

Cigna National Preferred Formulary Coverage Policy



Effective Date 1/1/2021

Next Review Date... 1/1/2022

Coverage Policy Number NPF108

Preferred Step Therapy Overactive Bladder Agents

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Related Coverage Resources

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. 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.

NPF Coverage Policy

Drugs Affected

- Detrol® (tolterodine tablets)
- Detrol LA® (tolterodine extended-release capsules)
- Ditropan XL® (oxybutynin extended-release tablets)
- Enablex® (darifenacin extended-release tablets)
- Gelnique™ (oxybutynin 10% gel)
- Myrbetriq® (mirabegron extended-release tablets)
- Oxybutynin (oxybutynin tablets, syrup)
- Oxytrol® (oxybutynin transdermal system)
- Oxytrol® for Women (oxybutynin transdermal system) [over-the-counter]
- Toviaz® (fesoterodine fumarate extended-release tablets)
- Trospium tablets
- Trospium extended-release capsules
- Vesicare® (solifenacin tablets)
- Vesicare LS™ (solifenacin succinate oral suspension)

This program has been developed to encourage the use of a Step 1 drug prior to the use of a Step 2 drug. If the Preferred Step Therapy rule is not met for a Step 2 drug 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: darifenacin extended-release tablets, Gelnique, Myrbetriq, oxybutynin immediate-release tablets, oxybutynin immediate-release syrup, oxybutynin extended-release tablets, solifenacin succinate tablets, tolterodine tartrate tablets, tolterodine tartrate extended-release capsules, Toviaz, trospium chloride tablets, trospium chloride extended-release capsules

Step 2: Detrol, Detrol LA, Ditropan XL, Enablex, Oxytrol (prescription), Oxytrol for Women (over-the-counter), Vesicare, Vesicare LS

Cigna covers Step 2 agents as medically necessary when the following criteria are met:

1. If the individual has tried one Step 1 product, authorization for a Step 2 product may be given.
2. If the individual is < 5 years of age, authorization for Vesicare LS may be given.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview

All of these products, except Myrbetriq, are antimuscarinics; Myrbetriq is a beta-3 adrenergic agonist.¹⁻¹⁵

- Oxybutynin tablets and syrup are indicated for the relief of symptoms of bladder instability associated with voiding in individuals with uninhibited neurogenic or reflex neurogenic bladder (i.e., urgency, frequency, urinary leakage, urge incontinence, dysuria) in individuals ≥ 5 years of age.^{1,2}
- Oxybutynin extended-release (ER) tablets are indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency and for the treatment of pediatric individuals ≥ 6 years of age with symptoms of detrusor over activity associated with a neurological condition (e.g., spina bifida).³
- Vesicare LS is indicated for the treatment of neurogenic detrusor over activity in pediatric individuals ≥ 2 years of age.¹³
- The other antimuscarinics and Myrbetriq are indicated for the treatment of OAB with symptoms of urge urinary incontinence, urgency, and frequency.^{4-12,14,15}

The Oxytrol transdermal patch is available as a prescription and an over-the-counter (OTC) product. The indication for the prescription Oxytrol patch was changed in October 2017 to 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 it contains the same dose of oxybutynin (3.9 mg/day) as the prescription product.¹⁴ Oxytrol for Women is indicated for OTC use in women ≥ 18 years of age.

Guidelines

The American Urological Association (AUA) and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) amended the 2012 guidelines for the diagnosis and treatment of overactive bladder (non-neurogenic) in adults in 2019.¹⁶ The guidelines recommend behavioral therapies (e.g., bladder training, bladder control strategies, pelvic floor muscle training, fluid management) as the first-line treatment in individuals with OAB. Oral antimuscarinics and oral β3-adrenoceptor agonists are second-line therapies; Myrbetriq appears to be similar in efficacy to the antimuscarinic agents. The 2019 amendment included combination therapy (an antimuscarinic with a β3-adrenoceptor agonist) as a potential second-line treatment for individuals refractory to monotherapy with either antimuscarinics or β3-adrenoceptor agonists. The guidelines note that oral antimuscarinics are similar in efficacy and the choice of agent for a particular individual is dependent on many factors, including the individual's history of antimuscarinic use; information regarding

adverse events (AEs) experienced in the past; impact of the AEs on the individual; individual preference, comorbidities, use of other medications; and cost. Individuals 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 β_3 -adrenoceptor 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 individuals who are at risk of or who have experienced dry mouth with the oral agents

The Canadian Urological Association (CUA) published guidelines on adult overactive bladder in 2017. Their recommendations are similar to those of the AUA.¹⁷ Behavioral therapies (bladder training [e.g., bladder control strategies, time voiding, prompted or scheduled voiding] and pelvic floor muscle therapy) and lifestyle changes (e.g., modified fluid/caffeine intake, weight control, and dietary modifications) are first-line options for all individuals. Second-line treatment should include the use of oral antimuscarinics, transdermal oxybutynin, and oral beta-3 adrenergic receptor agonists. Immediate-release antimuscarinics should be avoided if other formulations are available.

References

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2. Oxybutynin syrup [prescribing information]. Morton Grove, IL: Morton Grove Pharmaceuticals; July 2018.
3. Ditropan XL® extended release tablets [prescribing information]. Vacaville, CA: Alza Corporation; September 2019.
4. Oxytrol® transdermal system [prescribing information]. Irvine, CA: Allergan; October 2017.
5. Detrol® tablets [prescribing information]. New York, NY: Pharmacia & Upjohn Company, Division of Pfizer; October 2016.
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9. Vesicare® tablets [prescribing information]. Northbrook, IL: Astellas Pharma US, Inc.; April 2019.
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15. Myrbetriq® extended-release tablets [prescribing information]. Northbrook, IL: Astellas Pharma US, Inc.; April 2018.
16. Gormley AE, Lightner DJ, Burgio KL, et al. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: American Urological Association (AUA)/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) guideline amendment 2019. *J Urol*. 2019;202(3):558-563.
17. Canadian Urological Association guideline on adult overactive bladder. *Can Urol Assoc J*. 2017;11:E142-E173.

Last Revision Details

Annual revision	Add Vesicare LS to Step 2. Add Exceptions criterion for Vesicare LS to approve for use in children < 5 years of age.	08/05/2020
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