



SmartPA Criteria Proposal

Drug/Drug Class:	Urinary Tract Antispasmodics PDL Edit		
First Implementation Date:	November 2, 2005		
Revised Date:	October 14, 2021		
Prepared For:	MO HealthNet		
Prepared By:	MO HealthNet/Conduent		
Criteria Status:	 □Existing Criteria ☑Revision of Existing Criteria □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	Preferred Agents	Non-Preferred Agents
Information:	Oxybutynin	Darifenacin ER
	Oxybutynin ER	• Detrol [®]
	 Solifenacin Succinate 	Detrol [®] LA
	• Toviaz [®]	Ditropan XL [®]
		• Enablex [®]
		Flavoxate
		Gelnique [®]
		Gemtesa [®]
		Myrbetriq [®]
		Oxytrol [®]
		Tolterodine
		Tolterodine ER
		Trospium
		Trospium ER
		 Urogesic-Blue[™]
		Vesicare [®]
		 Vesicare LS[™]

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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

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met
- 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	OXYBUTYNIN	8 patches per 28 days
MG/24 HR		
SANCTURA 20 MG TABLET	TROSPIUIM	3 tablets per day
SANCTURA XR 60 MG CAPSULE	TROSPIUIM	1 capsule per day
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	4 tablets per day
	PHOSPHATE/ METHYLENE	
	BLUE/ HYOSCYAMINE	
VESICARE LS 1 MG/ML	SOLIFENACIN SUCCINATE	10 mL per day
VESICARE 5 MG TABLET	SOLIFENACIN SUCCINATE	1 tablet per day
VESICARE 10 MG TABLET	SOLIFENACIN	1 tablet per day

SmartPA PDL Proposal Form

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Required Documentation

Laboratory Results: Progress Notes: MedWatch Form: Other:

Disposition of Edit

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

Default Approval Period

1 year

References

- 1. USPDI, Micromedex; 2021.
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- 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.
- Ditropan XL [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; April 2021. 8.
- Toviaz [package insert]. New York, NY: Pfizer Labs; October 2020. 9.
- 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. Myrbetrig [package insert]. Northbrook, IL: Astellas Pharma US, Inc; March 2021.