Bladder Relaxant Preparations
Utilization Management Criteria

Therapeutic Class:	Bladder Relaxant Preparations
Non-Preferred Agents:	Flavoxate (oral); Oxybutynin 2.5 mg (oral); Trospium (oral); Tolterodine (oral); Tolterodine ER (oral); Tolterodine ER (AG) (oral); Detrol (oral); Detrol LA (oral); Oxytrol (transdermal); Vesicare tablet (oral); Darifenacin ER (oral); Trospium ER (oral); Toviaz (oral); Mirabegron ER (oral); Oxytrol for Women OTC (transdermal); Vesicare LS (oral); Gemtesa (oral); Myrbetriq granules for suspension (oral)
Preferred Agents:	Oxybutynin syrup (oral); Oxybutynin tablet (not 2.5 mg) (oral); Oxybutynin ER (oral); Solifenacin (oral); Fesoterodine ER (oral); Myrbetriq tablet (oral)
Implementation Date:	1/1/2026
Prepared For:	CT Medicaid
PDL Status:	Nonpreferred Agents
Background:	The bladder relaxant preparations include the anticholinergics, the β3 adrenergic receptor agonists, and the direct smooth muscle relaxant flavoxate. These agents are used in the treatment of symptoms of either overactive bladder (OAB) or neurogenic detrusor overactivity (NDO). Overactive bladder is characterized by symptoms of urgency, urinary frequency, and urgency urinary incontinence (UUI), which may be caused by pelvic floor muscle dysfunction, damage to connective tissue, or poor sphincter function. Neurogenic detrusor overactivity is a type of OAB specifically caused by neurological disorders or injuries affecting normal bladder control. All products in this review are indicated to treat symptoms of OAB; those that are indicated to treat NDO include Ditropan® XL (oxybutynin extended release), Myrbetriq®, Myrbetriq® Granules, Toviaz®, and Vesicare LS®. Gemtesa® recently received a new indication of OAB in males on pharmacologic therapy for benign prostatic hyperplasia (BPH). All agents are available in oral solid formulations; oxybutynin is additionally available as oral syrup, oral solution, and transdermal preparations (including an over-the counter [OTC] transdermal film indicated for use in women). Safety concerns include risk of anticholinergic adverse effects (e.g., central nervous system [CNS] effects, worsening of glaucoma, urinary retention) with the anticholinergics and risk of hypertension with the β3 adrenergic receptor agonists. Anticholinergic agents should be used with caution in elderly patients, especially those at risk of cognitive dysfunction. Unique safety considerations include QT prolongation with solifenacin and tolterodine and concomitant alcohol consumption with trospium. Current guidelines for treatment of symptoms of OAB in various populations state that antimuscarinic agents and β3 adrenergic receptor agonists may be considered in patients who fail conservative treatment. Extended-release (ER) formulations should be used whenever possible because they are associated

	with lower risk of adverse events compared with immediate-release (IR) formulations. Current guidelines suggest use of antimuscarinic agents and β3 adrenergic receptor agonists may be offered on a conditional status in patients with OAB and BPH. Recent comparative trials have not demonstrated significant differences among active treatments. Indirect comparisons among the renal and genitourinary tract antispasmodics do not indicate consistent superiority of any one agent across all evaluated outcomes.

Table 1. Bladder Relaxant Preparations Class Agents.

Generic Name	Brand Name	Approved Indications	Route of Administration	Generic Availability
Darifenacin ER	Enablex®[a]	OAB with symptoms of UUI, urgency, and frequency	PO	Y
Fesoterodine ER	Toviaz®	OAB with symptoms of UUI, urgency, and frequency; NDO	PO	Y
Flavoxate	Urispas®[a]	Symptomatic relief of dysuria, urgency, nocturia, suprapubic pain, frequency and incontinence as may occur in cystitis, prostatitis, urethritis, urethrocystitis/urethrotrigonitis	PO	Y
Mirabegron	Myrbetriq®	OAB with symptoms of UUI, urgency, and frequency, alone or in combination with solifenacin succinate; NDO	PO	Y
	Myrbetriq® Granules	NDO		N
Oxybutynin	Ditropan®[a] IR	Treatment of symptoms of bladder instability associated with voiding in patients with uninhibited neurogenic or reflex neurogenic bladder	PO	Y
	Ditropan®[a] XL ER tablet	OAB with symptoms of UUI, urgency, and frequency; NDO	PO	Y
	Oxytrol® transdermal patch	OAB in men with symptoms of UUI, urgency, and frequency	Transdermal	N
	Oxytrol® for Women ER film (OTC)	OAB in women	Transdermal	N
Solifenacin	Vesicare®	OAB with symptoms of UUI, urgency, and frequency	PO	Y
	Vesicare LS®	NDO	PO	N
Tolterodine	Detrol® IR tablet	OAB with symptoms of UUI, urgency, and frequency	PO	Y
	Detrol® LA ER capsule			
Trospium	Sanctura®[a] IR tablet	OAB with symptoms of UUI, urgency, and frequency	PO	Y
	Sanctura®[a] ER tablet			
Vibegron	Gemtesa®	OAB with symptoms of UUI, urgency, and frequency; OAB with symptoms of UUI, urgency and frequency with BPH	PO	N

[a]The branded formulation of this product is no longer marketed.
Abbreviations: BPH, benign prostatic hyperplasia; ER, extended-release; IR, immediate-release; NDO, neurogenic detrusor overactivity; OAB, overactive bladder; OTC, over the counter; PO, oral; UUI, urge urinary incontinence

All authorizations must be prescribed in accordance with FDA approved labeling. Use of samples to initiate therapy does not meet step therapy and/or continuation of therapy prior authorization requirements. Prior therapies will be verified through pharmacy claims and/or submitted chart notes

General Approval Criteria:

- For specific formulation requests
  - **For brand requests when a therapeutically equivalent generic is preferred:** Provider must provide a documented medical reason the preferred generic formulation cannot be used
  - **For generic requests when a therapeutically equivalent brand is preferred:** Provider must provide a documented medical reason the preferred brand formulation cannot be used
  - **For non-preferred dosage or formulation requests:** Provider must provide a documented medical reason the preferred dosage or formulation cannot be used

Initial Therapy – ONE of the following must be met:

- Claim is for a preferred agent **OR**
- Failure to achieve desired therapeutic outcomes with a trial of **one** preferred agent (defined as 30 day trial)

For Myrbetriq Granules and Vesicare suspension:

- Documentation of medical reason why tablet formulations may not be utilized.

The following age limits apply:

- **Toviaz** – patient age 6 years and older
- **Myrbetriq, Myrbetriq granules**- patient age 3 years and older
- **Ditropan XL**- patient age 6 years and older
- **Vesicare**- patient age 2 years and older
- **Flavoxate**- patient age 12 and older

In addition, the following quantity limits apply:

Brand Name	Generic Name	Max Dosing Limitation
Detrol 1 mg tablet	tolterodine	2 tablets per day
Detrol 2 mg tablet	tolterodine	2 tablets per day
Detrol LA 2 mg capsule	tolterodine ER	1 capsule per day
Detrol LA 4 mg capsule	tolterodine ER	1 capsule per day
Ditropan 5 mg tablet	oxybutynin	4 tablets per day
Ditropan XL 10 mg tablet	oxybutynin ER	2 tablets per day
Ditropan XL 15 mg tablet	oxybutynin ER	2 tablets per day
Ditropan XL 5 mg tablet	oxybutynin ER	1 tablet per day
Enablex 15 mg tablet	darifenacin	1 tablet per day
Enablex 7.5 mg tablet	darifenacin	1 tablet per day
Flavoxate 100 mg tablet	flavoxate	6 tablets per day

Gemtesa 75 mg tablet	vibegron	1 tablet per day
Myrbetriq ER 25 mg tablet	mirabegron ER	1 tablet per day
Myrbetriq ER 50 mg tablet	mirabegron ER	1 tablet per day
Oxybutynin 2.5 mg tablet	oxybutynin	3 tablets per day
Oxytrol 3.9 mg/ 24 hr patch	oxybutynin	8 patches per 28 days
Oxytrol for Women 3.9 mg / 24 hr	oxybutynin	8 patches per 28 days
Sanctura 20 mg tablet	trospium	3 tablets per day
Sanctura XR 60 mg capsule	trospium	1 capsule per day
Toviaz ER 4 mg tablet	fesoterodine	1 tablet per day
Toviaz ER 8 mg tablet	fesoterodine	1 tablet per day
Vesicare 10 mg tablet	solifenacin	1 tablet per day
Vesicare 5 mg tablet	solifenacin	1 tablet per day

Initial PA length: 1 year

Continuation Therapy: Documented compliance on current therapy regimen **AND** Documented continued clinical benefit **AND**

- For specific formulation requests
  - **For brand requests when a therapeutically equivalent generic is preferred:** Provider must provide a documented medical reason the preferred generic formulation cannot be used
  - **For generic requests when a therapeutically equivalent brand is preferred:** Provider must provide a documented medical reason the preferred brand formulation cannot be used
  - **For non-preferred dosage or formulation requests:** Provider must provide a documented medical reason the preferred dosage or formulation cannot be used

Continuation Length: 1 year

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Revision History

Date	Version	Revisions
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