

Cialis (tadalafil) - BPH coverage only

Policy Number: C6121-C

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
8/1/2009	08/15/2019	08/15/2020
J CODE	TYPE OF CRITERIA	LAST P&T APPROVAL/VERSION
NA	RxPA	Q3 2019 20190828C6121-C

PRODUCTS AFFECTED: Cialis (tadalafil)

DRUG CLASS:

Selective cGMP Phosphodiesterase Type 5 Inhibitors

ROUTE OF ADMINISTRATION:

Oral

PLACE OF SERVICE:

Retail Pharmacy

AVAILABLE DOSAGE FORMS: Cialis TABS 5MG, Tadalafil TABS 5MG, Cialis TABS 2.5MG
Tadalafil TABS 2.5MG

FDA-APPROVED USES: indicated for the treatment of erectile dysfunction (ED) and for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) and indicated for the treatment of ED and the signs and symptoms of BPH (ED/BPH).

COMPENDIAL APPROVED OFF-LABELED USES: None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS: for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) and indicated for the treatment of ED and the signs and symptoms of BPH (ED/BPH)

REQUIRED MEDICAL INFORMATION:

FOR NEW YORK HEALTHPLAN MEMBERS ONLY: Reviewer MUST check the Erectile Dysfunction Verification System (EDVS) for each request to determine member's sex offender status. IF a member is on the sex offender list the request must be forwarded to the medical director AND provider must provide the rationale for prescribing a PDE-5 inhibitors and note the reason(s) why alternative treatment options are inappropriate to treat the enrollee's health condition. Before issuing an adverse determination for a prescribed PDE5 inhibitor, the Medical Director must make reasonable attempts to engage in a peer-to-peer discussion with the requesting provider to understand the reasons behind the need for prescribing the requested PDE5 inhibitor or drug. The Medical Director may extend the review time, if requested by the provider or patient, or if such extension is in the best interest of the patient's health condition. For after-hours, holiday, and weekend pharmacy requests for prescription PDE5 inhibitors Molina Healthcare, Inc can authorize a seventy-two (72) hour emergency supply of the prescription PDE5 inhibitor and must note within the authorization file that the drug is prescribed to treat a condition other than sexual or erectile dysfunction and that the drug has been approved by the FDA to treat

that condition. The case must still be sent to the Medical director for checking the EDVS status of the member, as soon as possible on the next business day.

A. BENIGN PROSTATIC HYPERPLASIA (BPH)

1. Documentation of a diagnosis of BPH
AND
2. Documentation patient is not concurrently requiring nitrate therapy on a regular or intermittent basis
AND
3. Cialis (tadalafil) 5 mg is being prescribed for daily use for symptomatic benign prostatic hyperplasia (BPH) in a male that is 18 years of age or older. [Note: examples of signs and symptoms are incomplete emptying, weak stream, straining, urinary frequency, intermittency, urgency, or acute urinary retention.] [Cialis (tadalafil) is NOT covered when prescribed for sexual or erectile dysfunction]
AND
4. Documentation the patient had a trial(at least 7 days) and failure (or contraindication) to both a formulary alpha-1 blocker AND a formulary 5-alpha reductase inhibitor
AND
5. FOR NEW YORK HEALTHPLAN MEMBERS ONLY: Reviewer MUST check the Erectile Dysfunction Verification System (EDVS) for each request to determine member's sex offender status. IF a member is on the sex offender list the request must be forwarded to the medical director AND provider must provide the rationale for prescribing tadalafil and note the reason(s) why alternative treatment options are inappropriate to treat the enrollee's health condition.

DURATION OF APPROVAL: Initial authorization: 12 months, Continuation of therapy: 12 months
NEW YORK PATIENTS ONLY** PLEASE NOTE: FOR ANY MEMBER ON THE SEX OFFENDER LIST, APPROVAL CAN ONLY BE FOR 30 DAYS PER AUTHORIZATION******

QUANTITY: 30 tablets per 30 days

PRESCRIBER REQUIREMENTS: No requirements

AGE RESTRICTIONS: 18 years of age and older

GENDER:

Male

CONTINUATION OF THERAPY:

A. BENIGN PROSTATIC HYPERPLASIA (BPH):

1. Documented improvement in baseline symptoms
AND
2. Documentation that patient is tolerating therapy without drug related adverse reactions or toxicities

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION: All other uses of Cialis (tadalafil) are considered experimental/investigational or are not a covered benefit and therefore, will follow Molina's Off-Label policy.

OTHER SPECIAL CONSIDERATIONS: None

BACKGROUND:

Cialis is a phosphodiesterase 5 (PDE-5) inhibitor, indicated for the treatment of erectile dysfunction, the signs and symptoms of BPH, and the combination of erectile dysfunction and the signs and symptoms of BPH. This prior authorization is for plans who do not cover Cialis for erectile dysfunction

APPENDIX: None

REFERENCES:

1. Cialis [package insert]. Indianapolis, IN. Eli Lilly and Co; May 2017.
2. American Urological Association Education and Research, Inc. Guideline on the management of benign prostatic hyperplasia (BPH). Linthicum (MD): American Urological Association Education and Research, Inc.; 2014. 34 p.
3. Broderick GA, Brock GB, Roehrn CG, et al. Effects of Tadalafil on Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia in Men with or without Erectile Dysfunction. *Urology*. 2010; 75: 1452-1459.
4. Roehrn CG, Kaminetsky JC, Auerbach SM, et al. Changes in peak urinary flow and voiding efficiency in men with signs and symptoms of benign prostatic hyperplasia during once daily tadalafil treatment. *BJUI*. 2009; 105: 502-507.
5. Porst H, McVary KT, Montorsi F, et al. Effects of Once daily Tadalafil on Erectile Function in Men with Erectile Dysfunction and Signs and Symptoms of Benign Prostatic Hyperplasia. *European Urology*. 2009; 56: 727-736.
6. Clinical Pharmacology Gold Standard 2017.
7. Hatzimouratidis K, A review of the use of tadalafil in the treatment of benign prostatic hyperplasia in men with and without erectile dysfunction. *Ther Adv Urol*. 2014 Aug; 6(4): 135-147.