

Clinical Policy: Tadalafil BPH - ED (Cialis)

Reference Number: HNCA.CP.PMN.132

Effective Date: 06.01.18

Last Review Date: 08.18

Line of Business: Commercial, HIM

[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.

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)

If Cialis is used with finasteride to initiate BPH treatment, such use is recommended for up to 26 weeks.

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 \geq 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 contraindication or clinically significant adverse effects are experienced;
4. Member is NOT on nitrates and guanylate cyclase stimulators;
5. Dose does not exceed 5 mg/day (1 tablet/day).

Approval duration: Length of Benefit

B. Erectile Dysfunction (must meet all):

**Cialis is not covered for this diagnosis for HIM.*

1. Diagnosis of ED;
2. Age \geq 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 nitrates and guanylate cyclase stimulators;
5. Dose does not exceed 20 mg/day and plan approved quantity limit.

Approval duration: 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 and HIM.PHAR.21 for health insurance marketplace.

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/day (1 tablet/day).

Approval duration: Length of Benefit

B. Erectile Dysfunction (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 20 mg/day and plan approved quantity limit.

Approval duration: 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 and HIM.PHAR.21 for health insurance marketplace.

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 and HIM.PHAR.21 for health insurance marketplace 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

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 [®])	BPH: 1 to 8 mg once daily	8 mg/day
dutasteride (Avodart [®])	BPH: 0.5 mg once daily	0.5 mg/day
finasteride (Proscar [®])	BPH: 5 mg once daily	5 mg/day
prazosin (Minipress [®])	BPH: 2 mg twice daily	9 mg/day
tamsulosin (Flomax [®])	BPH: 0.4 mg once daily	0.8 mg/day
terazosin (Hytrin [®])	BPH: 5 to 10 mg once daily	20 mg/day
doxazosin (Cardura [®])	BPH: 1 to 8 mg once daily	8 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

- 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 as adempas (Riociguat)

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 once daily	5 mg/day
ED	10 - 20 mg 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; May 2017. Available at: <https://www.cialis.com/>. Accessed January 2018.
3. McVary KT, Roehrborn CG et al. American Urological Association guideline: management of benign prostatic hyperplasia (BPH). Published 2010; Reviewed and Validity Confirmed

2014. [https://www.auanet.org/guidelines/benign-prostatic-hyperplasia-\(2010-reviewed-and-validity-confirmed-2014\)#x2513](https://www.auanet.org/guidelines/benign-prostatic-hyperplasia-(2010-reviewed-and-validity-confirmed-2014)#x2513). Accessed June 2017.

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
Created HNCA policy; removed Medicaid line of business; ED: Modified Commercial and HIM ED approval duration to “Benefit Renewal Date (Quantity Limits are Plan Specific)” to review for benefit changes which may occur each year for ED; BPH: modified HIM approval duration to length of benefit.	09.20.18	10.16.18
Removed “Cialis is a formulary drug” from the Erectile Dysfunction criteria.	11.08.18	

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.

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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.

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Note:

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

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