# Clinical Policy: Overactive Bladder Agents

Reference Number: PA.CP.PMN.198
Effective Date: 4.17.19
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Revision Log

**Description**
The following are overactive bladder agents requiring prior authorization: mirabegron (Myrbetriq®), fesoterodine (Toviaz®), solifenacin (Vesicare®).

**FDA Approved Indication(s)**
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 PA Health & Wellness® 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: 12 months**

**B. Other diagnoses/indications**

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

**II. Continued Therapy**

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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 PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   **Approval duration: Duration of request or 12 months (whichever is less);** or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

## 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 – refer to PA.CP.PMN.53

## 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.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| oxybutynin (Ditropan XL®) | 5 to 10 mg PO QD | 30 mg/day |
| oxybutynin (Ditropan®) | 5 mg PO BID or TID | 20 mg/day |
| tolterodine IR (Detrol®) | 2 mg PO BID | 4 mg/day |
| trospium (Sanctura®) | 20 mg PO BID | 60 mg/day |
| trospium ER (Sanctura® XR) | 60 mg PO QD | 60 mg/day |

*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):
  - 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

| Drug Name | Dosing Regimen | Maximum Dose |
|---|---|---|
| Fesoterodine (Toviaz) | 4 mg PO QD | 8 mg/day |

| Drug Name | Dosing Regimen | Maximum Dose |
|---|---|---|
| Mirabegron (Myrbetriq) | 25 mg PO QD, alone or in combination with solifenacin succinate 5 mg PO QD | 50 mg/day |
| Solifenacin (Vesicare) | 5 mg PO QD | 10 mg/day |

## VI. Product Availability

| Drug Name | Availability |
|---|---|
| Fesoterodine (Toviaz) | Extended-release tablets: 4 mg, 8 mg |
| Mirabegron (Myrbetriq) | Extended-release tablets: 25 mg, 50 mg |
| Solifenacin (Vesicare) | Tablets: 5 mg, 10 mg |

## VII. References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: http://www.clinicalpharmacology-ip.com/. Accessed February 25, 2019.
2. Myrbetriq Prescribing Information. Northbrook, IL: Astellas Pharma US, Inc.; April 2018. Available at: https://www.myrbetriq.com/. Accessed February 25, 2019.
3. Vesicare Prescribing Information. Northbrook, IL: Astellas Pharma US, Inc.; February 2016. Available at: https://www.vesicare.com/. Accessed February 25, 2019.
4. Toviaz Prescribing Information. New York, NY: Pfizer Inc.; November 2017. Available at: http://www.toviaz.com/. Accessed February 25, 2019.
5. Gormley EA, Lightner DJ, Faraday M et al. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU guideline amendment. J Urol. 2015 May;193(5):1572-80. doi: 10.1016/j.juro.2015.01.087.
6. Diagnosis and treatment of overactive bladder (Non-neurogenic) in adults: AUA/SUFU Guidelines (May 2012) http://www.auanet.org/common/pdf/education/clinical-guidance/Overactive-Bladder.pdf. Accessed Feb 25, 2019.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| New Policy created. | 04.17.19 | |