Overactive Bladder Medications (Branded)

**Policy #**  00357  
**Original Effective Date:**  07/17/2013  
**Current Effective Date:**  07/18/2019  

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

**When Services May Be Eligible for Coverage**  
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider brand name over-active bladder medications (including, but not limited to Detrol LA® [tolterodine], Enablex® [darifenacin], Gelnique® [oxybutynin], Oxytrol® [oxybutynin], Sanctura XR® [trockipium], Toviaz® [fesoterodine], Vesicare® [solifenacin], and Myrbetriq® [mirabegron])‡ to be eligible for coverage** when one of the below patient selection criteria is met:

**Patient Selection Criteria**  
Coverage eligibility will be considered for brand name over-active bladder medications when one of the following criteria is met:

- Requested drug is a brand name overactive bladder medication (including topical over-active bladder medications): Patient has tried and failed one generic prescription over active bladder anti-cholinergic drug (e.g., darifenacin ER, oxybutynin IR, oxybutynin ER, tolterodine, tolterodine ER, trospium, trospium XR); OR
- Requested drug is a topical over active bladder medication (e.g., Oxytrol, Gelnique): Patient is unable to swallow or has difficulty swallowing; OR
- Requested drug is a brand name overactive bladder medication (including topical over-active bladder medications): There is clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient.

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When Services Are Considered Not Medically Necessary
Based on review of available data, the Company considers the use of brand name overactive bladder medications when patient selection criteria are not met or for usage not included in the above patient selection criteria to be not medically necessary.**

Background/Overview
Overactive bladder medications are typically drugs with anticholinergic actions but can also include drugs that work as beta-3 adrenergic agonists.

Rationale/Source
The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests the available generic overactive bladder medications will be ineffective or cause an adverse reaction to the patient. This policy also takes into consideration whether or not a patient is able to swallow. Based on a review of the data, in the absence of the above mentioned caveats, there is no advantage of using a brand name overactive bladder medication over the available generic over-active bladder medications. Generic drugs are considered to have equal bioavailability and efficacy in comparison to brand name drugs.

References
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Policy History
Original Effective Date:  07/17/2013
Current Effective Date:  07/18/2019
06/27/2013    Medical Policy Committee review
07/17/2013    Medical Policy Implementation Committee approval. New policy.
07/10/2014    Medical Policy Committee review
07/16/2014    Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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06/25/2015 Medical Policy Committee review
07/15/2015 Medical Policy Implementation Committee approval. Added tolterodine ER as a
generic option.
06/30/2016 Medical Policy Committee review
07/20/2016 Medical Policy Implementation Committee approval. Added new generic
darifenacin ER.
07/06/2017 Medical Policy Committee review
07/19/2017 Medical Policy Implementation Committee approval. Coverage eligibility
unchanged.
07/05/2018 Medical Policy Committee review
07/18/2018 Medical Policy Implementation Committee approval. Coverage eligibility
unchanged.
07/03/2019 Medical Policy Committee review
07/18/2019 Medical Policy Implementation Committee approval. Coverage eligibility
unchanged.

Next Scheduled Review Date: 07/2020

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures,
equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment,
would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness,
injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration,
and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other
health care provider, and not more costly than an alternative service or sequence of services
at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or
treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are
based on credible scientific evidence published in peer-reviewed medical literature generally
recognized by the relevant medical community, Physician Specialty Society recommendations and
the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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