Clinical Policy: Overactive Bladder Agents
Reference Number: CP.PMN.198
Effective Date: 05.01.16
Last Review Date: 08.20
Line of Business: HIM, Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
The following are overactive bladder agents requiring prior authorization: mirabegron (Myrbetriq®), fesoterodine (Toviaz®), solifenacin (Vesicare®, Vesicare LS™), and darifenacin (Enablex®).

FDA Approved Indication(s)
Myrbetriq, Toviaz, Vesicare, and Enablex are indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency. Vesicare is specifically indicated for adults.

Vesicare LS is indicated for the treatment of neurogenic detrusor overactivity in pediatric patients aged 2 years and older.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that overactive bladder agents are medically necessary when the following criteria are met:

I. Initial Approval Criteria
A. Overactive Bladder (must meet all):
   1. Diagnosis of overactive bladder;
   2. Member meets one of the following (a or b):
      a. Age is between 2 to 17 years, and both of the following (i and ii):
         i. Request is for Vesicare LS;
         ii. Member has neurogenic detrusor overactivity;
      b. Age ≥ 18 years;
   3. Failure of 2 formulary generic overactive bladder agents (e.g., tolterodine, oxybutynin, trospium) for 30 days, unless clinically significant adverse effects are experienced or all are contraindicated;
   4. If request is for brand Vesicare or Enablex: Medical justification supports inability to use the generic version of the requested product (e.g., contraindications to excipients in the generic);
   5. If request is for Vesicare LS and age ≥ 18 years: Medical justification supports inability to use oral solifenacin (e.g., contraindications to excipients, inability to swallow);
6. Dose does not exceed the FDA-approved maximum recommended dose or health plan approved quantity limit for the relevant drug.

**Approval duration: 12 months**

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid and HIM.PHAR.21 for health insurance marketplace.

II. Continued Therapy

A. **Overactive Bladder** (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for Vesicare LS and age ≥ 18 years: Medical justification supports continued inability to use oral solifenacin (e.g., contraindications to excipients, inability to swallow);
4. If request is for a dose increase, new dose does not exceed the FDA-approved maximum recommended dose or health plan approved quantity limit for the relevant drug.

**Approval duration: 12 months**

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

**Approval duration: Duration of request or 12 months (whichever is less); or**

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid and HIM.PHAR.21 for health insurance marketplace.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – CP.PMN.53 for Medicaid and HIM.PHAR.21 or evidence of coverage documents.

IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.
Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Hypersensitivity to any component in the requested product
  - Enablex, Toviaz, and Vesicare are also contraindicated in patients with, or at risk for, the following conditions:
    - Urinary retention
    - Gastric retention
    - Uncontrolled narrow-angle glaucoma

- Boxed warning(s): none reported

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fesoterodine (Toviaz)</td>
<td>4 mg PO QD</td>
<td>8 mg/day</td>
</tr>
<tr>
<td>Mirabegron (Myrbetriq)</td>
<td>25 mg PO QD, alone or in combination with solifenacin succinate 5 mg PO QD</td>
<td>50 mg/day</td>
</tr>
<tr>
<td>Solifenacin (Vesicare)</td>
<td>5 mg PO QD</td>
<td>10 mg/day</td>
</tr>
<tr>
<td>Solifenacin (Vesicare LS)</td>
<td>9-15 kg: 2 mL PO QD</td>
<td>9-15 kg: 4 mL</td>
</tr>
<tr>
<td></td>
<td>&gt; 15-30 kg: 3 mL PO QD</td>
<td>&gt; 15-30 kg: 5 mL</td>
</tr>
<tr>
<td></td>
<td>&gt; 30-45 kg: 3 mL PO QD</td>
<td>&gt; 30-45 kg: 6 mL</td>
</tr>
<tr>
<td></td>
<td>&gt; 45-60 kg: 4 mL PO QD</td>
<td>&gt; 45-60 kg: 8 mL</td>
</tr>
<tr>
<td></td>
<td>&gt; 60 kg: 5 mL PO QD</td>
<td>&gt; 60 kg: 10 mL</td>
</tr>
<tr>
<td></td>
<td>After administration of the recommended starting dose, the dose may be increased to the lowest effective dose but should not exceed the maximum recommended dose</td>
<td></td>
</tr>
<tr>
<td>Darifenacin (Enablex)</td>
<td>7.5 mg PO QD</td>
<td>15 mg/day</td>
</tr>
</tbody>
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VI. Product Availability

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fesoterodine (Toviaz)</td>
<td>Extended-release tablets: 4 mg, 8 mg</td>
</tr>
<tr>
<td>Mirabegron (Myrbetriq)</td>
<td>Extended-release tablets: 25 mg, 50 mg</td>
</tr>
<tr>
<td>Solifenacin (Vesicare)</td>
<td>Tablets: 5 mg, 10 mg</td>
</tr>
<tr>
<td>Solifenacin (Vesicare LS)</td>
<td>Oral suspension: 5 mg/5 mL (1 mg/mL)</td>
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CLINICAL POLICY
Overactive Bladder Agents

<table>
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<tr>
<th>Drug Name</th>
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<tbody>
<tr>
<td>Darifenacin (Enablex)</td>
<td>Extended-release tablets: 7.5 mg, 15 mg</td>
</tr>
</tbody>
</table>

VII. References

Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Policy. 2Q 2019 annual review: Policy created and adapted from HIM.PA.40; No significant changes from previously approved corporate policy; references reviewed and updated.</td>
<td>02.25.19 05.19</td>
</tr>
<tr>
<td>2Q 2020 annual review: no significant changes; references reviewed and update.</td>
<td>01.24.20 05.20</td>
</tr>
<tr>
<td>Added requirement for medical justification for inability to use generic for requests for brand Vescicare or Enablex; removed HIM-specific notations regarding Enablex (can now use of this policy instead of HIM.PA.103); added requirement that request does not exceed health plan approved quantity limit; RT4: specified Vescicare is only indicated for adults per updated FDA labeling and added Vescicare LS with corresponding criteria.</td>
<td>05.28.20 08.20</td>
</tr>
</tbody>
</table>

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and
The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

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**Note:**

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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