Clinical Policy: Overactive Bladder Agents

Reference Number: HIM.PA.40
Effective Date: 05.01.16
Last Review Date: 05.18
Line of Business: HIM

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: darifenacin (Enablex®), mirabegron (Myrbetriq®), fesoterodine (Toviaz®), solifenacin (Vesicare®).

FDA Approved Indication(s)

Enablex, 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 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. If request is for Enablex, medical justification supports inability to use generic darifenacin (e.g., contraindication to an excipient in the generic product);
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 HIM.PHAR.21 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 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: 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 HIM.PHAR.21 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 – 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.

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
- Enablex, Tovias, 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

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Darifenacin (Enablex)	7.5 mg PO QD	15 mg/day
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
Darifenacin (Enablex)	Extended-release tablets: 7.5 mg, 15 mg
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.; 2018. Available at: http://www.clinicalpharmacology-ip.com/. Accessed June 1, 2018.
2. Detrol LA Prescribing Information. New York. NY: Pfizer Inc.; July 2017. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021228s021lbl.pdf. Accessed January 30, 2018.
3. Myrbetriq Prescribing Information. Northbrook, IL: Astellas Pharma US, Inc.; April 2018. Available at: https://www.myrbetriq.com/. Accessed June, 1, 2018.
4. Vesicare Prescribing Information. Northbrook, IL: Astellas Pharma US, Inc.; February 2016. Available at: https://www.vesicare.com/. Accessed June 1, 2018.
5. Toviaz Prescribing Information. New York, NY: Pfizer Inc.; November 2017. Available at: http://www.toviaz.com/. Accessed January 30, 2018.
6. Enablex Prescribing Information. Irvine, CA: Allergan; September 2016. Available at: http://www.enablex.com/. Accessed January 30, 2018.
7. 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..
8. Diagnosis and treatment of overactive bladder (Non-neurgenic) in adults: AUA/SUFU Guidelines http://www.auanet.org/common/pdf/education/clinical-guidance/Overactive-Bladder.pdf Accessed: January 30, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Changed guidelines to new format. Adjusted for flow. Renumbered guideline from HIM.PST.100.3 to HIM.PA.40. Removed section D. Contraindication or intolerance to **ALL** formulary medications. Added new reference #6	05.16	05.16
Clinical changes made to criteria: Modified trial and failure criteria to require trial of lower tiered formulary agents first prior to approval of tier 3 agents per formulary; Added max dose requirement in initial criteria and re-auth. Non-clinical changes; Converted to new template; Added Myrbetriq to policy; Updated references	01.17	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
2Q 2018 annual review: changed number of trials for all drugs to 2 formulary medications instead of 3 for Enablex, Mybetriq, and Toviaz and 2 for vesicare for a consistent approach; Detrol LA removed from policy it is now NF; added requirement medical justification to use the brand Enablex; references reviewed and updated.	02.06.18	05.18
No significant changes: added dosing regimen for Myrbetriq in combination with solifenacin succinate.	06.28.18	

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.

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