

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY:	Benign Prostatic Hypertrophy/ Urinary Incontinence	P&T DATE:	12/11/2018
CLASS:	Renal Disease/Genitourinary Disorders	REVIEW HISTORY:	5/17, 9/15, 5/13,
LOB:	MCL	(MONTH/YEAR)	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, 5mg/5mL Soln.	--		\$8.22
	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 ER (Ditropan LA)	5mg, 10mg, 15mg	ST	Step therapy to treatment failure of Oxybutynin IR in the past 180 days.	\$39.12
	Trospium (Sanctura)	20mg	PA, ST, QL	Reserved for treatment failure or intolerance to Oxybutynin IR (unless over 65) and Oxybutynin ER in the past 365 days.	\$47.62
	Trospium Chloride ER (Sanctura XR)	60mg	PA, ST	Reserved for treatment failure or intolerance to Oxybutynin IR (unless over 65), Oxybutynin ER, and Trospium IR (unless over 65) in the past 365 days.	\$149.43
	Solifenacin (Vesicare)	5mg, 10mg	PA	Reserved for treatment failure or intolerance to Oxybutynin IR (unless over 65), Oxybutynin ER, Trospium IR/XR, Darifenacin, and Tolterodine ER.	\$351.63
	Tolterodine (Detrol LA)	2mg, 4mg	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	\$138.77
	Fesoterodine (Toviaz) ER	4mg, 8mg	PA	Reserved for treatment failure or intolerance to Oxybutynin IR (unless over 65), Oxybutynin ER, Trospium IR/XR, Darifenacin, and Tolterodine ER	\$378.95 [†]
Beta-3 Agonist	Darifenacin (Enablex)	7.5mg, 15mg	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	\$210.76
Beta-3 Agonist	Mirabegron (Myrbetriq)	25mg, 50mg	PA, QL	It is reserved as treatment failure of: 1) Oxybutynin IR (except those over 65); 2) Oxybutynin ER, and; 3) Sanctura XR. Limited to 30 tablets per 30 days	\$362.07
Alpha-1 Antagonists	Tamsulosin (Flomax)	0.4mg	--		\$7.24
	Terazosin (Hytrin)	1mg, 2mg, 5mg, 10mg			\$2.87
	Doxazosin (Cardura)	1mg, 2mg, 4mg, 8mg	--		\$16.40
	Doxazosin (Cardura XL)	4mg, 8mg	NF		--*
	Prazosin (Minipress)	1mg, 2mg, 5mg	--		\$26.26
	Alfuzosin (Urotraxal)	10mg	--		\$6.71

	Silodosin (Rapaflo)	4mg, 8mg	NF		\$247.63
5-alpha Reductase Inhibitors	Finasteride (Proscar)	5mg	--		\$4.99
	Dutasteride (Avodart)	0.5mg	NF		\$15.22

F = Formulary, ST = Step therapy, PA = Prior Authorization required, IR = Immediate Release, ER = Extended Release.

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.

⊕ 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)

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

Oxybutynin ER (Ditropan LA)

- Coverage Criteria:** Step therapy to treatment failure of Oxybutynin IR in the past 180 days.
- Limits:** None
- Required Information for Approval:** No PA is required if the member has filled Oxybutynin with HPSJ in the past 180 days.

Trospium IR (Sanctura)

- Coverage Criteria:** Reserved for treatment failure or intolerance to Oxybutynin IR (unless over 65) and Oxybutynin ER in the past 365 days.
- Limits:** None
- Required Information for Approval:** Chart notes and pharmacy fill history indicating treatment failure of Oxybutynin IR and ER, including the type and severity of reaction or intolerability.

Trospium ER (Sanctura XR)

- Coverage Criteria:** Third Line Agent Reserved for treatment failure or intolerance to Oxybutynin IR (unless over 65), Oxybutynin ER, and Trospium IR (unless over 65) in the past 365 days.
- Limits:** None
- Required Information for Approval:** Chart notes and pharmacy fill history indicating treatment failure of Oxybutynin IR, ER and Trospium IR, including the type and severity of reaction or intolerability.

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 Oxybutynin IR (unless over 65), Oxybutynin ER, Trospium IR (unless over 65), Trospium XR, Darifenacin, and Tolterodine ER.
- Limits:** None
- Required Information for Approval:** Chart notes and pharmacy fill history indicating treatment failure of Oxybutynin IR, Oxybutynin ER, Trospium IR/XR, Darifenacin, and Tolterodine ER.

Beta Agonist

Mirabegron (Myrbetriq)

- Coverage Criteria:** Reserved for treatment failure or intolerance to Oxybutynin IR (unless over 65), Oxybutynin ER, and Sanctura XR in the past 365 days.
- Limits:** 30 tablets per 30 days
- Required Information for Approval:** Chart notes and pharmacy fill history indicating treatment failure of Oxybutynin IR, Oxybutynin ER, and Trospium ER.

Alpha Blockers

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

Finasteride (Proscar)

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

REFERENCES

- Hesch K. *Agents for Treatment of Overactive Bladder: a Therapeutic Class Review*. Proc (Bayl Univ Med Cent). 2007 Jul; 20(3): 307-314.
- Nickel JC. *Comparison of Clinical Trials with Finasteride and Dutasteride*. Rev Urol. 2004; 6(Suppl 9): S31-S39.
- 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

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

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