BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES	
SECTION: DRUGS	
ORIGINAL EFFECTIVE DATE:	**3/17/2016**
LAST REVIEW DATE:	**2/18/2021**
LAST CRITERIA REVISION DATE:	**2/18/2021**
ARCHIVE DATE:	

ENABLEX® (darifenacin ER) oral
TOVIAZ® (fesoterodine fumarate ER) oral
GEMTESA® (vibegron) oral

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.**

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Criteria:

- **Criteria for initial therapy:** Enablex (darifenacin), Toviaz (fesoterodine), and Gemtesa (vibegron) are 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:
     a. Generic darifenacin ER
     b. Generic oxybutynin IR or ER
     c. Generic tolterodine IR or ER
     d. Generic trospium IR or ER

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

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

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

  Initial approval duration: 6 months

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

  1. Individual's condition responded while on therapy
     a. Response is defined as **TWO** of the following:
        i. Reduced number of urge urinary incontinence per day
        ii. Reduced number/frequency of micturition per day
        iii. Increased void volume per micturition
        iv. 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
    a. 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.

Myrbetriq (mirabegron) and Gemtesa (vibegron), beta-3 adrenergic agonists, offer 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) extended release tab product information, revised by Allergan, Inc. 09-2016, at DailyMed http://dailymed.nlm.nih.gov accessed January 14, 2021.

Toviaz (fesoterodine) extended release tab product information, revised by Pfizer Laboratories Div Pfizer, Inc. 11-2017, at DailyMed http://dailymed.nlm.nih.gov accessed January 14, 2021.

Myrbetriq (mirabegron) extended release tab product information, revised by Astellas Pharma US, Inc. 12-2019, at DailyMed http://dailymed.nlm.nih.gov accessed January 14, 2021.

VESIcare (solifenacin) tab product information, revised by Astellas Pharma US, Inc. 05-2020, at DailyMed http://dailymed.nlm.nih.gov accessed January 14, 2021.

Gemtesa (vibegron) tab product information, revised by Urovant Sciences, Inc. 12-2020, at DailyMed http://dailymed.nlm.nih.gov accessed January 14, 2021.

Darifenacin extended release tab product information, revised by Par Pharmaceutical, Inc. 12-2015, at DailyMed http://dailymed.nlm.nih.gov accessed January 14, 2021.

Oxybutynin extended release tab product information, revised by Lannett Compnay, Inc. 10-2019, at DailyMed http://dailymed.nlm.nih.gov accessed January 14, 2021.

Oxybutynin tab product information, revised by Teva Pharmaceuticals USA, Inc. 12-2019, at DailyMed http://dailymed.nlm.nih.gov accessed January 14, 2021.

Tolterodine extended release cap product information, revised by Mylan Pharmaceuticals, Inc. 08-2019, at DailyMed http://dailymed.nlm.nih.gov accessed January 14, 2021.

Tolterodine extended release tab product information, revised by Marlex Pharmaceuticals, Inc. 08-2020, at DailyMed http://dailymed.nlm.nih.gov accessed January 14, 2021.

Tolterodine tab product information, revised by Teva Pharmaceuticals USA, Inc. 04-2015, at DailyMed http://dailymed.nlm.nih.gov accessed January 14, 2021.

Trospium extended release cap product information, revised by Actavis Pharma, Inc. 08-2014, at DailyMed http://dailymed.nlm.nih.gov accessed January 14, 2021.

Trospium tab product information, revised by Apotex Corp 08-2019, at DailyMed http://dailymed.nlm.nih.gov accessed January 14, 2021.

Lukacz ES. Treatment of urinary incontinence/overactive bladder in females. In: UpToDate, Brubaker L, Schmader KE, Givens J, Eckler K (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Accessed on January 14, 2021.

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McVary KT, Saini R. Loer urinary tract symptoms in men. In: UpToDate, O'Leary MP, Givens J (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Accessed on January 14, 2021.