Clinical Policy: Urinary Antispasmodic Agents

Reference Number: OH.PHAR.PPA.63
Effective Date: 01.01.21
Last Review Date: 11.20
Line of Business: Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

GENITOURINARY AGENTS: URINARY ANTISPASMODICS

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
OXYBUTYNIN ER (generic of Ditropan® XL) OXYBUTYNIN syrup (generic of Ditropan®) OXYBUTYNIN tablets (generic of Ditropan®) OXYTROL® FOR WOMEN OTC patch (oxybutynin)	SOLIFENACIN (generic of Vesicare®)	DARIFENACIN (generic of ENABLEX®) GELNIQUE® (oxybutynin) MYRBETRIQ® (mirabegron) TOLTERODINE (generic of Detrol®) TOLTERODINE SR (generic of Detrol® LA) TOVIAZ®(fesoterodine) TROSPIUM (generic of Sanctura®) TROSPIUM ER (generic of Sanctura® XR)

FDA Approved Indication(s)

- Enablex, Gelnique, Myrbetriq, tolterodine, tolterodine sr, Toviaz, trospium er, Vesicare, oxybutynin, and oxybutynin er are indicated for the treatment of:
  - •Overactive bladder (OAB)
  - •Urinary incontinence

- Oxybutynin and trospium er are also indicated for the treatment of neurogenic bladder

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 Enablex®, Gelnique®, Myrbetriq®, tolterodine, tolterodine sr, Toviaz®, trospium er, Vesicare® are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Prescribed indication is FDA-approved or supported by standard pharmacopeias (must meet all)**:**

1. The member has had therapeutic failure to a trial of no less than 30 days of at least two preferred medications with different active ingredients not requiring prior approval unless any of the following:
   a. Allergy to medications not requiring prior approval
   b. Contraindications to or drug interaction with medications not requiring prior approval
   c. History of unacceptable/toxic side effects to medications not requiring prior approval
2. If member is less than 18 years of age and the requested medication is tolterodine sr (Detrol LA) or Gelnique there was an inadequate clinical response to a trial of no less than 30 days of oxybutynin (IR or ER).

Approval duration: 12 months

II. 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 policies – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid or evidence of coverage documents

III. 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 for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Oxybutynin Er (Ditropan® XL)	5 to 10 mg PO QD	30 mg/day
Oxybutynin syrup (Ditropan®)	5 mg PO BID or TID	20 mg/day
Oxybutynin tablets (Ditropan®)	5 mg PO BID or TID	20 mg/day
Oxytrol® for women otc patch (oxybutynin)	1 patch (3.9 mg) topically twice weekly (every 3 to 4 days)	2 patches/week

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
- Refer to Clinical Pharmacology or other appropriate clinical resource for contraindications or black box warnings

IV. Dosage and Administration
A. Varies by drug product. See FDA approved dosing and administration.

V. Product Availability
A. Varies by drug product. Refer to Clinical Pharmacology or other appropriate clinical resource for product availability

VI. References
Refer to package insert

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	11.19	
Policy updated. Added requested non-preferred medication may be approved if there has been a therapeutic failure to a trial of no less than 30 days of at least two preferred medications with different active ingredients not requiring a prior authorization	11.20	

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.

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