Clinical Policy: Tadalafil BPH - ED (Cialis)

Reference Number: CP.PMN.132
Effective Date: 06.01.18
Last Review Date: 08.20
Line of Business: Commercial, HIM*, 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 (PDE-5) inhibitor.

**For Health Insurance Marketplace (HIM)*, *tadalafil 2.5 mg, 10 mg, and 20 mg tablets are non-formulary and cannot be approved using these criteria; refer to the formulary exception policy, HIM.PA.103.*

FDA Approved Indication(s)

Cialis is indicated for the treatment of:

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

Limitation(s) of use: If Cialis is used with finasteride to initiate BPH treatment, such use is recommended for up to 26 weeks because the incremental benefit of Cialis decreases from 4 weeks until 26 weeks, and the incremental benefit of Cialis beyond 26 weeks is unknown.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) 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 BPH;
2. Age ≥ 18 years;
3. Failure of one alpha blocker (e.g., alfuzosin, doxazosin, prazosin, tamsulosin or terazosin) and one 5-alpha reductase inhibitor (finasteride or dutasteride), at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Member is not on concomitant nitrates (e.g., Nitrodur, Nitrobid, Nitrostat, Isordil, Ismo);
5. Member is not on concomitant guanylate cyclase stimulator, such as riociguat (Adempas);
6. Dose does not exceed 5 mg (1 tablet) per day.

Approval duration:

Medicaid/HIM – 12 months
Commercial – Length of Benefit

B. Erectile Dysfunction (must meet all)**:**
**Cialis is not covered for this diagnosis for HIM and Medicaid.*
1. Diagnosis of ED;
2. Age ≥ 18 years;
3. Failure of generic Viagra® (sildenafil 25 mg, 50 mg, 100 mg) unless contraindicated or clinically significant adverse effects are experienced;
4. Member is not on concomitant nitrates (e.g., Nitrodur, Nitrobid, Nitrostat, Isordil, Ismo);
5. Member is not on concomitant guanylate cyclase stimulator, such as riociguat (Adempas). Dose does not exceed 20 mg per day and the health plan-approved quantity limit.

Approval duration:
Medicaid – Not covered
HIM – Not covered, use Stendra or generic Viagra *(prior authorization is required for these agents)*
Commercial – Benefit Renewal Date (quantity limits are plan specific)

C. Other diagnoses/indications
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Benign Prostatic Hyperplasia (must meet all)**:**
1. Currently receiving medication via Centene benefit 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 (1 tablet) per day.

Approval duration:
Medicaid/HIM – 12 months
Commercial – Length of Benefit

B. Erectile Dysfunction (must meet all)**:**
**Cialis is not covered for this diagnosis for HIM and Medicaid.*
1. Currently receiving medication via Centene benefit 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 20 mg per day and the health plan-approved quantity limit.

Approval duration:
Medicaid – Not covered
HIM – Not covered, use Stendra or generic Viagra *(prior authorization is required for these agents)*

Commercial – Benefit Renewal Date (quantity limits are plan specific)

C. 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 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BPH: benign prostatic hyperplasia
ED: erectile dysfunction
FDA: Food and Drug Administration
GC: guanylate cyclase
PDE-5: phosphodiesterase-5

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
doxazosin (Cardura®, Cardura XL®)	BPH: 1 to 8 mg PO QD	8 mg/day
dutasteride (Avodart ®)	BPH: 0.5 mg PO QD	0.5 mg/day
finasteride (Proscar®)	BPH: 5 mg PO QD	5 mg/day
prazosin (Minipress®)	BPH: 2 mg PO BID	9 mg/day
tamsulosin (Flomax®)	BPH: 0.4 mg PO QD	0.8 mg/day
terazosin (Hytrin®)	BPH: 5 to 10 mg PO QD	20 mg/day
sildenafil (Viagra®)	ED: 50 mg PO 1 hour (0.5 - 4 hours) before sexual activity	100 mg/day

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.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Cialis is contraindicated in patients using nitric oxide donors, such as organic nitrates or organic nitrites in any form. Cialis was shown to potentiate the hypotensive effect of nitrates (e.g., Nitrodur, Nitrobid, Nitrostat, Isordil, Ismo)

- Cialis is contraindicated with administration of guanylate cyclase (GC) stimulators, such adempas (Riociguat)
- History of known serious hypersensitivity reaction to Cialis or Adcirca®

- Boxed warning(s): none reported

Appendix D: General Information

- Cialis should not be used in conjunction with other PDE-5 inhibitors, such as sildenafil.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
BPH	2.5 - 5 mg PO QD	5 mg/day
ED	10 - 20 mg PO as needed prior to sexual activity or 2.5 mg once daily, without regard to timing of sexual activity	5 mg/day for ED for once daily use; 20 mg/dose for ED for as needed use, not to exceed 1 dose/24 hours

VI. Product Availability

Tablets: 2.5 mg, 5 mg, 10 mg, 20 mg

VII. References

1. Cialis Drug Monograph. Clinical Pharmacology. Accessed January 2018. http://www.clinicalpharmacology-ip.com
2. Cialis Prescribing Information. Indianapolis, IN: Eli Lilly and Company; February 2018. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=bcd8f8ab-81a2-4891-83db-24a0b0e25895. Accessed April 24, 2020.
3. McVary KT, Roehrborn CG, et al. American Urological Association guideline: management of benign prostatic hyperplasia (BPH). Published 2010; Reviewed and Validity Confirmed 2014. Accessed April 24, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy: no significant changes from previously approved corporate policy; split from HIM.PA.39 and CP.CPA.277; policies combined for HIM and commercial lines of business; added Medicaid; added age and removed requirement of male use only as this is implied; modified redirection to formulary phosphodiesterase-5 inhibitor to require that the agent being requested is a formulary agent as most formulary agent require PA; changed approval duration from benefit renewal date to 12 months; references reviewed and updated.	02.25.18	05.18
ED: Added redirection to sildenafil. Modified Commercial ED approval duration to length of benefit.	06.12.18	08.18
3Q 2019 annual review: no significant changes; references reviewed and updated.	05.21.19	08.19
3Q 2020 annual review: for Commercial ED criteria set revise approval duration from length of benefit to "Benefit Renewal Date (quantity	04.24.20	08.20

Reviews, Revisions, and Approvals	Date	P&T Approval Date
limits are plan specific)"; for ED criteria set removed criteria requiring request for formulary product as criteria would also apply for non-formulary requests; references reviewed		

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.

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.