



TADALAFIL (Cialis®)
Benign Prostatic Hyperplasia (BPH)
UTILIZATION MANAGEMENT CRITERIA

DRUG CLASS: Phosphodiesterase 5 (PDE5) Inhibitor

BRAND (generic) NAMES: Cialis (tadalafil)
5mg tablets ONLY

FDA-APPROVED INDICATIONS

- Erectile dysfunction (ED)
- The signs and symptoms of benign prostatic hyperplasia (BPH)
- ED and the signs and symptoms of BPH (ED/BPH)

RATIONALE:

According to 2010 American Urological Association (AUA) guidelines, watchful waiting is considered the preferred therapy for mild lower urinary tract symptoms (LUTS) due to BPH with American Urological Association Symptom Index (AUA-SI) score < 8 and for patients with moderate or severe symptoms (AUA-SI \geq 8) who are not bothered by their LUTS.

<http://www.auanet.org/content/clinical-practice-guidelines/clinical-guidelines.cfm?sub=bph>

Watchful waiting should also include the following measures to decrease BPH symptoms: avoiding decongestants and antihistamines, decreasing fluid intake near bedtime, and decreasing caffeine and alcohol intake generally. Currently, first line agents consist of alpha blockers [Hytrin (terazosin), Cardura (doxazosin), Flomax (tamsulosin), Uroxatral (alfuzosin) or Rapaflo (silodosin)], 5- alpha reductase inhibitors [Proscar (finasteride), Avodart (dutasteride)] and combinations of the two classes of medications [Jalyn (dutasteride plus tamsulosin)].

COVERAGE AUTHORIZATION CRITERIA

Initial Coverage Criteria

Cialis (Tadalafil) is covered for the following conditions and situations:

- Using Cialis 5mg once daily tablets; **AND**
- Men \geq 45 years of age; **AND**
- BPH symptoms of at least moderate severity (AUA-SI \geq 8), that are bothersome, and that have not responded to non-pharmacological measures; **AND**
- Patients who have tried and failed, are intolerant to, or have contraindications to the following classes of medications: alpha blockers AND 5-alpha reductase inhibitors. [ex. Proscar (finasteride), Avodart (dutasteride), Jalyn (dutasteride plus tamsulosin), Hytrin (terazosin), Cardura (doxazosin), Flomax (tamsulosin), Uroxatral (alfuzosin) or Rapaflo (silodosin)]; **AND**
- Urology consultation has been obtained.
 - a. Urology consultant has determined that daily 5 mg Cialis (tadalafil) is more appropriate than other therapy options.
 - b. A urologist provides the initial 3 months (trial) prescription for Cialis (tadalafil) 5 mg daily.

If the above criteria are met, initial approval will be for 3 months.

Quantity Limit: A quantity limit of 30 tablets per 30 days will be allowed if the above criteria are met.

Continuation Coverage Criteria

For coverage of continued daily 5mg Cialis therapy for **one year** after the initial three months trial, the following conditions must be met (including those listed in the initial coverage criteria):

- a. AUA-SI score is documented to have decreased after initial trial of therapy.
- Re-application for continued coverage, if desired, must occur annually thereafter and must meet these same conditions.

Cialis (tadalafil) is NOT covered for the following conditions or situations:

- Quantities over a member's benefit limit for the treatment of ED alone;
- Used in combination with nitrates;
- Used in patients who have had a total prostatectomy.

WARNINGS AND PRECAUTIONS:

Contraindicated in combination with any form of organic nitrates. Cialis was shown to potentiate the hypotensive effect of nitrates.

- Patients should not use Cialis if sex is inadvisable due to cardiovascular status
- Use of Cialis with alpha blockers, antihypertensives or substantial amounts of alcohol may lead to hypotension
- Cialis is not recommended in combination with alpha blockers for the treatment of BPH because efficacy of the combination has not been adequately studied and because of the risk of blood pressure lowering. Caution is advised when Cialis is used as a treatment for ED in men taking alpha blockers.
- If taking potent inhibitors of CYP3A4, dose should be adjusted: Cialis for use as needed: ≤10 mg every 72 hours. For once daily use: dose not to exceed 2.5 mg
- Patients should seek emergency treatment if an erection lasts >4 hours. Use Cialis with caution in patients predisposed to priapism
- Patients should stop Cialis and seek medical care if a sudden loss of vision occurs in one or both eyes, which could be a sign of Non Arteritic Ischemic Optic Neuropathy (NAION). Discuss increased risk of NAION in patients with history of NAION
- Patients should stop Cialis and seek prompt medical attention in the event of sudden decrease or loss of hearing
- Prior to initiating treatment with Cialis for BPH, consideration should be given to other urological conditions that may cause similar symptoms

DOSAGE AND ADMINISTRATION:

- **Cialis for once daily use:**
 - BPH: 5 mg, taken at approximately the same time every day
 - ED and BPH: 5 mg, taken at approximately the same time every day
- Cialis may be taken without regard to food

REFERENCES:

Tadalafil (Cialis) product information. Eli Lilly and Company. Indianapolis, IN. 2011.

<http://pi.lilly.com/us/cialis-pi.pdf>

Management of BPH (Revised, 2010). American Urological Association-Clinical Guidelines.

<http://www.auanet.org/>