

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY:	Benign Prostatic Hypertrophy/ Urinary Incontinence	P&T DATE:	5/9/2017
CLASS:	Renal Disease/Genitourinary Disorders	REVIEW HISTORY:	9/15, 5/13, 9/12, (MONTH/YEAR)
LOB:	MCL		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	Oxybutynin (Ditropan)	5mg, 5mg/5mL Soln.	--		\$19.26
	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.	\$82.13
	Trospium Chloride ER (Sanctura XR)	60mg	PA, ST	Third Line Agent Reserved for treatment failure or intolerance to Oxybutynin IR (unless over 65) and ER in the past 365 days.	\$149.43
	Solifenacin (Vesicare)	5mg, 10mg	PA	It is step to intolerance or treatment failure of: 1) Oxybutynin IR (except those over 65); 2) Oxybutynin ER, and; 3) Sanctura XR	\$305.87
	Tolterodine (Detrol LA)	2mg, 4mg	PA	It is step to intolerance or treatment failure of: 1) Oxybutynin IR (except those over 65); 2) Oxybutynin ER, and; 3) Sanctura XR	\$183.09
	Fesoterodine (Toviaz)	4mg, 8mg	PA	It is step to intolerance or treatment failure of: 1) Oxybutynin IR (except those over 65); 2) Oxybutynin ER, and; 3) Sanctura XR	\$185.00
	Darifenacin (Enablex)	7.5mg, 15mg	PA	It is step to intolerance or treatment failure of: 1) Oxybutynin IR (except those over 65); 2) Oxybutynin ER, and; 3) Sanctura XR	\$209.00
Alpha-1 Antagonists	Tamsulosin (Flomax)	0.4mg	--		\$9.54
	Terazosin (Hytrin)	1mg, 2mg, 5mg, 10mg			\$4.76
	Doxazosin (Cardura)	1mg, 2mg, 4mg, 8mg	--		\$22.11
	Prazosin (Minipress)	1mg, 2mg, 5mg	--		\$30.83
	Alfuzosin (Urotraxal)	10mg	--		\$9.35
5-alpha Reductase Inhibitors	Finasteride (Proscar)	5mg	--		\$11.61
	Dutasteride (Avodart)		NF		--

F = Formulary, ST = Step therapy, PA = Prior Authorization required, IR = Immediate Release, ER = Extended Release. ¥based on claims data from 4/2016-3/2017 *Gelnique 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. Age > 65
3. 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 HSPJ 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 ER (Sanctura XR)

- Coverage Criteria:** Third Line Agent Reserved for treatment failure or intolerance to Oxybutynin IR (unless over 65) and 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 intolerance.

Solifenacin (Vesicare), Tolterodine ER (Detrol LA), Fesoterodine (Toviaz), Darifenacin (Enablex)

- Coverage Criteria:** Reserved for treatment failure or intolerance to Oxybutynin IR (unless over 65) and ER in the past 365 days.
- Limits:** None
- 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

5-Alpha Reductase Inhibitors

Finasteride (Proscar)

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

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.

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

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