



Effective Date: 09/01/2014  
Last P&T Approval/Version: 01/26/2022  
Next Review Due By: 01/2023  
Policy Number: C6121-C

## Cialis (tadalafil) – BPH Coverage Only

### PRODUCTS AFFECTED

Cialis (tadalafil)

### COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

#### **Documentation Requirements:**

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive

#### **DIAGNOSIS:**

for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH)

#### **REQUIRED MEDICAL INFORMATION:**

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

**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

## Drug and Biologic Coverage Criteria

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.

FOR TADALAFIL FOR PULMONARY HYPERTENTION PLEASE REFER TO PULMONARY ARTERIAL HYPERTENTION(PAH) CRITERIA C9837-A

### 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. Prescriber attests that 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 FDA labeled 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.

### 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

### 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\*\*\*\*

### PRESCRIBER REQUIREMENTS:

No requirements

### AGE RESTRICTIONS:

18 years of age and older

### QUANTITY:

30 tablets per 30 days

## Drug and Biologic Coverage Criteria

### PLACE OF ADMINISTRATION:

The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

## DRUG INFORMATION

### ROUTE OF ADMINISTRATION:

Oral

### DRUG CLASS:

Selective cGMP Phosphodiesterase Type 5 Inhibitors

**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

## APPENDIX

### APPENDIX:

None

## BACKGROUND AND OTHER CONSIDERATIONS

### 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

### 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

## CODING/BILLING INFORMATION

*Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement*

HCPCS CODE	DESCRIPTION
NA	

### AVAILABLE DOSAGE FORMS:

Cialis TABS 5MG, Tadalafil TABS 5MG, Cialis TABS 2.5MG Tadalafil TABS 2.5MG

## REFERENCES

1. Cialis [package insert]. Indianapolis, IN. Eli Lilly and Co; February 2018.
2. Lerner LB, McVary, KT, Barry MJ et al: Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA Guideline part I, initial work-up and medical management. J Urol 2021; 206: 806.
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. 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.