

Pharmacy Benefit Determination Policy

Policy Subject: BPH Agents Policy Number: SHS PBD44 Category: Urologicals Policy Type: <input type="checkbox"/> Medical <input checked="" type="checkbox"/> Pharmacy Department: Pharmacy	Dates: Effective Date: April 22, 2015 Revision Date: November 1, 2017 Approval Date: February 27, 2019 Next Review Date: February 2020
Product (check all that apply): <input checked="" type="checkbox"/> Group HMO/POS <input checked="" type="checkbox"/> Individual HMO/POS <input checked="" type="checkbox"/> PPO <input checked="" type="checkbox"/> ASO	Clinical Approval By: Medical Directors PHP: Peter Graham, MD Pharmacy and Therapeutics Committee PHP: Peter Graham, MD

Policy Statement:

Physicians Health Plan, PHP Insurance & Service Company, and Sparrow PHP will cover Cialis 5mg daily through the Pharmacy Benefit based on approval by the Clinical Pharmacist or Medical Director using the following determination guidelines

Drugs and Applicable Coding:

Clinical Determination Guidelines:

Document the following with chart notes

A. Uncomplicated mild-to-mod. Lower Urinary Tract Symptoms (LUTS)

1. Symptoms: Not bothersome enough to need drug treatment or surgical intervention
2. Treatment plan: Watchful waiting
 - a. Specific time targeted reduction of fluid intake
 - b. Avoidance/moderation of caffeine and alcohol intake
 - c. Techniques: Relaxed/double voiding; urethral milking; distraction (penile squeeze, breathing, perineal pressure); bladder retraining
 - d. Substitute needed drugs with those with low urinary effects and/or optimizing dosage time
 - e. Treat constipation

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B. Complicated LUTS

Agents	Efficacy	Comments
Alpha-1 blockers		
Uroxatrol (alfuzosin), Cardura (doxazosin), Rapaflo (silodosin), Flomax (tamsulosin) Hytrin (terazosin)	<ul style="list-style-type: none"> • International Prostate Symptom Score (IPSS) ↓ 30-50% • Peak flow rate (Q_{max}): ↑ 20-25% 	<ul style="list-style-type: none"> • First line drug treatment • Rapid onset of action • Good efficacy • Low rate/severity of adverse effects (AE) • Better responses w small prostate (<40ml)
5 Alpha Reductase Inhibitors		
Avodart (dutasteride), Proscar (finasteride)	<ul style="list-style-type: none"> • IPSS: ↓15-30% • Prostate volume: ↓18-28% • Q_{max}: ↑1.5-2mls 	<ul style="list-style-type: none"> • Use for annoying mod-severe LUTS & enlarged prostates (>40ml) or ↑ PSA (>1.4ng/ml) • Prevent disease progression w regard to urinary retention and need for surgery • Long-term treatment due to slow onset
Muscarinic Receptor Antagonist		
Enablex (darifenacin), Toviaz (fesoterodine) Ditropan (oxybutynin), Vesicare (solifenacine), Detrol (tolterodine), Sanctura (trospium Cl)	<ul style="list-style-type: none"> • Urge incontinence: ↓ • Urgency related voiding: ↓ 	<ul style="list-style-type: none"> • Use for mod-severe LUTS w bladder storage symptoms
Phosphodiesterase type 5 inhibitors		
Cialis daily (tadalafil)	<ul style="list-style-type: none"> • IPSS: ↓ 22-37% • Q_{max}: ↑2.4mls 	<ul style="list-style-type: none"> • Use for younger men with low BMI and more severe LUTS • Efficacy & tolerability for >1-year unknown • Reducing prostate size & slowing disease progression unknown

C. Other Therapies: Contraindicated, failed or significant adverse effects with 2 of each category below:

1. Alpha-1 blockers: 3-month trial
2. 5 alpha reductase inhibitor: 8-month trial

D. Approval (Cialis daily)

1. Initial: 6 months
2. Re-approval: 1 year

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Appendix I: Monitoring & Patient Safety - Adverse Reactions and Monitoring

Drug	Adverse Reactions	Monitoring	REMS
Alpha-1 Blockers Uroxatrol (alfuzosin) Cardura (doxazosin) Rapaflo (silodosin) Flomax (tamsulosin) Hytrin (terazosin)	<ul style="list-style-type: none"> • CV: postural hypotension (0.2-3.9%) • CNS: Dizziness (5-19%), HA (1-21%) • GU: Abnormal ejaculation (8-28%) • Neuro/MSK: Muscle weakness (7-11%) • Resp: Rhinitis (13-18%) • Misc: Infections (9-11%) • Preg Category: C (terazosin, doxazosin); B (alfuzosin, silodosin, tamsulosin) 	<ul style="list-style-type: none"> • CV: BP • GU: Urinary symptoms 	None Needed
5 Alpha Reductase Inhibitors Avodart (dutasteride) Proscar (finasteride)	<ul style="list-style-type: none"> • GU: Impotence (5-19%) 	<ul style="list-style-type: none"> • GU: r/o other GU dx; prostate CA • Lab: PSA (all prior & during) 	None Needed
Muscarinic Receptor Antagonist Enablex (darifenacin) Toviaz (fesoterodine) Ditropan (oxybutynin) VESIcare (solifenacine) Detrol (tolterodine) Sanctura (trospium Cl)	<ul style="list-style-type: none"> • CNS: Dizziness (5-17%), drowsiness (6-14%) • GI: Xerostomia (19-71%), constipation (15-21%), nausea (5-12%) 	<ul style="list-style-type: none"> • CNS: anticholinergic effects • GU: Incontinence episodes, CrCl, postvoid residual • Hepatic: LFT's 	
Phosphodiesterase Type 5 Inhibitors Cialis daily (tadalafil)	<ul style="list-style-type: none"> • CV: Flushing (1-13%) • CNS: HA (3-42%) • GI: Dyspepsia (1-13%), Nausea (10-11%) • Neuro/MSK: Myalgia (1-14%), back/extremity pain (1-12%) • Resp: RTI (3-13%), nasopharyngitis (2-13%) • Preg. Category: B 	<ul style="list-style-type: none"> • CV: BP • GU: Urine flow • Lab: PSA 	None Needed

References and Resources:

1. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; alfuzosin, doxazosin, silodosin, tamsulosin, terazosin, accessed Jan 2019
2. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; dutasteride, finasteride, accessed Jan 2019
3. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; tadalafil, accessed Jan 2019
4. EAU guidelines on the treatment and follow-up of non-neurogenic male lower urinary tract symptoms including benign prostatic obstruction. European Urology 2013;64:118-140.
5. Current medical treatment of lower urinary tract symptoms/BPH: Do we have a standard? 2014: [www.co-urology.com:24\(1\);21-28](http://www.co-urology.com:24(1);21-28).
6. <https://uroweb.org/wp-content/uploads/EAU-Guidelines-Management-of-non-neurogenic-male-LUTS-2016.pdf> Accessed November 2017

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	2/27/19
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