Clinical Policy: Tadalafil (Cialis)

Reference Number: AZ.CP.PHAR.42
Effective Date: 11.16.16
Last Review Date: 09.12.18
Line of Business: Arizona Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Tadalafil (Cialis®) is a phosphodiesterase-5 inhibitor.

FDA approved indication

Cialis is indicated for:
- Treatment of erectile dysfunction (ED) [not covered, benefit exclusion]
- Treatment of signs and symptoms of benign prostatic hyperplasia (BPH)
- Treatment of ED and the signs and symptoms of BPH

Limitation of use:
- Patients taking nitrates (e.g., Nitrodur®, Nitrobid®, Nitrostat®, Isordil®, Ismo®)
- Patients taking guanylate cyclase stimulators (e.g. Adempas (riociguat))

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® that Cialis is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Benign Prostatic Hyperplasia (must meet all)**:**
1. Diagnosis of symptomatic BPH;
2. Member is male;
3. Patient is NOT on nitrates and guanylate cyclase stimulators (e.g., Adempas (riociguat));
4. Failure or clinically significant adverse effects to ONE alpha blocker (e.g., terazosin, doxazosin, tamsulosin)
5. Failure or clinically significant adverse effects to ONE 5-alpha reductase inhibitor (e.g., finasteride);
6. Dose does not exceed 5 mg/day.

Approval duration: Up to One Year

B. Other diagnoses/indications

1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Benign Prostatic Hyperplasia (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Centene Corporation or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 5 mg/day.

Approval duration: Up to One Year

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – CP.PMN.53 or evidence of coverage documents;
B. Treatment of ED without concomitant BPH is a benefit exclusion per AHCCCS AMPM Policy 310-V;
C. Patients taking nitrates e.g. Nitrodur®, Nitrobid®, Nitrostat®, Isordil®, Ismo®;
D. Patients taking guanylate cyclase stimulators (e.g., Adempas (riociguat)).

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
ED: Erectile Dysfunction
BPH: Benign Prostatic Hyperplasia

Appendix B: General Information

- PDE5 inhibitors should not be used in patients who have conditions that might predispose them to priapism, such as sickle cell anemia, multiple myeloma, or leukemia, or in patients with anatomical deformation of the penis, such as angulation, cavernosal fibrosis, or Peyronie's disease.
- Cialis is not recommended for use 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.
- Cialis is not recommended for use in combination with guanylate cyclase stimulators, such as Adempas (riociguat) as Cialis may potentiate the hypotensive effects of guanylate cyclase stimulators.
- Cialis for once daily use is approved for BPH and should be used up to a maximum dose of 5 mg PO QD.
- Cialis 5mg and 10mg tablets are indicated only for the treatment of ED.

- Cialis is also marketed as Adcirca for the treatment of pulmonary arterial hypertension. Do not take both Cialis and Adcirca.

Appendix C: Therapeutic Alternatives

Drug	Dosing Regimen	Dose Limit/Maximum Dose
doxazosin (Cardura®/ Cardura XL)	BPH Immediate Release: 1 mg PO QD, titrate to 2 mg QD and thereafter to 4 mg QD and 8 mg QD Dosing range: 1 – 8 mg Extended Release: 4 mg PO QD Dosing range: 4 - 8 mg	8 mg/day
terazosin (Hytrin®)	BPH 1 mg PO QD; increase the dose to 2 mg, 5 mg, or 10 mg QD in a stepwise fashion Dosing range: 1 - 20 mg	20 mg/day
tamsulosin (Flomax®)	BPH 0.4 - 0.8 mg PO QD	0.8 mg/day
alfuzosin (Uroxatral®)	BPH 10 mg PO QD	10 mg/day
Rapaflo® (silodosin)	BPH 4 - 8 mg PO QD	8 mg/day
finasteride (Proscar®)*	BPH 5 mg PO QD	5 mg/day
dutasteride (Avodart®)*	BPH 0.5 mg PO QD	0.5 mg/day
dutasteride/ tamsulosin(Jalyn)*	BPH 0.5/0.4 mg PO QD	0.5/0.4 mg/day

**Requires Prior Authorization*
Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
BPH	2.5 - 5 mg PO QD	5 mg/day

VI. Product Availability

Tablet: 2.5 mg, 5 mg, 10 mg, and 20 mg

VII. References

1. Cialis (tadalafil) [package insert]. Indianapolis, IN: Eli Lilly and Company; February 2018.
2. Cialis (tadalafil) [product monograph]. Toronto, Canada: Eli Lilly Canada; March 2016.
3. Viagra [package insert]. New York, NY: Pfizer, Inc.; September 2015.

4. Levitra [package insert]. Wayne, NJ: Bayer Pharmaceuticals Corporation; September 2015.
5. Staxyn [package insert]. Wayne, NJ: Bayer Pharmaceuticals Corporation; September 2015.
6. Stendra [package insert]. Mountain View, CA: Vivus;September 2015.
7. Guay, AT, et al. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for the Evaluation and Treatment of Male Sexual Dysfunction: A Couple's Problem-2003 Update. *Endocrine Practice*, 2003; 9(1): 77-95
8. Lue TF. Drug therapy: Erectile dysfunction. *N Engl J Med* 2000;342:1802.
9. Steele, D. Drugs causing sexual dysfunction and their alternatives: A Reference Tool. *Urol Nurs*. 1989 Oct-Dec;9(6):10-12.
10. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed January 12, 2016.
11. American Hospital Formulary Service Drug Information [Internet database]. Available at: http://www.medicinescomplete.com/mc/ahfs/current/. Accessed January 12, 2016.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template; minor changes to verbiage and grammar. References updated.	10.05.17	11.17
Annual Review – Used CP.HNMC.09 as template. Updated references.	09.12.18	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a

discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.