Drug Coverage Policy

Effective Date……09/15/2026
Coverage Policy Number…… ST007
Policy Title……Overactive Bladder Medications Step Therapy Policy for Employer Plans: Value/ Advantage Drug List

Overactive Bladder Medications Step Therapy Policy for Employer Plans: Value/Advantage Drug List

- Gemtesa® (virabegron tablets – Urovant Sciences)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used

as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview
These products, except oxybutynin tablets and syrup and Vesicare LS, are indicated for the **treatment of overactive bladder** (OAB) with symptoms of urge urinary incontinence, urgency, and frequency.[1-15] Gemtesa and Myrbetriq are beta$_3$-adrenergic agonists; the other products are antimuscarinics. Myrbetriq is indicated for use as monotherapy or in combination with solifenacin.[14] Gemtesa is indicated for males with OAB with symptoms of urge urinary incontinence, urgency, and urinary frequency on other pharmacological therapy for benign prostatic hyperplasia.[15]

The Oxytrol transdermal patch is available as a prescription and an over-the-counter (OTC) product. Prescription Oxytrol is indicated for the treatment of OAB in men with symptoms of urge urinary incontinence, urgency, and frequency.[4] The OTC formulation is marketed as Oxytrol for Women and is indicated for use in women ≥ 18 years of age.[16] The prescription and OTC Oxytrol contain the same dose of oxybutynin (3.9 mg/day).[4,16]

Pediatric Indications
Oxybutynin tablets and syrup are indicated for the **relief of symptoms of bladder instability** associated with voiding in patients (≥ 5 years of age) with uninhibited neurogenic or reflex neurogenic bladder (i.e., urgency, frequency, urinary leakage, urge incontinence, dysuria).[1,2] Oxybutynin extended-release (ER) tablets are indicated for the treatment of pediatric patients ≥ 6 years of age with symptoms of **detrusor overactivity associated with a neurological condition** (e.g., spina bifida).[3] Myrbetriq, Toviaz, Vesicare LS are indicated for the treatment of **neurogenic detrusor overactivity** in pediatric patients ≥ 3 years of age, ≥ 6 years, and ≥ 2 years of age, respectively.[11,13,14]

Guidelines
The American Urological Association (AUA) and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) guidelines for the diagnosis and treatment of idiopathic overactive bladder (2024).[17] The guidelines recommend behavioral therapies (e.g., bladder training, bladder control strategies, pelvic floor muscle training, fluid management) as the first-line treatment in patients with OAB. Oral antimuscarinics and oral beta-3 adrenergic agonists are second-line therapies. Myrbetriq appears to be similar in efficacy to the antimuscarinic agents. Combination therapy (an antimuscarinic with a beta-3 adrenergic agonist) as a potential second-line treatment for patients refractory to monotherapy with either antimuscarinics or beta-3 adrenergic agonists. The guidelines note that oral antimuscarinics are similar in efficacy and the choice of agent for a particular patient is dependent on many factors, including the patient's history of antimuscarinic use; information regarding adverse events (AEs) experienced in the past; impact of the AEs on the patient; patient preference, comorbidities, use of other medications; and cost. Patients who experienced inadequate symptom control and/or unacceptable AEs with one antimuscarinic may experience better symptom control and/or a more acceptable AE profile if the dose were modified or if they were treated with another antimuscarinic or with a beta-3 adrenergic agonist. Even though the guidelines do not prefer one antimuscarinic over another, when given a choice between an immediate-release (IR) and an ER formulation, the ER formulation is preferred over the IR formulation due to lower rates of dry mouth. Transdermal

and topical formulations of oxybutynin can be offered in lieu of oral antimuscarinics to patients who are at risk of or who have experienced dry mouth with the oral agents.

Coverage Policy

POLICY STATEMENT
This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration. Meeting Step therapy Program Criteria does not satisfy any other prior authorization or medical necessity criteria requirements.

Step 1: generic darifenacin extended-release tablets, generic fesoterodine fumarate extended-release tablets, generic mirabegron extended-release tablets, generic mirabegron granules for extended-release oral suspension, generic oxybutynin immediate-release tablets, generic oxybutynin immediate-release syrup, generic oxybutynin extended-release tablets, generic solifenacin succinate tablets, generic tolterodine tartrate tablets, generic tolterodine tartrate extended-release capsules, generic trospium chloride tablets, generic trospium chloride extended-release capsules

Step 2: Gemtesa

Overactive Bladder Medications are covered as medically necessary when ONE of the following criteria is met (1 or 2). Any other exception is considered not medically necessary.

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.

2. Approve Gemtesa if being requested for the treatment of overactive bladder symptoms in a patient with benign prostatic hypertrophy.

References

1. Oxybutynin tablets [prescribing information]. Parsippany, NJ: Teva; September 2024.
2. Oxybutynin syrup [prescribing information]. Philadelphia, PA: Lannett; February 2020.
3. Oxybutynin extended-release tablets [prescribing information]. Philadelphia, PA: Lannett; May 2023.
4. Oxytrol® transdermal system [prescribing information]. North Chicago, IL: AbbVie/Allergan; May 2024.
5. Detrol® tablets [prescribing information]. Morgantown, WV: Viatris; February 2023.
6. Detrol® LA extended release capsules [prescribing information]. Morgantown, WV: Viatris; March 2023.
7. Trospium tablets [prescribing information]. Elmwood Park, NJ: Glenmark; August 2025.
8. Trospium extended-release capsules [prescribing information]. Chantilly, VA: Granules; September 2020.
9. Vesicare® tablets [prescribing information]. Northbrook, IL: Astellas; October 2022.
10. Darifenacin extended-release tablets [prescribing information]. Warren, NJ: Cipla; February 2024.
11. Toviaz®extended-release tablets [prescribing information]. New York, NY: Pfizer; February 2024.

12. Gelnique® 10% gel [prescribing information]. Madison, NJ: Allergan; March 2019.
13. Vesicare LS™ [prescribing information]. Northbrook, IL: Astellas; October 2022.
14. Myrbetriq® extended-release tablets, Myrbetriq® Granules [prescribing information]. Northbrook, IL: Astellas; April 2021.
15. Gemtesa® [prescribing information]. Marlborough, MA: Sumitomo; February 2025.
16. Oxytrol® for Women transdermal system [prescribing information]. North Chicago, IL: AbbVie/Allergan; August 2024.
17. Cameron AP, Chung DE, Dielubanza EJ, et al. The AUA/SUFU guideline on the diagnosis and treatment of idiopathic overactive bladder. *J Urol.* 2024;212(1):11-20.

Revision Details

Summary of Changes	Review Date	Effective Date
New policy.	06/04/2026	07/15/2026
Mirabegron granules for extended-release oral suspension: Generic mirabegron granules for extended-release oral suspension were added to Step 1.	08/06/2026	09/15/2026

The policy effective date is in force until updated or retired.

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