

SmartPA Criteria Proposal

Drug/Drug Class:	Urinary Tract Antispasmodics PDL Edit
First Implementation Date:	November 2, 2005
Proposed Date:	June 17, 2021
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: Overactive bladder (OAB) is increased urinary urgency, with or without urge urinary incontinence, usually with frequency and nocturia. This bothersome medical condition affects more than 17 million men and women of all ages, although its incidence increases significantly with age. Research shows that this triad of symptoms – urinary frequency, urgency, and urge incontinence, alone or in combination – can have a significant impact on a participant’s quality of life. Several different medications are available for treating OAB and are classified as antimuscarinic or anticholinergic drugs. These agents affect the nerve and muscle function of the detrusor muscle, causing it to relax, thus reducing the frequency and intensity of the bladder contractions. They can also increase bladder capacity.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	<ul style="list-style-type: none"> • Oxybutynin • Oxybutynin ER • Solifenacin Succinate • Toviaz® 	<ul style="list-style-type: none"> • Darifenacin ER • Detrol® • Detrol® LA • Ditropan XL® • Enablex® • Flavoxate • Gelnique® • Gemtesa® • Myrbetriq® • Oxytrol® • Tolterodine • Tolterodine ER • Trospium • Trospium ER • Urogesic-Blue™ • Vesicare® • Vesicare LS™

Type of Criteria: Increased risk of ADE
 Appropriate Indications

Preferred Drug List
 Clinical Edit

Data Sources: Only Administrative Databases

Databases + Prescriber-Supplied

Setting & Population

- Drug class for review: Urinary Tract Antispasmodics
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- For oxybutynin ER: approved as first-line therapy for participants aged 6 to 15 years **OR**
- Failure to achieve desired therapeutic outcomes with trial on 3 or more preferred agents
 - Documented trial period of preferred agents **OR**
 - Documented ADE/ADR to preferred agents
- **For Vesicare LS: Clinical Consultant Review for participants aged 10 years or older**

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Lack of adequate trial on required preferred agents
- Claim exceeds maximum dosing limitations for the following:

Drug Description	Generic Equivalent	Max Dosing Limitation
DETROL 1 MG TABLET	TOLTERODINE	2 tablets per day
DETROL 2 MG TABLET	TOLTERODINE	2 tablets per day
DETROL LA 2 MG CAPSULE	TOLTERODINE ER	1 capsule per day
DETROL LA 4 MG CAPSULE	TOLTERODINE ER	1 capsule per day
DITROPAN 5 MG TABLET	OXYBUTYNIN	4 tablets per day
DITROPAN XL 5 MG TABLET	OXYBUTYNIN ER	1 tablet per day
DITROPAN XL 10 MG TABLET	OXYBUTYNIN ER	2 tablets per day
DITROPAN XL 15 MG TABLET	OXYBUTYNIN ER	2 tablets per day
ENABLEX 7.5 MG TABLET	DARIFENACIN	1 tablet per day
ENABLEX 15 MG TABLET	DARIFENACIN	1 tablet per day
FLAVOXATE 100 MG TABLET	FLAVOXATE	6 tablets per day
GEMTESA 75 MG TABLET	VIBEGRON	1 tablet per day
MYRBETRIQ ER 25 MG TABLET	MIRABEGRON ER	1 tablet per day
MYRBETRIQ ER 50 MG TABLET	MIRABEGRON ER	1 tablet per day
OXYTROL 3.9 MG/24 HR PATCH	OXYBUTYNIN	8 patches per 28 days
OXYTROL FOR WOMEN 3.9 MG/24 HR	OXYBUTYNIN	8 patches per 28 days
TOVIAZ ER 4 MG TABLET	FESOTERODINE	1 tablet per day
TOVIAZ ER 8 MG TABLET	FESOTERODINE	1 tablet per day
UROGESIC-BLUE TABLET	METHENAMINE/SODIUM ACID PHOSPHATE/ METHYLENE BLUE/ HYOSCYAMINE	4 tablets per day
VESICARE LS 1 MG/ML	SOLIFENACIN SUCCINATE	10 mL per day
VESICARE 5 MG TABLET	SOLIFENACIN SUCCINATE	2 tablets per day

Required Documentation

Laboratory Results:
MedWatch Form:

Progress Notes:
Other:

Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

1. USPDI, Micromedex; 2021.
2. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.
3. Drug Effectiveness Review Project – Drug Class Review on “Agents for Overactive Bladder.” Center for Evidence-Based Policy, Oregon Health & Science University; March 2009; updated January 2016
4. Evidence-Based Medicine Analysis: “Urinary Tract Antispasmodics”, UMKC-DIC; March 2021.
5. Evidence-Based Medicine and Fiscal Analysis: “Urinary Tract Antispasmodic Agents – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; June 2021.
6. Detrol LA [package insert]. New York, NY: Pfizer Inc; July 2018.
7. Detrol [package insert]. New York, NY: Pfizer; November 2016.
8. Ditropan XL [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; April 2021.
9. Toviaz [package insert]. New York, NY: Pfizer Labs; October 2020.
10. Vesicare [package insert]. Northbrook, IL: Astellas Pharma US; June 2020.
11. Enablex [package insert]. Irvine, CA: Allergan USA, Inc; September 2016.
12. Gelnique [package insert]. Madison, NJ: Allergan USA, Inc; March 2019.
13. Myrbetriq [package insert]. Northbrook, IL: Astellas Pharma US, Inc; March 2021.