PREFERRED STEP THERAPY POLICY

POLICY: Overactive Bladder Medications Preferred Step Therapy Policy

- Darifenacin extended-release tablets (generic only)
- Detrol® (tolterodine tablets – Pfizer, generic)
- Detrol LA® (tolterodine extended-release capsules – Pfizer, generic)
- Ditropan XL® (oxybutynin extended-release tablets – Janssen, generic)
- Gelnique™ (oxybutynin 10% gel – Allergan)
- Myrbetriq® (mirabegron extended-release tablets – Astellas, generic)
- Myrbetriq® Granules (mirabegron for extended-release oral suspension – Astellas)
- Oxybutynin tablets, syrup (generic only)
- Oxytrol® (oxybutynin transdermal system – Allergan)
- Oxytrol® for Women (oxybutynin transdermal system – Actavis) [over-the-counter]
- Toviaz® (fesoterodine fumarate extended-release tablets – Pfizer, generic)
- Trospium tablets (generic only)
- Trospium extended-release capsules (generic only)
- Vesicare® (solifenacin tablets –Astellas, generic)
- Vesicare LS™ (solifenacin succinate oral suspension – Astellas)

REVIEW DATE: 05/21/2025

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.

CIGNA NATIONAL FORMULARY COVERAGE:

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.[1-14] Myrbetriq is a beta-3 adrenergic agonist; the other products are antimuscarinics. Myrbetriq is indicated for use as monotherapy or in combination with solifenacin.[14]

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.[15] The prescription and OTC Oxytrol contain the same dose of oxybutynin (3.9 mg/day).[4,15]

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 AE 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, if 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.

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 Preferred Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Preferred Step Therapy criteria below. All approvals are provided for 1 year in duration.

Step 1: generic darifenacin extended-release tablets, generic fesoterodine fumarate extended-release tablets, Gelnique, generic mirabegron extended-release tablets, Myrbetriq, Myrbetriq Granules, 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: Detrol, Detrol LA, Ditropan XL, Enablex, Oxytrol (prescription), Oxytrol for Women (over-the-counter), Toviaz, Vesicare, Vesicare LS

Overactive Bladder Medications Preferred Step Therapy Policy **product(s) is(are) covered as medically necessary when the following preferred step therapy criteria is(are) met. 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. If the patient is < 3 years of age, approve Vesicare LS.

REFERENCES

1. Oxybutynin tablets [prescribing information]. Princeton, NJ: Eywa; May 2019.
2. Oxybutynin syrup [prescribing information]. Philadelphia, PA: Lannett; Feburary 2020.
3. Ditropan XL® extended release tablets [prescribing information]. Titusville, NJ: Janssen; December 2022.
4. Oxytrol® transdermal system [prescribing information]. Irvine, CA: Allergan; May 2024.
5. Detrol® tablets [prescribing information]. New York, NY: Pfizer; October 2016.
6. Detrol® LA extended release capsules [prescribing information]. New York, NY: Pfizer; July 2018.
7. Trospium tablets [prescribing information]. Mahwah NJ: Glenmark; December 2023.

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; August 2021.
11. Toviaz® extended-release tablets [prescribing information]. New York, NY: Pfizer; November 2021.
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 [prescribing information]. Northbrook, IL: Astellas; April 2021.
15. Gemtesa® [prescribing information]. Irvine, CA: Urovant Sciences; July 2023.
16. Oxytrol® for Women transdermal system. [prescribing information]. Madison, NJ: Allergan; August 2016.
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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	07/26/2023
Early Annual Revision	**Mirabegron ER tablets**: Generic mirabegron extended-release tablets were added to Step 1. There were no other changes to the criteria.	05/08/2024
Annual Revision	No criteria changes.	05/21/2025