Clinical Policy: Overactive Bladder Agents
Reference Number: CP.PMN.198
Effective Date: 05.01.16
Last Review Date: 05.19
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 cannot 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) each used for 30 days, unless contraindicated or clinically significant adverse effects are experienced;
      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 (Dentol®)</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):
  - Enablex, Toviaz, 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
- 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
Reviews, Revisions, and Approvals

| 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 |

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.

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.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions. Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.
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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.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the non-formulary policy; HIM.PA.103.

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