Clinical Policy Title:	tadalafil BPH - ED
Policy Number:	RxA.68
Drug(s) Applied:	Cialis®
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Cialis® is a phosphodiesterase-5 (PDE-5) inhibitor 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
tadalafil (Cialis®)	BPH	5 mg once daily	5 mg/day
tadalafil (Cialis®)	ED	10 - 20 mg as needed prior to sexual activity or 2.5 mg once daily, without regard to timing of sexual activity. May increase to 5 mg based upon efficacy and tolerability.	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

Dosage Forms

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

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

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

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

Approval Duration
Commercial: 12 months
Medicaid: 12 months

B. Erectile Dysfunction (must meet all):

**Cialis is not covered for this diagnosis for HIM and certain commercial plan(s).*

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 nitrates and guanylate cyclase stimulators;
5. Dose does not exceed 20 mg/day and plan approved quantity limit.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. Benign Prostatic Hyperplasia (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance 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
Commercial: 12 months
Medicaid: 12 months

B. Erectile Dysfunction (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance 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
Commercial: 12 months
Medicaid: 12 months

III. Appendices

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
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

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/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.

References

1. Cialis Drug Monograph. Clinical Pharmacology. Accessed February 6, 2021. http://www.clinicalpharmacology-ip.com
2. Cialis Prescribing Information. Indianapolis, IN: Eli Lilly and Company; February 2018. Available at: https://www.cialis.com/. Accessed February 6, 2021.
3. McVary KT, Roehrborn CG et al. American Urological Association guideline: management of benign prostatic hyperplasia (BPH). Published 2010; Reviewed and Validity Confirmed2014. https://www.auanet.org/guidelines/benign-prostatic-hyperplasia-(2010-reviewed-and- validity-confirmed-2014)#x2513. Accessed June 2017

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy was established.	01/2020	02/07/2020
Policy was reviewed. Approval duration was updated to 12 months. Continued Therapy Approval criteria	05/2020	05/21/2020

II.A.1 and II.B.1 were rephrased to "Currently receiving medication that has been authorized by RxAdvance"		
Policy was reviewed: 1. Clinical Policy Title Table was updated. 2. Drug(s) Applied was updated. 3. Last Review Date was updated. 4. Line of Business Policy Applies to was update to all lines of business. 5. Dosing regimen was updated to 5 mg once daily for BPH. 6. APPENDIX B: Therapeutic Alternatives verbiage was updated to "Below are suggested therapeutic alternatives based on clinical guidance...." 7. Initial Approval criteria: Commercial and Medicaid approval duration were updated to 12 months. 8. Continued Approval criteria: Commercial and Medicaid approval duration were updated to 12 months. 9. APPENDIX B: Therapeutic Alternatives: Hytrin® was removed from therapeutic alternatives table due to off market. 10. References were updated. 11. Updated ED dosing information to: May increase to 5 mg based upon efficacy and tolerability.	02/06/2021	03/09/2021