Overactive Bladder Medications (Branded)

Policy # 00357
Original Effective Date: 07/17/2013
Current Effective Date: 11/11/2024

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.*

For Patients with "Step Therapy" (generic before brand) ONLY:

Based on review of available data, the Company may consider brand name over-active bladder medications including, but not limited to Detrol LA®‡ (tolterodine), Gelnique®‡ (oxybutynin), Oxytrol®‡ (oxybutynin), Toviaz®‡ (fesoterodine), Vesicare®‡ (solifenacin), Vesicare LS™‡ (solifenacin), and Gemtesa®‡ (vibegron) 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 overactive bladder medications): Patient has tried and failed one generic prescription overactive bladder anticholinergic drug (e.g., darifenacin ER, fesoterodine ER, oxybutynin IR, oxybutynin ER, solifenacin, tolterodine, tolterodine ER, trospium, trospium XR, mirabegron ER); OR
- Requested drug is a topical overactive 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 overactive 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.****

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.*

For Patients with "Prior Authorization" ONLY:

Based on review of available data, the Company may consider Gemtesa (vibegron) or Vesicare LS (solifenacin) to be **eligible for coverage **** when the below patient selection criteria are met for the requested drug:

Patient Selection Criteria

Coverage eligibility will be considered for Gemtesa (vibegron) or Vesicare LS (solifenacin) when the following criteria are met for the requested drug:

- For Gemtesa requests ONLY:
    - Patient has a diagnosis of overactive bladder; AND
    - Patient is greater than or equal to 18 years of age; AND
    - Patient has tried and failed (e.g., intolerance or inadequate response) TWO formulary overactive bladder medications (e.g., darifenacin ER, fesoterodine ER, oxybutynin ER, solifenacin, tolterodine, tolterodine ER, trospium, trospium XR, mirabegron ER) unless there is clinical evidence or patient history that suggests the use of the alternative options will be ineffective or cause an adverse reaction to the patient.
      *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

- For Vesicare LS requests ONLY:
  - Patient has a diagnosis of neurogenic detrusor overactivity; AND
  - Patient is greater than or equal to 2 years of age AND less than 18 years of age; AND
  - Patient meets ONE of the following:
    - Patient is younger than 5 years of age; OR
    - Patient has tried and failed GENERIC oxybutynin immediate release syrup unless there is clinical evidence or patient history that suggests the use of the alternative agent will be ineffective or cause an adverse reaction to the patient. *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Gemtesa (vibegron) or Vesicare LS (solifenacin) when the required alternatives have not been tried and failed to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Gemtesa (vibegron) for any indication other than overactive bladder or for patients younger than 18 years of age to be **investigational.***

Based on review of available data, the Company considers the use of Vesicare LS (solifenacin) for any indication other than neurogenic detrusor overactivity or in patients younger than 2 years of age or older than 18 years of age to be **investigational.***

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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.*

For Patients with BOTH "Prior Authorization" AND "Step Therapy":

Based on review of available data, the Company may consider brand name over-active bladder medications including, but not limited to Detrol LA (tolterodine), Gelnique (oxybutynin), Oxytrol (oxybutynin), Toviaz (fesoterodine), Vesicare (solifenacin), Vesicare LS (solifenacin), and Gemtesa (vibegron) to be **eligible for coverage**** when the patient selection criteria for the requested drug are met:

Patient Selection Criteria

Coverage eligibility will be considered for brand name over-active bladder medications when the criteria for the requested drug are met:

- For Gemtesa requests ONLY:
    - Patient has a diagnosis of overactive bladder; AND
    - Patient is greater than or equal to 18 years of age; AND
    - Patient has tried and failed (e.g., intolerance or inadequate response) TWO formulary overactive bladder medications (e.g., darifenacin ER, fesoterodine ER, oxybutynin ER, solifenacin, tolterodine, tolterodine ER, trospium, trospium XR, mirabegron ER) unless there is clinical evidence or patient history that suggests the use of the alternative options will be ineffective or cause an adverse reaction to the patient.
      *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

- For Vesicare LS requests ONLY:
  - Patient has a diagnosis of neurogenic detrusor overactivity; AND
  - Patient is greater than or equal to 2 years of age AND less than 18 years of age; AND
  - Patient meets ONE of the following:
    - Patient is younger than 5 years of age; OR
    - Patient has tried and failed GENERIC oxybutynin immediate release syrup unless there is clinical evidence or patient history that suggests the use of the alternative agent will be ineffective or cause an adverse reaction to the patient. *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- For Oxytrol or Gelnique requests ONLY:
  - Patient is unable to swallow or has difficulty swallowing; OR
  - Patient has tried and failed one GENERIC prescription overactive bladder anti-cholinergic drug (e.g., darifenacin ER, fesoterodine ER, oxybutynin IR, oxybutynin ER, solifenacin, tolterodine, tolterodine ER, trospium, trospium XR, mirabegron ER); OR
  - There is clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient.

  *(Note: These specific patient selection criteria are additional Company requirements for coverage eligibility and will be denied as not medically necessary** if not met).*
- For all other brand name overactive bladder medications:
  - Patient has tried and failed one GENERIC prescription overactive bladder anticholinergic drug (e.g., darifenacin ER, fesoterodine ER, oxybutynin IR, oxybutynin ER, solifenacin, tolterodine, tolterodine ER, trospium, trospium XR, mirabegron ER); OR
  - There is clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient.

  *(Note: These specific patient selection criteria are additional Company requirements for coverage eligibility and will be denied as not medically necessary** if not met).*

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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 the patient has not tried and failed the required generic alternative agents to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices, or biological products.

Based on review of available data, the Company considers the use of Gemtesa (vibegron) for any indication other than overactive bladder or for patients younger than 18 years of age to be **investigational.***

Based on review of available data, the Company considers the use of Vesicare LS (solifenacin) for any indication other than neurogenic detrusor overactivity or in patients younger than 2 years of age or older than 18 years of age to be **investigational.***

Background/Overview

Overactive bladder medications are typically drugs with anticholinergic actions but can also include drugs that work as beta-3 adrenergic agonists. Most are administered as an oral tablet or liquid, but topical products exist in the form of a gel or transdermal patch.

Guidelines supported by the American Urological Association (AUA) recommend behavioral therapies (e.g., bladder training, bladder control strategies, pelvic floor muscle training, fluid management) as the first line treatment in patients with overactive bladder. Oral anticholinergics and oral beta-3 adrenergic agonists are second-line therapies. The guidelines note that oral anticholinergics are similar in efficacy and the choice of agent for a particular patient is dependent on many factors, including the patient's history of anticholinergic use, adverse events experienced in the past, patient preference, comorbidities, use of other medications, and cost.

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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Regarding step therapy, the patient selection criteria presented in this policy take 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 overactive bladder medications. Generic drugs are considered to have equal bioavailability and efficacy in comparison to brand name drugs.

Regarding prior authorization, the patient selection criteria for Gemtesa and Vesicare LS take into consideration the FDA-approved indications for the respective product as well as the ages for which the products are indicated. It should be noted that Vesicare LS is only indicated for pediatric patients greater than or equal to 2 years of age and Gemtesa is only indicated for adult patients. Additionally, these criteria take into account clinical evidence or patient history that suggests the available formulary overactive bladder medications will be ineffective or cause an adverse reaction to the patient.

References

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18. Gemtesa [package insert]. Urovant Sciences, Inc. Irvine, CA. January 2021
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Policy History

Original Effective Date: 07/17/2013
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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.
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.
07/02/2020	Medical Policy Committee review
07/08/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/01/2021	Medical Policy Committee review
04/14/2021	Medical Policy Implementation Committee approval. Added new drugs, Gemtesa and Vesicare LS to policy with prior authorization criteria. Split the policy into step only, PA only, and PA/step sections.
09/02/2021	Medical Policy Committee review
09/08/2021	Medical Policy Implementation Committee approval. Removed Myrbetriq from step therapy sections. Also removed reference to obsolete drug, Sanctura XR.
08/04/2022	Medical Policy Committee review
08/10/2022	Medical Policy Implementation Committee approval. Updated Gemtesa requirement to allow for a trial of Myrbetriq.
08/03/2023	Medical Policy Committee review
08/09/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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08/01/2024	Medical Policy Committee review
08/14/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/03/2024	Medical Policy Committee review
10/08/2024	Medical Policy Implementation Committee approval. Updated Gemtesa PA criteria to replace brand name Myrbetriq with generic mirabegron in drug trial criterion. Added generic fesoterodine ER and mirabegron ER as generic options in both step therapy and PA portions of the policy. Also, removed reference to obsolete drug, Enablex.

Next Scheduled Review Date: 10/2025

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

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**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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.