Benign Prostatic Hyperplasia (BPH) Agents:

Selective cGMP Phosphodiesterase Type 5 (PDE5) Inhibitors

WA.PHAR.44 Benign Prostatic Hyperplasia (BPH) Agents PDE5 Inhibitors

Background:

Benign prostatic hyperplasia (BPH) is an enlarged prostate. It is a common disorder that progressively increases with age in men that results in lower urinary tract symptoms (LUTS), including increased frequency of urination, nocturia, urgency, and weak urinary stream. Although LUTS secondary to BPH (LUTS/BPH) is not often a life-threatening condition, the impact of LUTS/BPH on quality of life (QOL) can be significant and should not be underestimated.

Alpha 1-Adrenoceptor Antagonist and selective cyclic guanosine monophosphate (cGMP) phosphodiesterase type-5 (PDE5) inhibitors relax the muscles of the prostate and bladder and reduce the symptoms of BPH. 5-Alph Reductase Inhibitors block the production of dihydrotestosterone (DHT) which plays a role in prostate development and growth.

Medical necessity

Drug	Medical Necessity
tadalafil (CIALIS®)	Tadalafil (Cialis®) may be considered medically necessary when used as a second-line treatment for symptoms of BPH.

Clinical policy:

Drug	Clinical Criteria (Initial Approval)
tadalafil (CIALIS®)	1. Diagnosis of benign prostatic hyperplasia (BPH) 2. History of failure, contraindication or intolerance to **BOTH** of the following: a. Greater than or equal to (≥) 4 week trial of an Alpha 1-Adrenoceptor Antagonist (e.g. alfuzosin, doxazosin, silodosin, terazosin, tamsulosin) b. Greater than or equal to (≥) 6 month trial of 5-Alpha Reductase Inhibitor (e.g. dutasteride, finasteride) 1. Maximum dose less than or equal to (≤) 5mg per day **Approve for 12 months**

Dosage and quantity limits

Drug Name	Dose and Quantity Limits
tadalafil (CIALIS®)	5mg per day; #30 tablets per 30-day supply

References

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3. Product Information: PROSCAR® oral tablets, finasteride oral tablets. Merck Sharp & Dohme Corp (per Manufacturer), Whitehouse Station, NJ, 2011.
4. Product Information: AVODART® oral capsules, dutasteride oral capsules. GlaxoSmithKline (Per FDA), Research Triangle Park, NC, 2011.
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8. Roehrborn CG, McVary KT, Elion-Mboussa A, et al. Tadalafil administered once daily for lower urinary tract symptoms secondary to benign prostatic hyperplasia: a dose finding study. J Urol 2008;180:1228-1234.
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