

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY:	Benign Prostatic Hypertrophy/ Urinary Incontinence	P&T DATE:	12/8/2020
CLASS:	Renal Disease/Genitourinary Disorders	REVIEW HISTORY:	12/19, 12/18,
LOB:	MCL	(MONTH/YEAR)	5/17, 9/15, 5/13, 9/12, 9/11, 2/10

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.

OVERVIEW

Table 1: BPH and OAB Formulary Restrictions:

Class	Drug	Available Strengths	Formulary Status	Restriction (Blank = No restriction)	Cost Per Rx
Smooth Muscle Relaxants-Antimuscarinics	Oxybutynin (Ditropan)	5mg tablets	--	--	\$7.14
		5mg/5mL syrup	--	--	\$5.83
	Oxybutynin Transdermal Gel (Gelnique)	28mg/0.92g (3%), 100mg/1g (10%) Gel	PA, ST, QL	92g per 30 days 30g per 30 days Step therapy to treatment failure of Oxybutynin IR in the past 180 days.	--*
	Oxybutynin Transdermal Patches (Oxytrol)	3.9mg/patch	NF		\$693.45
	Oxybutynin ER (Ditropan LA)	5mg tablets	QL	Oxybutynin ER and Trospium ER are limited to 1 capsule per day. Oxybutynin ER 15 mg is limited to 2 tablets per day. Trospium IR is limited to 2 tablets per day	\$9.17
		10mg tablets	QL		\$8.47
		15mg tablets	QL		\$10.82
	Trospium (Sanctura)	20mg	QL		\$24.66
	Trospium Chloride ER (Sanctura XR)	60mg	QL		\$86.77
	Solifenacin (Vesicare)	5mg tablets	ST		Reserved for treatment failure or intolerance to tier 1 antimuscarinic agents.
		10mg tablets		\$9.98	
	Tolterodine (Detrol LA)	2mg capsules	--	--	\$57.69
		4mg capsules	--	--	\$44.93
	Fesoterodine ER (Toviaz)	4mg capsules	ST	Reserved for treatment failure or intolerance to tier 1 antimuscarinic agents.	--
		8mg capsules			--
Darifenacin ER (Enablex)	7.5mg ER tablets	PA	--Reserved for intolerance or treatment failure of: 1) Oxybutynin IR (except those over 65); 2) Oxybutynin ER, 3) Trospium IR (unless over 65), and Trospium ER	\$56.08	
	15mg ER tablets			\$94.07	
Beta-3 Agonist	Mirabegron ER (Myrbetriq)	25mg ER tablets	PA, QL	Reserved for treatment failure or intolerance to 2 antimuscarinic agents.	\$406.70
		50mg ER tablets			\$409.22
Alpha-1 Antagonists	Tamsulosin (Flomax)	0.4mg capsules	--	--	\$2.76
		1mg capsules			\$5.55
	Terazosin (Hytrin)	2mg capsules	--	--	\$5.73
		5mg capsules			\$4.92
		10mg capsules			\$5.35
	Doxazosin (Cardura)	1mg tablets	--	--	\$6.92
		2mg tablets			\$6.37
4mg tablets		\$6.10			

		8mg tablets			\$6.90
	Doxazosin (Cardura XL)	4mg tablets	NF		--*
		8mg tablets			--*
	Prazosin (Minipress)	1mg capsules	--	--	\$11.93
		2mg capsules			\$18.23
		5mg capsules			\$21.14
	Alfuzosin (Urotraxal)	10mg ER tablets	--		\$4.13
	Silodosin (Rapaflo)	4mg capsules	NF	--	--
		8mg capsules			\$27.55
5-alpha Reductase Inhibitors	Finasteride (Proscar)	5mg	--	--	\$2.75
	Dutasteride (Avodart)	0.5mg	NF	--	\$6.41
Phosphodiesterase-5 Enzyme Inhibitor	Tadalafil	5 mg	NF	--	--
Other	Onabotulinumtoxin A (Botox)	50 units	MA		--
		100 units	MA	--	--
		200 units	MA		--

F = Formulary, ST = Step therapy, PA = Prior Authorization required, MA=Medical Authorization required, IR = Immediate Release, ER = Extended Release. *Gelnique and Doxazosin XL had no fills in the past year.

Clinical Justification:

All trials of newer anticholinergic drugs that led to their approval in overactive bladder (OAB) were done against placebo. From smaller active comparator trials, it appears that many of these agents have equal efficacy. One big difference in these agents is tolerability. This main differentiator appears to divide drugs by their release profile. Extended release drugs appear to be tolerable in those patients unable to tolerate immediate release, while those who tolerate immediate release, see no added benefits from Extended Release formulations. This forms the basis of HPSJ formulary criteria for OAB drugs. Alpha-1 antagonists carry no restrictions, though Tamsulosin and Alfuzosin are selective, and tend to have fewer side effects. For 5-alpha reductase inhibitors, Finasteride and Dutasteride have shown similar long-term efficacy and safety.

Triage:

1. Appropriate diagnosis
2. Previous medications tried for urinary urgency or BPH

EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HPSJ Medical Review Guidelines (UM06).

Smooth Muscle Relaxants

Oxybutynin IR (Ditropan), Oxybutynin ER (Ditropan LA), Trospium IR (Sanctura), Trospium ER (Sanctura XR), Tolterodine ER (Detrol LA), Darifenacin (Enablex), Solifenacin (Vesicare), Fesoterodine (Toviaz)

Oxybutynin IR (Ditropan)

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A

Oxybutynin ER (Ditropan LA)

- Coverage Criteria:** None
- Limits:** 1 tablet per day. 15 mg strength is limited to 2 tablets per day.
- Required Information for Approval:** None

Trospium IR (Sanctura)

- Coverage Criteria:** None
- Limits:** 2 tablets per day.
- Required Information for Approval:** None

Trospium ER (Sanctura XR)

- Coverage Criteria:** None
- Limits:** 1 capsule per day.
- Required Information for Approval:** None

Tolterodine ER (Detrol LA), Darifenacin (Enablex)

- Coverage Criteria:** Reserved for treatment failure or intolerance to Oxybutynin IR (unless over 65), Oxybutynin ER, Trospium IR unless over 65) and Trospium XR.
- Limits:** None
- Required Information for Approval:** Chart notes and pharmacy fill history indicating treatment failure of Oxybutynin IR, Oxybutynin ER, and Trospium IR (unless over 65) and Trospium XR.

Solifenacin (Vesicare), Fesoterodine (Toviaz)

- Coverage Criteria:** Reserved for treatment failure or intolerance to tier 1 antimuscarinic agents.
- Limits:** None
- Required Information for Approval:** Chart notes and pharmacy fill history indicating treatment failure to tier 1 antimuscarinic agents.

Beta Agonist
<i>Mirabegron (Myrbetriq)</i>

Mirabegron (Myrbetriq)

- Coverage Criteria:** Reserved for treatment failure or intolerance to 2 antimuscarinic agents.
- Limits:** 30 tablets per 30 days
- Required Information for Approval:** Chart notes and pharmacy fill history indicating treatment failure or intolerance to 2 antimuscarinic agents.

Alpha Blockers
<i>Tamsulosin (Flomax), Alfuzosin (Urotraxal), Terazosin (Hytrin), Doxazosin (Cardura), Prazosin (Minipress)</i>

Tamsulosin (Flomax), Alfuzosin (Urotraxal), Terazosin (Hytrin), Doxazosin (Cardura), Prazosin (Minipress)

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Non-Formulary:** Silodisin (Rapaflo)

5-Alpha Reductase Inhibitors
<i>Finasteride (Proscar)</i>

Finasteride (Proscar)

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A

Other:
<i>Onabotulinumtoxin A (Botox)</i>

- Coverage Criteria:** Medical Authorization required
- Limits:** N/A
- Required Information for Approval:** Medical Authorization required

☒ REFERENCES

1. Hesch K. *Agents for Treatment of Overactive Bladder: a Therapeutic Class Review*. Proc (Bayl Univ Med Cent). 2007 Jul; 20(3): 307-314.
2. Nickel JC. *Comparison of Clinical Trials with Finasteride and Dutasteride*. Rev Urol. 2004; 6(Suppl 9): S31-S39.
3. Gormey EA, Lightner DJ, Burgio DL, Chai TC, Clemens JQ, Culkin DJ, et al. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU guideline. J Urol. 2015 May; 193(5): 1572-80
4. Gormley A., Lightner D., Burgio K. et al., *Diagnosis and Treatment of Non-Neurogenic Overactive Bladder (OAB) in Adults: an AUA/SUFU Guideline (2019)*. AUA/SUFU Guideline: Published 2012; Amended 2014, 2019. Doi: [https://www.auanet.org/guidelines/overactive-bladder-\(oab\)-guideline](https://www.auanet.org/guidelines/overactive-bladder-(oab)-guideline).

☒ REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	Formulary realignment 2-2010.xlsx	2/2010	Allen Shek PharmD BCPS
Update to Policy	Formulary realignment 9-11.xlsx	9/2011	Allen Shek PharmD BCPS
Update to Policy	Formulary Alternatives 9-12.docx	9/2012	Allen Shek PharmD BCPS
Update to Policy	Formulary Realignment PT 5-21-13.xlsx	5/2013	Allen Shek PharmD BCPS
Update to Policy	Formulary Realignment 09-23-2015.xlsx	9/2015	Jonathan Szkotak, PharmD BCACP
Update to Policy	HPSJ Coverage Policy – Renal & Urinary – BPH and Urinary Incontinence 2015-09.docx	9/2015	Jonathan Szkotak, PharmD BCACP
Update to Policy	HPSJ Coverage Policy – Renal & Urinary – BPH and Urinary Incontinence 2017-05.docx	5/2017	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Renal & Urinary – BPH and Urinary Incontinence 2018-12.docx	12/2018	Matthew Garrett, PharmD
Update to Policy	HPSJ Coverage Policy – Renal & Urinary – BPH and Urinary Incontinence 2019-12.docx	12/2019	Matthew Garrett, PharmD
Review of Policy	BPH and Urinary Incontinence	12/2020	Matthew Garrett, PharmD

Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy