Clinical Policy: Overactive Bladder Agents
Reference Number: HIM.PA.40
Effective Date: 05.01.16
Last Review Date: 05.18
Line of Business: HIM

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: darifenacin (Enablex®), mirabegron (Myrbetriq®), fesoterodine (Toviaz®), solifenacin (Vesicare®).

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

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. Age ≥ 18 years;
   3. Failure of 2 formulary generic overactive bladder agents (e.g., tolterodine, oxybutynin, trospium) each used for 30 days, unless contraindicated or clinically significant adverse effects are experienced;
   4. If request is for Enablex, medical justification supports inability to use generic darifenacin (e.g., contraindication to an excipient in the generic product);
   5. Dose does not exceed the FDA-approved maximum recommended dose for the relevant drug.

Approval duration: 12 months

B. Other diagnoses/indications
   1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnostics/Indications for which coverage is NOT authorized).

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 a dose increase, new dose does not exceed the FDA-approved maximum recommended dose 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 HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**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 – 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.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>oxybutynin (Ditropan XL®)</td>
<td>5 to 10 mg PO QD</td>
<td>30 mg/day</td>
</tr>
<tr>
<td>oxybutynin (Ditropan®)</td>
<td>5 mg PO BID or TID</td>
<td>20 mg/day</td>
</tr>
<tr>
<td>tolterodine IR (Dantrof®)</td>
<td>2 mg PO BID</td>
<td>4 mg/day</td>
</tr>
<tr>
<td>trospium (Sanctura®)</td>
<td>20 mg PO BID</td>
<td>60 mg/day</td>
</tr>
<tr>
<td>trospium ER (Sanctura® XR)</td>
<td>60 mg PO QD</td>
<td>60 mg/day</td>
</tr>
</tbody>
</table>

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

*Appendix C: Contraindications*

- Enablex, Tovias, and Vesicare are contraindicated in patients with, or at risk for, the following conditions:
  - Urinary retention
  - Gastric retention
  - Uncontrolled narrow-angle glaucoma
- Myrbetriq: not applicable

**V. Dosage and Administration**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Darifenacin (Enablex)</td>
<td>7.5 mg PO QD</td>
<td>15 mg/day</td>
</tr>
<tr>
<td>Fesoterodine (Toviaz)</td>
<td>4 mg PO QD</td>
<td>8 mg/day</td>
</tr>
<tr>
<td>Drug Name</td>
<td>Dosing Regimen</td>
<td>Maximum Dose</td>
</tr>
<tr>
<td>------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>--------------</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>
</tbody>
</table>

VI. Product Availability

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

VII. References


Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Reason</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Changed guidelines to new format. Adjusted for flow. Renumbered guideline from HIM.PST.100.3 to HIM.PA.40. Removed section D. Contraindication or intolerance to ALL formulary medications. Added new reference #6</td>
<td>05.16</td>
<td>05.16</td>
</tr>
<tr>
<td>Clinical changes made to criteria: Modified trial and failure criteria to require trial of lower tiered formulary agents first prior to approval of tier 3 agents per formulary; Added max dose requirement in initial criteria and re-auth. Non-clinical changes; Converted to new template; Added Myrbetriq to policy; Updated references</td>
<td>01.17</td>
<td></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 accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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