Clinical Policy: Overactive Bladder Agents

Reference Number: IL.ERX.PMN.198
Effective Date: 06.01.21
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Line of Business: Illinois Medicaid

Revision Log

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®), 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.

Myrbetriq, Myrbetriq Granules, Toviaz and Vesicare LS are indicated for the treatment of neurogenic detrusor overactivity in pediatric patients:

- Aged 3 years and older and weighing 35 kg or more (Myrbetriq);
- Aged 3 years and older (Myrbetriq Granules);
- Aged 6 years and older and weighing greater than 25 kg (Toviaz);
- Aged 2 years and older (Vesicare LS).

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 Envolve Pharmacy Solutions 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. Member has neurogenic detrusor overactivity, and request is for one of the following (i, ii, iii, or iv):
      i. Vesicare LS, and age is between 2 to 17 years;
      ii. Myrbetriq Granules, and age is between 3 to 17 years;
      iii. Myrbetriq, age is between 3 to 17 years, and member weighs at least 35 kg;
      iv. Toviaz, age is between 6 to 17 years, and member weights at least 25 kg ;
   b. Age ≥ 18 years;
3. Failure of 2 formulary generic overactive bladder agents (e.g., oxybutynin, bethanechol, and solifenacin) each used for 30 days, unless contraindicated or clinically significant adverse effects are experienced;
4. 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);
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 ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions 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 for the relevant drug.

Approval duration: 12 months

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 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 – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Contraindications/Boxed Warnings

- Contraindication(s):
  - Hypersensitivity to any component in the requested product
  - 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

Drug Name	Dosing Regimen	Maximum Dose
Fesoterodine (Toviaz)	*Pediatric patients*: > 25 kg to ≤ 35 kg: Recommended dose is 4 mg PO QD. If needed, dosage may be increased to 8 mg PO QD. > 35 kg: Recommended starting dose is 4 mg PO QD. After one week, increase to 8 mg PO QD. *Adults*: 4 mg PO QD	8 mg/day
Mirabegron (Myrbetriq)*	25 mg PO QD, alone or in combination with solifenacin succinate 5 mg PO QD	50 mg/day
Mirabegron (Myrbetriq Granules)*	*Pediatric patients*: 11 to < 22 kg: 3 mL (24 mg) PO QD 22 to < 35 kg: 4 mL (32 mg) PO QD	50 mg/day

Drug Name	Dosing Regimen	Maximum Dose
	≥ 35 kg: 6 mL (48 mg) PO QD *Adults*: A recommended dosage for Myrbetriq Granules for adults has not been determined.	
Solifenacin (Vesicare)	5 mg PO QD	10 mg/day
Solifenacin (Vesicare LS)	9-15 kg: 2 mL PO QD > 15-30 kg: 3 mL PO QD > 30-45 kg: 3 mL PO QD > 45-60 kg: 4 mL PO QD > 60 kg: 5 mL PO QD 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	9-15 kg: 4 mL > 15-30 kg: 5 mL > 30-45 kg: 6 mL > 45-60 kg: 8 mL > 60 kg: 10 mL
Darifenacin (Enablex)	7.5 mg PO QD	15 mg/day

**Myrbetriq and Myrbetriq Granules are two different products, and they are not substitutable on a milligram per-milligram basis. Do not combine Myrbetriq and Myrbetriq Granules to achieve the total dose.*

VI. Product Availability

Drug Name	Availability
Fesoterodine (Toviaz)	Extended-release tablets: 4 mg, 8 mg
Mirabegron (Myrbetriq)	Extended-release tablets: 25 mg, 50 mg
Mirabegron (Myrbetriq Granules)	Granules for extended-release oral suspension: 8 mg/mL after reconstitution
Solifenacin (Vesicare)	Tablets: 5 mg, 10 mg
Solifenacin (Vesicare LS)	Oral suspension: 5 mg/5 mL (1 mg/mL)
Darifenacin (Enablex)	Extended-release tablets: 7.5 mg, 15 mg

VII. References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. Available at: http://www.clinicalpharmacology-ip.com/. Accessed January 24, 2020.
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3. Vesicare Prescribing Information. Northbrook, IL: Astellas Pharma US, Inc.; May 2020. Available at: https://www.vesicare.com/. Accessed June 3, 2020.
4. Vesicare LS Prescribing Information. Northbrook, IL: Astellas Pharma US, Inc.; May 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209529s000lbl.pdf. Accessed June 3, 2020.
5. Toviaz Prescribing Information. New York, NY: Pfizer Inc.; July 2021. Available at: http://www.toviaz.com/. Accessed July 7, 2021.
6. Gormley EA, Lightner DJ, Burgio KL, et al. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU guideline (2019). Available at: https://www.auanet.org/guidelines/overactive-bladder-(oab)-guideline. Accessed January 24, 2020.
7. Enablex Prescribing Information. Irvine, CA: Allergan; September 2016. Available at: http://www.enablex.com/. Accessed June 3, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	04.15.21	05.21
RT4: added Toviaz's pediatric extension of the overactive bladder indication; updated Myrbetriq pediatric extension and added criteria modification for age	07.27.21	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
expansion		

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

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