BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 3/17/16**
SECTION: DRUGS	**LAST REVIEW DATE: 2/21/19**
	LAST CRITERIA REVISION DATE: 2/21/19
	ARCHIVE DATE:

OVERACTIVE BLADDER MEDICATIONS, NON-PREFERRED BRANDS: ENABLEX® (darifenacin ER) oral tablet 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.

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.

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.**

OVERACTIVE BLADDER MEDICATIONS, NON-PREFERRED BRANDS: ENABLEX® (darifenacin ER) oral tablet TOVIAZ® (fesoterodine fumarate ER) oral tablet (cont.)

Criteria:

- **Criteria for initial therapy:** Non-preferred brands Enablex (darifenacin) and Toviaz (fesoterodine) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual is 18 years of age or older

  2. A confirmed diagnosis of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency

  3. Individual has failure, contraindication or intolerance to **TWO** of the following generic agents for OAB:
     - Generic darifenacin ER
     - Oxybutynin IR or ER
     - Tolterodine IR or ER
     - Trospium IR or ER

  4. Individual has failure, contraindication or intolerance to **BOTH** Myrbetric (mirabegron) and VESIcare (solifenacin) for OAB

  5. There are **NO** contraindications.
     - Contraindications include:
       - Urinary retention
       - Gastric retention
       - Uncontrolled narrow-angle glaucoma
       - Hypersensitivity to any component of the product

  6. Individual does not have severe hepatic impairment (Child-Pugh Class C)

  Initial approval duration: 12 months

- **Criteria for continuation of coverage (renewal request):** Non-preferred brands Enablex (darifenacin) and Toviaz (fesoterodine) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual's condition responded while on therapy
     - Response is defined as:
       - Reduced number of urge urinary incontinence per day
       - Reduced number/frequency of micturition per day
       - Increased void volume per micturition
       - The condition has not worsened while on therapy

  2. Individual has been adherent with the medication

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3. Individual has not developed any contraindications that may exclude continued use
    - Contraindications as listed in the criteria for initial therapy section

4. There are no significant interacting drugs

Renewal duration: 12 months

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.

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Resources:

Enablex (darifenacin) product information accessed 01-17-19 at DailyMed: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=a712f252-16d9-47df-b2bf-6794228f3a88

Toviaz (fesoterodine) product information accessed 01-17-19 at DailyMed: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5be745f0-8ae7-4c3c-9962-37d6263326f1

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

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ 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

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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.

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