DRUG DETERMINATION POLICY

Title: DDP-07 PDE-5 Inhibitors for Treatment of BPH

Effective Date: 03/17/2020

Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

This policy describes the determination process for coverage of specific drugs that require prior approval.

This policy does not guarantee or approve Benefits. Coverage depends on the specific Benefit plan. Drug Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

2.0 Background or Purpose:

Phosphodiesterase-5 inhibitor (e.g., tadalafil [Cialis]) is considered a lifestyle drug for erectile dysfunction that is also indicated for benign prostatic hyperplasia (BPH). These criteria were developed and implemented to ensure standard BPH drug therapy prior to use.

3.0 Clinical Determination Guidelines:

Document the following with chart notes:

A. Benign prostatic hyperplasia:

1. Other therapies: contraindication, failure, or significant adverse effects with two of each drug category.

    a. Alpha-1 blockers (e.g., alfuzosin, doxazosin, tamsulosin): 3-month trial.

    b. 5 alpha reductase inhibitor (e.g. finasteride, dutasteride): 8-month trial.

2. Approval duration of PDE-5 inhibitors:

    a. Initial: six months.

    b. Re-approval: one year.

4.0 Coding:

None.

5.0 Unique Configuration/Prior Approval/Coverage Details:

None.

6.0 References, Citations & Resources:

1. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; alfuzosin, doxazosin, silodosin, tamusulosin, terazosin, accessed December 2019.
2. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; dutasteride, finasteride, accessed December 2019.
3. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; tadalafil, accessed December 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.
6. https://uroweb.org/wp-content/uploads/EAU-Guidelines-Management-of-non-neurogenic-male-LUTS-2016.pdf; accessed November 2017.

7.0 Appendices:

Appendix I: Monitoring & Patient Safety

Drug	Adverse Reactions	Monitoring	REM
Alpha-1 Blockers Uroxatrol (alfuzosin) Cardura (doxazosin) Rapaflo (silodosin) Flomax (tamsulosin) Hytrin (terazosin)	• Cardiovascular: postural hypotension (0.2-3.9%) • Central nervous system: dizziness (5-19%), headache (1-21%) • Genitourinary: abnormal ejaculation (8-28%) • Musculoskeletal: muscle weakness (7-11%) • Respiratory: rhinitis (13-18%) • Miscellaneous: infections (9-11%) • Pregnancy Category: C (terazosin, doxazosin); B (alfuzosin, silodosin, tamulosin)	• Cardiovascular: blood pressure • Genitourinary: Urinary symptoms	None
5 Alpha Reductase Inhibitors Avodart (dutasteride) Proscar (finasteride)	• Genitourinary: impotence (5-19%)	• Genitourinary (GU): rule out other GU diagnosis; prostate cancer • Lab: PSA (all prior and during)	None
Muscarinic Receptor Antagonist Enablex (darifenacin) Toviaz (fesoterodine) Ditropan (oxybutynin) VESIcare (solifenacine) Detrol (tolterodine) Sanctura (trospium Cl)	• Central nervous system: dizziness (5-17%), drowsiness (6-14%) • Gastrointestinal: xerostomia (19-71%), constipation (15-21%), nausea (5-12%)	• Central nervous system: anti-cholinergic effects • Genitourinary: incontinence episodes, creatinine clearance , post-void residual • Hepatic: liver function tests	

Drug	Adverse Reactions	Monitoring	REM
Phosphodiesterase Type 5 Inhibitors Cialis daily (tadalafil)	• Cardiovascular: flushing (1-13%) • Central nervous system: headache (3-42%) • Gastrointestinal: dyspepsia (1-13%), nausea (10-11%) • Musculoskeletal: myalgia (1-14%), back/extremity pain (1-12%) • Respiratory: respiratory tract infection (3-13%), nasopharyngitis (2-13%) • Pregnancy: Category: B	• Cardiovascular: blood pressure (BP) • Genitourinary: urine flow • Lab: PSA	None

8.0 Revision History:

Original Effective Date: April 22, 2015

Next Review Date: 03/17/2021

Revision Date	Reason for Revision
2/19	Transitioned to new format
4/1/19	To P & T workgroup
12/19	Annual review; formatting, replaced abbreviations, updated references