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/or 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.

Medical Necessity Requirements for: Fesoterodine ER generic and TOVIAZ (fesoterodine fumarate ER)

Criteria for Initial Therapy:

Indication
- Overactive bladder (OAB)
- Neurogenic detrusor overactivity (NDO)

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Age Requirement

- **For Overactive bladder (OAB):** 18 years or older
- **For Neurogenic detrusor overactivity (NDO):** 6 years or older and weighing at least 25 kilograms

Baseline Clinical Evaluation

- **For Overactive bladder (OAB):** Symptoms of urge urinary incontinence, urgency, and frequency
- **For Neurogenic detrusor overactivity (NDO):** Symptoms of urinary urgency, frequency, urge incontinence, and nocturia bladder dysfunction seen with multiple sclerosis (MS), spinal cord injury (SCI), or congenital abnormalities affecting bladder function

Alternative Therapies

- **For adult with Overactive bladder (OAB): ALL** of the following:
  - Failure (trial for at least three months duration), contraindication per FDA label, intolerance, or is not a candidate for **TWO** of the following:
    1. Generic darifenacin extended release
    2. Generic oxybutynin immediate release or extended release
    3. Generic trospium immediate release or extended release
  - Failure (trial for at least three months duration), contraindication per FDA label, intolerance, or is not a candidate for **BOTH** of the following:
    1. Myrbetriq (mirabegron)
    2. Vesicare (solifenacin)
- **For pediatric with Overactive bladder (OAB):**
  - Failure (trial for at least three months duration), contraindication per FDA label, intolerance, or is not a candidate for:
    1. Generic oxybutynin immediate release or extended release
- **For pediatric with Neurogenic detrusor overactivity (NDO):**
  - Failure (trial for at least three months duration), contraindication per FDA label, intolerance, or is not a candidate for **BOTH** of the following:
    1. Myrbetriq (mirabegron)
    2. Vesicare LS (solifenacin suspension) according to FDA age and weight

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE generic fesoterodine products** used for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- Does not have **ANY** of the following:
  - Use with strong CYP3A4 inhibitors in pediatric individuals weighing less than 35 kilograms
  - Urinary retention
  - Gastric retention
  - Uncontrolled narrow angle glaucoma
  - Severe hepatic impairment (Child Pugh Class C)
  - Clinically significant bladder outlet obstruction

  - Decreased gastrointestinal motility disorder such as severe constipation
- Will not be used if:
  - Age 6 years or older weighing less than 35 kilograms with estimated glomerular filtration rate less than 30 mL/min/1.73m² or requires dialysis
  - Age 6 years or older weighing greater than 35 kilograms with estimated glomerular filtration rate less than 15 mL/min/1.73m² or requires dialysis

Documentation Requirements
- A completed request form must be submitted including:
  - Chart notes
  - Lab results
  - Supporting clinical documentation

Initial Therapy Criteria Approval Duration
- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):
Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Clinical Response
- **TWO** of the following:
  - Reduced number of urge urinary incontinence per day
  - Reduced number/frequency of urination per day
  - Increased void volume per urination
  - Condition has not worsened while on therapy

Adherence
- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria
- Have failure, contraindication or intolerance with **THREE generic fesoterodine products** used for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety
- Does not have **ANY** of the following:
  - Use with strong CYP3A4 inhibitors in pediatric individuals weighing less than 35 kilograms
  - Urinary retention
  - Gastric retention
  - Uncontrolled narrow angle glaucoma
  - Severe hepatic impairment (Child Pugh Class C)
  - Clinically significant bladder outlet obstruction

  - Decreased gastrointestinal motility disorder such as severe constipation
  - Angioedema of the face, lips, tongue, and/or larynx
- Will not be used if:
  - Age 6 years or older weighing less than 35 kilograms with estimated glomerular filtration rate less than 30 mL/min/1.73m² or requires dialysis
  - Age 6 years or older weighing greater than 35 kilograms with estimated glomerular filtration rate less than 15 mL/min/1.73m² or requires dialysis

Documentation Requirements
- Chart notes
- Supporting clinical documentation with evidence of improvement in given indication
- Lab values that confirm safe use

Continuation Therapy Criteria Approval Duration
- 12 months OR end of plan year

Medical Necessity Requirements for GEMTESA (vibegron)

Criteria for Initial Therapy:

Indication
- Overactive bladder (OAB)
- Overactive bladder (OAB) in males on pharmacological therapy for benign prostatic hyperplasia (BPH)

Age Requirement
- 18 years or older

Baseline Clinical Evaluation
- **For Overactive bladder (OAB):**
  - Symptoms of urge urinary incontinence, urgency, and frequency for at least 3 months with an average of 8 or more urinations per day and at least 1 urge urinary incontinence (UUI) per day, or an average of 8 or more urinations per day and an average of at least 3 urgency episodes per day
  - Urge urinary incontinence was defined as leakage of urine of any amount because of a feeling an urge or need to urinate immediately
- **For Overactive bladder (OAB) in males on pharmacological therapy for benign prostatic hyperplasia (BPH):**
  - Average of 8 or more urinations per day, 3 or more urgency episodes per day with or without incontinence, and 2 or more nocturia episodes per night
  - An International Prostate Symptoms Score (IPSS) greater than or equal to 8
  - Prostate cancer has been ruled out

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Alternative Therapies

- **For Overactive bladder (OAB) BOTH** of the following:
  - Failure (trial for at least three months duration), contraindication per FDA label, intolerance, or is not a candidate for **TWO** of the following agents for overactive bladder (OAB):
    1. Generic darifenacin extended release
    2. Generic oxybutynin immediate release or extended release
    3. Generic trospium immediate release or extended release
  - Failure (trial for at least three months duration), contraindication per FDA label, intolerance, or is not a candidate for **BOTH** of the following:
    1. Myrbetriq (mirabegron)
    2. Vesicare (solifenacin)
- **For Overactive bladder (OAB) in males on pharmacological therapy for benign prostatic hyperplasia (BPH):** Failure (trial for at least six months duration), contraindication per FDA label, intolerance, or is not a candidate for **BOTH** of the following:
  - Alpha blocker monotherapy
  - Alpha blocker + 5 alpha reductase inhibitor

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- Does **NOT** have:
  - Severe hepatic impairment (Child Pugh Class C)
  - Severe renal impairment (estimated glomerular filtration rate less than 15 mL/min/1.73 m² with or without hemodialysis)

Documentation Requirements

- A completed request form must be submitted including:
  - Chart notes
  - Lab results (including estimated glomerular filtration rate)
  - Supporting clinical documentation

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Clinical Response

- **TWO** of the following:
  - Evidence of reduced number of urge urinary incontinence per day

- Evidence of reduced number/frequency of urination per day
- Evidence of increased void volume per urination
- Condition has not worsened while on therapy

Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- Does **NOT** have:
  - Severe hepatic impairment (Child Pugh Class C)
  - Severe renal impairment (estimated glomerular filtration rate less than 15 mL/min/1.73 m² with or without hemodialysis)
  - Significant urinary retention
  - Angioedema of the face, lips, tongue, and/or larynx

Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement in given indication
- Lab values that confirm safe use (including estimated glomerular filtration rate)

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Criteria for Off-Label Use Requests:

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

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.

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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.

Neurogenic detrusor overactivity (NDO), or detrusor hyperreflexia, is a condition where disrupted nerve signals cause the bladder's detrusor muscle to contract involuntarily and frequently, resulting in urinary incontinence. This occurs due to neurological abnormalities that affect communication between the brain and bladder, often triggered by spinal cord injuries, neurological conditions (e.g., multiple sclerosis, Parkinson's disease, stroke), or congenital issues.

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

Definitions:

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

American Urological Association Symptom Index (AUA-SI) score / International Prostate Symptoms Score (IPSS)

Circle the best answer that represents your response. The test is used to measure your severity of symptoms.	Not at all	Less than 1 in 5 times	Less than half the time	About half	More than half the time	Almost always

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				the time		
Incomplete emptying: over the past month, how often have you had a sensation of not emptying your bladder completely after you have finished urinating?	0	1	2	3	4	5
Frequency: over the past month, how often have you had to urinate again less than 2 hours after you finished urinating?	0	1	2	3	4	5
Intermittency: over the past month, how often have you found you stopped and started again several times when you urinate?	0	1	2	3	4	5
Urgency: over the past month, how often have you found it difficult to postpone urination?	0	1	2	3	4	5
Weak stream: over the past month, how often have you had a weak urinary stream?	0	1	2	3	4	5
Straining: over the past month, how often have you had to push or strain to begin urination?	0	1	2	3	4	5
	None	1 Time	2 times	3 times	4 times	5 or more
Nocturia: over the last month, how many times did you most typically get up to urinate from the time you went to bed at night until the time you get up in the morning?	0	1	2	3	4	5+
Your total score (add your number from answers to the 7 items from above for your total score)						
Total symptom score: Mild = 1-7, Moderate = 8-19, Severe = 20-35						

	Delighted	Pleased	Mostly satisfied	Mixed	Mostly dissatisfied	Unhappy	Terrible
Quality of life: if you were to spend the rest of your life with your urinary condition the way it is now, how would you feel about it?	0	1	2	3	4	5	6

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 03, 2025.

Fesoterodine extended-release tab product information, revised by Camber Pharmaceuticals, Inc. 02-2025. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 03, 2025.

Gemtesa (vibegron) tab product information, revised by Sumitomo Pharma America, Inc. 02-2025. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed November 03, 2025.

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 December 2025. Topic last updated on January 22, 2024. Accessed January 16, 2026.

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Lukacz ES. Female urinary incontinence: Treatment. In: UpToDate, Schmader KE, Brubaker L, Eckler K, Li H(Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Literature current through December 2025. Topic last updated June 26, 2025. Accessed January 16, 2026.

McVary KT, Saini R. Lower urinary tract symptoms in males. In: UpToDate, O'Leary MP, Li H (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Literature current through December 2025. Topic last updated May 06, 2025. Accessed January 16, 2026.

Clemens JQ. Urinary incontinence in men. In: UpToDate, O'Leary MP, Li H (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Literature current through December 2025. Topic last updated July 10, 2025. Accessed January 16, 2026.

Cameron AP, Chung DE, Dielubanza EJ, et al.: The AUA/SUFU Guideline on the Diagnosis and Treatment of Idiopathic Overactive Bladder. J Urology 2024 July; 212: 11-20 https://doi.org/10.1097/JU.0000000000003985. Accessed January 18, 2026.

Rovner ES, Owens-Grillo J, Thomas E, et al.: Bladder Function and Safety of Vibegron in Men with Overactive Bladder Receiving Treatment for Benign Prostatic Hyperplasia: Outcomes from the Phase 3 Randomized Controlled COURAGE Trial. Neurourology and Urodynamics, 2025; 1–6 https://doi.org/10.1002/nau.70199. Accessed January 17, 2026.

ClinicalTrials.gov Bethesda (MD): National Library of Medicine (US). Identifier NCT03902080: Phase 3 Double-Blind, Randomized, Placebo-Controlled, Multi-Center Study to Evaluate the Efficacy, Safety and Tolerability of Vibegron in Men With Overactive Bladder (OAB) Symptoms on Pharmacological Therapy for Benign Prostatic Hyperplasia (BPH). Available from: http://clinicaltrials.gov. Last update posted August 07, 2024. Last verified June 2024. Accessed January 17, 2026.