



PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 3/17/16
LAST REVIEW DATE: 3/15/18
LAST CRITERIA REVISION DATE: 3/01/17
ARCHIVE DATE:

OVERACTIVE BLADDER MEDICATIONS, NON-PREFERRED BRANDS:

DETROL® (tolterodine tartrate) oral tablet
DETROL LA® (tolterodine tartrate ER) oral capsule
DITROPAN XL® (oxybutynin chloride ER) oral tablet
ENABLEX® (darifenacin ER) oral tablet
GELNIQUE® (oxybutynin chloride) transdermal gel
TOVIAZ® (fesoterodine fumarate ER) oral tablet

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

OVERACTIVE BLADDER MEDICATIONS, NON-PREFERRED BRANDS (cont.)

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

Description:

Overactive bladder (OAB) occurs when bladder muscle contractions are not controlled. When these muscle contractions happen too often or cannot be controlled, symptoms of overactive bladder, such as urinary frequency, urgency, and incontinence (leakage) occur.

The urinary bladder contains nerves, muscles, and connective tissue. The most important muscle in the bladder is the detrusor muscle. In normal circumstances, the bladder stretches as it fills with urine. When the volume in the bladder reaches approximately 300 mL, the stretch in the wall of the bladder triggers a nerve response to initiate urination. This reaction results in loosening of the sphincter in the neck of the bladder that connects the bladder to the urethra and contraction of the detrusor muscle to begin urination. This response is under voluntary control and can be overridden by the individual to prevent urination if it is not the right time or place. An overactive bladder can result from dysfunction of the nerves or muscles in the bladder, most commonly the detrusor muscle. In OAB, the detrusor can contract inappropriately regardless of how much urine is stored in the bladder, resulting in a condition known as detrusor overactivity or hyperactive detrusor.

All medications for OAB are effective for reducing incontinence episodes and urinary frequency and all medications for OAB have an adequate track record for safety. No medication for OAB has been shown to be safer or more effective overall than any other.

There are many generically available oral antimuscarinic/anticholinergic medications for the treatment of OAB, formulated as immediate- and extended-release products.

Antimuscarinic/anticholinergic medications are associated with several adverse effects including dry mouth, dry eyes, blurry vision, urinary retention, constipation and somnolence. The safety profiles of antimuscarinic/anticholinergic medications are similar overall, but may differ slightly based on route of administration.

Mirabegron (Myrbetriq), a beta-3 adrenergic agonist, offers an option for patients unable to tolerate antimuscarinic/anticholinergic adverse effects. Over-the-counter (OTC) oxybutynin transdermal patches provide a non-oral dosing option.

Guidelines recommend behavioral therapies (such as bladder training, bladder control strategies, pelvic floor muscle training, and fluid management) as first-line treatment for OAB, either alone or in combination with oral antimuscarinics or beta-3-AR agonists.

OVERACTIVE BLADDER MEDICATIONS, NON-PREFERRED BRANDS (cont.)

Criteria:

- **Criteria for initial therapy:** Non-preferred brands Detrol, Detrol LA, Ditropan XL, Enablex, Gelnique, and Toviaz is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. A confirmed diagnosis of **ONE** of the following:
 - **For Detrol, Detrol LA, Enablex, Gelnique, and Toviaz:**
 - Individual is 18 years of age or older with a confirmed diagnosis of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency
 - **For Ditropan XL either** of the following:
 - Individual is 6 years of age or older with a confirmed diagnosis of symptoms of detrusor overactivity associated with a neurological condition (e.g., spina bifida)
 - Individual is 18 years of age or older with a confirmed diagnosis of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency
 2. Individual has failure, contraindication or intolerance to **ALL** of the following generic agents for OAB:
 - Darifenacin ER
 - Flavoxate
 - Oxybutynin IR
 - Oxybutynin ER
 - Tolterodine IR
 - Tolterodine ER
 - Trospium IR
 - Trospium ER
 3. Individual has failure, contraindication or intolerance to **BOTH** Myrbetric (mirabegron) and VESicare (solifenacin) for OAB
 4. There are **NO** contraindications.
 - Contraindications include:
 - Urinary retention
 - Gastric retention
 - Uncontrolled narrow-angle glaucoma
 - Hypersensitivity to any component of the product

Initial approval duration: 12 months

- **Criteria for continuation of coverage (renewal request):** Non-preferred brands Detrol, Detrol LA, Ditropan XL, Enablex, Gelnique, and Toviaz is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. The individual has benefited from therapy but remains at high risk



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2. The condition has not progressed or worsened while on therapy
3. Individual has not developed any contraindications or other exclusions to its continued use

Renewal duration: 12 months

Resources:

Detrol. Package Insert. Revised by manufacturer 08-2012. Accessed 03-02-2016, 02-28-2017.

Detrol LA. Package Insert. Revised by manufacturer 08-2012. Accessed 03-02-2016, 02-28-2017.

Ditropan XL. Package Insert. Revised by manufacturer 02-2015. Accessed 03-02-2016.

Ditropan XL. Package Insert. Revised by manufacturer 10-2016. Accessed 02-28-2017.

Enablex. Package Insert. Revised by manufacturer 03-2012. Accessed 03-09-2016.

Enablex. Package Insert. Revised by manufacturer 10-2013. Accessed 02-28-2017.

Gelnique. Package Insert. Revised by manufacturer 07-2015. Accessed 03-02-2016, 02-28-2017.

Sanctura. Package Insert. Revised by manufacturer 07-2012. Accessed 03-02-2016.

Sanctura XR. Package Insert. Revised by manufacturer 08-2012. Accessed 03-02-2016.

Toviaz. Package Insert. Revised by manufacturer 01-2014. Accessed 03-02-2016, 02-28-2017.



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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
 Call 866-325-1794 to check the status of a request.
 All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
 Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.

REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information			
Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information			
Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information		
Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information			
Medication Name:	Strength:	Dosage Form:	
Directions for Use:	Quantity:	Refills:	Duration of Therapy/Use:

Check if requesting **brand** only Check if requesting **generic**

Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review	
<input type="checkbox"/> Standard <input type="checkbox"/> Urgent. Sign here: _____	<input type="checkbox"/> Exigent (requires prescriber to include a written statement)

Clinical Information	
1. What is the diagnosis? Please specify below. ICD-10 Code: _____ Diagnosis Description: _____	
2. <input type="checkbox"/> Yes <input type="checkbox"/> No Was this medication started on a recent hospital discharge or emergency room visit?	
3. <input type="checkbox"/> Yes <input type="checkbox"/> No There is absence of ALL contraindications.	

4. What medication(s) has the individual tried and failed for this diagnosis? Please specify below.
 Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. Are there any supporting labs or test results? Please specify below.

Date	Test	Value

Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: _____ Date: _____

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.