are considered ***medically necessary*** and will be approved when **ALL** the following criteria are met:

  1. Individual has a confirmed diagnosis of **ONE** of the following:
     a. Individual is 18 years of age or older with overactive bladder (**OAB**) and has symptoms of urge urinary incontinence, urgency, and frequency

b. Individual 6 years of age or older weighing at least 25 Kg with neurogenic detrusor overactivity (**NDO**) [ex., spinal bifida]

2. Individual has **ONE** of the following:
   a. **Adult** individual (18 years of age or older) with **OAB**:
      i. Individual has failure, contraindication per FDA label, intolerance, or is not a candidate for **TWO** of three of the following:
         1. Generic darifenacin ER
         2. Generic oxybutynin IR or ER
         3. Generic trospium IR or ER
      ii. Individual has failure, contraindication per FDA label, intolerance, or is not a candidate for **BOTH** Myrbetriq (mirabegron) and Vesicare (solifenacin)
   b. **Pediatric** individual with **OAB** who has failure, contraindication per FDA label, intolerance, or is not a candidate for generic oxybutynin IR or ER
   c. **Pediatric** individual with **NDO** who has failure, contraindication per FDA label, intolerance, or is not a candidate for **BOTH** Myrbetriq (mirabegron) and Vesicare LS (solifenacin suspension) according to FDA age and weight

3. **For brand Toviaz (fesoterodine)**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for **generic fesoterodine** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

4. There are **NO** FDA-label contraindications such as:
   a. Urinary retention
   b. Gastric retention
   c. Uncontrolled narrow-angle glaucoma

5. Individual does not have **ANY** of the following:
   a. Severe hepatic impairment (Child-Pugh Class C)
   b. Clinically significant bladder outlet obstruction
   c. Decreased gastrointestinal motility disorder such as severe constipation

6. Agent will not be used if **ONE** of the following applies:
   a. Agent will not be used in an individual who is 6 years or age or older weighing between 25 kg up to 35 kg with an estimated glomerular filtration rate of less than 30 mL/min/1.73m^2 or who requires dialysis
   b. Agent will not be used in an individual who is 6 years or age or older weighing greater than 35 kg with an estimated glomerular filtration rate of less than 15 mL/min/1.73m^2 or who requires dialysis

7. Pediatric individual weighing greater than 25 kg and up to 35 kg is not also using strong CYP3A4 inhibitors such as ketoconazole, itraconazole, posaconazole, and others

Initial approval duration: 6 months

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- **Criteria for continuation of coverage (renewal request):** Toviaz (fesoterodine) and fesoterodine are considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy)**:

  1. Individual's condition has responded while on therapy with response defined as **TWO** of the following:
     a. There is evidence of reduced number of urge urinary incontinence per day
     b. There is evidence of reduced number/frequency of micturition per day
     c. There is evidence of increased void volume per micturition
     d. The condition has not worsened while on therapy

  2. Individual has been adherent with the medication

  3. **For brand Toviaz (fesoterodine):** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for **generic fesoterodine** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

  4. Individual has not developed any contraindications (as listed in the Initial Criteria section) or other significant adverse drug effects that may exclude continued use such as angioedema of the face, lips, tongue, and/or larynx

  5. Individual does not have severe hepatic impairment (Child-Pugh Class C)

  6. Pediatric individual weighing greater than 25 kg and up to 35 kg is not taking strong CYP3A4 inhibitors such as ketoconazole, itraconazole, posaconazole, and others

  Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

  1. **Off-Label Use of Non-Cancer Medications**

  2. **Off-Label Use of Cancer Medications**

GEMTESA (vibegron)

- **Criteria for initial therapy:** Gemtesa (vibegron) and/or generic equivalent (if available) are considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual is 18 years of age or older

  2. Individual has a confirmed diagnosis of overactive bladder (OAB) and has symptoms of urge urinary incontinence, urgency, and frequency

3. Individual has failure, contraindication per FDA label, intolerance, or is not a candidate for **TWO** of the following agents for OAB:
    a. Generic darifenacin ER
    b. Generic oxybutynin IR or ER
    c. Generic trospium IR or ER

4. Individual has failure, contraindication per FDA label, intolerance, or is not a candidate for **BOTH** Myrbetriq (mirabegron) and Vesicare (solifenacin) for OAB

5. **If available**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

6. Individual does not have severe hepatic impairment (Child-Pugh Class C)

7. Individual does not severe renal impairment (eGFR <15 mL/min/1.73 m with or without hemodialysis)

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Gemtesa (vibegron) and/or generic equivalent (if available) are considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Individual's condition has responded while on therapy with response defined as **TWO** of the following:
    a. There is evidence of reduced number of urge urinary incontinence per day
    b. There is evidence of reduced number/frequency of micturition per day
    c. There is evidence of increased void volume per micturition
    d. The condition has not worsened while on therapy

2. Individual has been adherent with the medication

3. **If available**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

4. Individual has not developed any significant adverse drug effects that may exclude continued use such as significant urinary retention

5. Individual does not have severe hepatic impairment (Child-Pugh Class C)

6. Individual does not severe renal impairment (eGFR <15 mL/min/1.73 m with or without hemodialysis)

Renewal duration: 12 months

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  2. **Off-Label Use of Cancer Medications**

Description:

Overactive bladder (OAB) occurs when bladder muscle contractions are not controlled. When these muscle contractions happen too often or cannot be controlled, symptoms of overactive bladder, such as urinary frequency, urgency, and incontinence (leakage) occur.

The urinary bladder contains nerves, muscles, and connective tissue. The most important muscle in the bladder is the detrusor muscle. In normal circumstances, the bladder stretches as it fills with urine. When the volume in the bladder reaches approximately 300 mL, the stretch in the wall of the bladder triggers a nerve response to initiate urination. This reaction results in loosening of the sphincter in the neck of the bladder that connects the bladder to the urethra and contraction of the detrusor muscle to begin urination. This response is under voluntary control and can be overridden by the individual to prevent urination if it is not the right time or place. An overactive bladder can result from dysfunction of the nerves or muscles in the bladder, most commonly the detrusor muscle. In OAB, the detrusor can contract inappropriately regardless of how much urine is stored in the bladder, resulting in a condition known as detrusor overactivity or hyperactive detrusor.

All medications for OAB are effective for reducing incontinence episodes and urinary frequency and all medications for OAB have an adequate track record for safety. No medication for OAB has been shown to be safer or more effective overall than any other.

There are many generically available oral antimuscarinic/anticholinergic medications for the treatment of OAB, formulated as immediate- and extended-release products.

Antimuscarinic/anticholinergic medications are associated with several adverse effects including dry mouth, dry eyes, blurry vision, urinary retention, constipation and somnolence. The safety profiles of antimuscarinic/ anticholinergic medications are similar overall but may differ slightly based on route of administration. Myrbetriq (mirabegron) and Gemtesa (vibegron), beta-3 adrenergic agonists, offer an option for patients unable to tolerate antimuscarinic/anticholinergic adverse effects. Over the counter (OTC) oxybutynin transdermal patches provide a non-oral dosing option.

Guidelines recommend behavioral therapies (such as bladder training, bladder control strategies, pelvic floor muscle training, and fluid management) as first-line treatment for OAB, either alone or in combination with oral antimuscarinics or beta-3-AR agonists

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Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Resources:

Toviaz (fesoterodine) extended-release tab product information, revised by Pfizer Laboratories Div Pfizer, Inc. 02-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 25, 2024.

Fesoterodine extended-release tab product information, revised by Camber Pharmaceuticals, Inc. 03-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 25, 2024.

Gemtesa (vibegron) tab product information, revised by Sumitomo Pharma America, Inc. 10-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 25, 2024.

Nepple KG, Cooper CS. Management of bladder dysfunction in children. In: UpToDate, Baskin LS, Mattoo TK, Hoppin AG (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through November 2024. Topic last updated on January 22, 2024. Accessed December 30, 2024.

Lukacz ES. Urinary incontinence/overactive bladder (OAB) in females: Treatment. In: UpToDate, Brubaker L, Schmader KE, Eckler K, Law K (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Literature current through November 2024. Topic last updated November 14, 2024. Accessed December 30, 2024.

Lukacz ES. Female urinary incontinence: Treatment. In: UpToDate, Schmader KE, Brubaker L, Eckler Law K (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Literature current through November 2024. Topic last updated February 22, 2024. Accessed December 30, 2024.

McVary KT, Saini R. Lower urinary tract symptoms in males. In: UpToDate, O'Leary MP, Law K (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Literature current through November 2024. Topic last updated April 05, 2024. Accessed December 30, 2024.

Clemens JQ. Urinary incontinence in men. In: UpToDate, O'Leary MP, Law K (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Literature current through November 2024. Topic last updated March 26, 2024. Accessed December 30, 2024.