Clinical Policy: Overactive Bladder Agents
Reference Number: HIM.PA.40
Effective Date: 05/16
Last Review Date:
Line of Business: Health Insurance Marketplace

Coding Implications
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: tolterodine (Detrol® LA), darifenacin (Enablex®), mirabegron (Myrbetriq®), fesoterodine (Toviaz®), solifenacin (Vesicare®).

FDA approved indication
Detrol LA, 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 (including office chart notes and lab results) supporting that member has met all approval criteria **

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. If request is for darifenacin (generic), tolterodine extended-release or Vesicare, failure of ≥ 2 formulary medications (e.g., oxybutynin, tolterodine immediate release, trospium) at up to maximally indicated doses, each trialed for ≥30 days, unless all are contraindicated or clinically significant adverse effects are experienced;
   b. If request is for Enablex, Myrbetriq or Toviaz, member meets the following (i and ii):
      i. Failure of ≥ 2 formulary medications (e.g., oxybutynin, tolterodine immediate release, trospium) at up to maximally indicated doses, each trialed for ≥ 30 days, unless all are contraindicated or clinically significant adverse effects are experienced;
      ii. Failure of a 30 day trial of Vesicare at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced *(Note: Vesicare requires a prior authorization);*
3. 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. Documentation of positive response 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 health plan benefit and documentation supports positive response to therapy; 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 Key
FDA: Food and Drug Administration

V. References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.clinicalpharmacology-ip.com/.
2. Detrol LA [Prescribing Information] New York. NY: Pfizer Inc.; August 2012. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021228s021lbl.pdf. Accessed January 12, 2017.
3. Enablex [Prescribing Information] Rockaway, NJ: Warner Chilcott.; March 2012. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021513s010lbl.pdf. Accessed January 12, 2017.
4. Toviaz [Prescribing Information] New York, NY: Pfizer Inc.; August 2012. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022030s009lbl.pdf. Accessed January 12, 2017.
5. Vesicare [Prescribing Information] Northbrook, IL: Astellas Pharma US, Inc.; October 2013. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021518s016lbl.pdf. Accessed January 12, 2017.
6. Myrbetriq [Prescribing Information] Northbrook, IL: Astellas Pharma US, Inc.; August 2016.

7. 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: March 2016.

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	

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.