

## STEP THERAPY POLICY

- POLICY:** Overactive Bladder Medications Step Therapy Policy
- Detrol<sup>®</sup> (tolterodine tartrate tablets – Pfizer, generic)
  - Detrol LA<sup>®</sup> (tolterodine tartrate extended-release capsules – Pfizer, generic)
  - Ditropan XL<sup>®</sup> (oxybutynin chloride extended-release tablets – Janssen, generic)
  - Enablex<sup>®</sup> (darifenacin extended-release tablets, Allergan, generic)
  - Gelnique<sup>®</sup> (oxybutynin 10% gel – Allergan)
  - Gemtesa<sup>®</sup> (virabegron tablets – Urovant Sciences)
  - Myrbetriq<sup>®</sup> (mirabegron extended-release tablets – Astellas)
  - Myrbetriq<sup>®</sup> Granules (mirabegron for extended-release oral suspension – Astellas)
  - Oxybutynin chloride tablets, syrup (generic only)
  - Oxytrol<sup>®</sup> (oxybutynin transdermal system – Allergan)
  - Oxytrol<sup>®</sup> for Women (oxybutynin transdermal system – Actavis) [over-the-counter]
  - Toviaz<sup>®</sup> (fesoterodine fumarate extended-release tablets – Pfizer, generic)
  - Trospium chloride tablets (generic only)
  - Trospium chloride extended-release capsules (generic only)
  - Vesicare<sup>®</sup> (solifenacin succinate tablets – Astellas, generic)
  - Vesicare LS<sup>™</sup> (solifenacin succinate oral suspension – Astellas)

**REVIEW DATE:** 07/20/2022

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### 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.<sup>1-15</sup> Gemtesa and Myrbetriq are beta3-adrenergic agonists; the other products are antimuscarinics. Myrbetriq is indicated for use as monotherapy or in combination with solifenacin.<sup>14</sup>

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.<sup>4</sup> The OTC formulation is marketed as Oxytrol for Women and is indicated for use in women  $\geq 18$  years of age.<sup>16</sup> The prescription and OTC Oxytrol contain the same dose of oxybutynin (3.9 mg/day).<sup>4,16</sup>

### Pediatric Indications

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

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## 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.<sup>17</sup> 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. The 2019 amendment included 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.

The Canadian Urological Association published guidelines for adult OAB in 2017. Their recommendations are similar to those of the AUA.<sup>18</sup> Behavioral therapies and lifestyle changes (e.g., modified fluid/caffeine intake, weight control, dietary modifications) are first-line options in all patients. Second-line treatment should include the use of oral antimuscarinics, transdermal oxybutynin, and oral beta-3 adrenergic agonists. IR antimuscarinics should be avoided if other formulations are available.

## 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.

**Automation:** A patient with a of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

- Step 1:** generic darifenacin extended-release tablets, generic fesoterodine fumarate extended-release tablets, 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, Gelnique, Gemtesa, Myrbetriq, Myrbetriq Granules, Oxytrol (prescription), Oxytrol for Women (over-the-counter), Toviaz, Vesicare, Vesicare LS

## CRITERIA

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

2. If the patient cannot swallow or has difficulty swallowing tablets or capsules, approve Gelnique, Myrbetriq Granules, or Oxytrol (prescription or over-the-counter).
3. If the patient is < 5 years of age, approve Vesicare LS, Myrbetriq tablets, or Myrbetriq Granules.
4. If the patient is  $\geq$  65 years of age, approve Gemtesa or Myrbetriq tablets.
5. No other exceptions are recommended.

## REFERENCES

1. Oxybutynin tablets [prescribing information]. Princeton, NJ: Eywa Pharma; May 2019.
2. Oxybutynin syrup [prescribing information]. Philadelphia, PA: Lannett; February 2020.
3. Ditropan XL<sup>®</sup> extended release tablets [prescribing information]. Titusville, NJ: Janssen; March 2021.
4. Oxytrol<sup>®</sup> transdermal system [prescribing information]. Irvine, CA: Allergan; October 2017.
5. Detrol<sup>®</sup> tablets [prescribing information]. New York, NY: Pfizer; October 2016.
6. Detrol<sup>®</sup> LA extended release capsules [prescribing information]. New York, NY: Pfizer; July 2018.
7. Trosipium tablets [prescribing information]. Mahway, NJ: Glenmark; October 2020.
8. Trosipium extended-release capsules [prescribing information]. Parsippany, NJ: Actavis; August 2014.
9. Vesicare<sup>®</sup> tablets [prescribing information]. Northbrook, IL: Astellas; April 2019.
10. Enablex<sup>®</sup> extended-release tablets [prescribing information]. Madison, NJ: Allergan; July 2021.
11. Toviaz<sup>®</sup> extended-release tablets [prescribing information]. New York, NY: Pfizer; June 2021.
12. Gelnique<sup>®</sup> 10% gel [prescribing information]. Madison, NJ: Allergan; March 2019.
13. Vesicare LS<sup>™</sup> [prescribing information]. Northbrook, IL: Astellas; May 2020.
14. Myrbetriq<sup>®</sup> extended-release tablets, Myrbetriq<sup>®</sup> Granules [prescribing information]. Northbrook, IL: Astellas; April 2021.
15. Gemtesa<sup>®</sup> [prescribing information]. Irvine, CA: Urovant Sciences; December 2020.
16. Oxytrol<sup>®</sup> for Women transdermal system. General information available at: <https://www.empr.com/drug/oxytrol-for-women/>. Accessed on July 14, 2022.
17. 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.
18. Canadian Urological Association guideline on adult overactive bladder. *Can Urol Assoc J.* 2017;11:E142-E173.