Clinical Policy: Overactive Bladder Agents

Reference Number: CP.PMN.198
Effective Date: 05.01.16
Last Review Date: 05.21 Revision Log
Line of Business: Commercial, 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®, Vesicare LS™), 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. Vesicare is specifically indicated for adults.

Vesicare LS is indicated for the treatment of neurogenic detrusor overactivity in pediatric patients aged 2 years and older.

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. Member meets one of the following (a or b):
   a. Age is between 2 to 17 years, and both of the following (i and ii):
      i. Request is for Vesicare LS;
      ii. Member has neurogenic detrusor overactivity;
   b. 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. If request is for brand Vesicare or Enablex: Medical justification supports inability to use the generic version of the requested product (e.g., contraindications to excipients in the generic);
5. 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);

6. Dose does not exceed the FDA-approved maximum recommended dose or health plan approved quantity limit for the relevant drug.

Approval duration: 12 months

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.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 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 or health plan approved quantity limit 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 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.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid 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.

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):
  - 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

Drug Name	Dosing Regimen	Maximum Dose
Fesoterodine (Toviaz)	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
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

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
Solifenacin (Vesicare LS)	Oral suspension: 5 mg/5 mL (1 mg/mL)

Drug Name	Availability
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.
2. Myrbetriq Prescribing Information. Northbrook, IL: Astellas Pharma US, Inc.; April 2018. Available at: https://www.myrbetriq.com/. Accessed January 15, 2021.
3. Vesicare Prescribing Information. Northbrook, IL: Astellas Pharma US, Inc.; May 2020. Available at: https://www.vesicare.com/. Accessed January 15, 2021.
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 January 15, 2021.
5. Toviaz Prescribing Information. New York, NY: Pfizer Inc.; November 2017. Available at: http://www.toviaz.com. Accessed January 15, 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 15, 2021.
7. Enablex Prescribing Information. Irvine, CA: Allergan; September 2016. Available at: http://www.enablex.com/. Accessed January 15, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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
Added requirement for medical justification for inability to use generic for requests for brand Vesicare or Enablex; removed HIM-specific notations regarding Enablex (can now use of this policy instead of HIM.PA.103); added requirement that request does not exceed health plan approved quantity limit; RT4: specified Vesicare is only indicated for adults per updated FDA labeling and added Vesicare LS with corresponding criteria.	05.28.20	08.20
Per December SDC and prior clinical guidance, added Commercial line of business.	12.15.20	
2Q 2021 annual review: no significant changes; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	01.15.21	05.21

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.

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.