Clinical Policy: Overactive Bladder Agents
Reference Number: CP.PMN.198
Effective Date: 05.01.16
Last Review Date: 05.20
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®), and darifenacin (Enablex®).

*For Health Insurance Marketplace (HIM), if request is through pharmacy benefit, Enablex is non-formulary and should not be approved using these criteria; refer to the formulary exception policy, HIM.PA.103.

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.

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) for 30 days, unless clinically significant adverse effects are experienced or all are contraindicated;
      4. Dose does not exceed the FDA-approved maximum recommended dose for the relevant drug.

      Approval duration:
      Medicaid – 12 months
      HIM – 12 months for Myrbetriq, Toviaz, and Vesicare (refer to HIM.PA.103 for Enablex)

   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 a dose increase, new dose does not exceed the FDA-approved
         maximum recommended dose for the relevant drug.
   
   Approval duration:
   Medicaid – 12 months
   HIM – 12 months for Myrbetriq, Toviaz, and Vesicare (refer to HIM.PA.103 for
   Enablex)

   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.

<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 (Detrolı®)</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/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>Darifenacin (Enablex)</td>
<td>7.5 mg PO QD</td>
<td>15 mg/day</td>
</tr>
</tbody>
</table>

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

VII. References

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. 02.25.19 05.19

2Q 2020 annual review: no significant changes; references reviewed and update. 01.24.20 05.20

**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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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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