# Clinical Policy: Tadalafil BPH - ED (Cialis, Chewtadzy)

Reference Number: CP.PMN.132
Effective Date: 06.01.18
Last Review Date: 08.25
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®, Chewtadzy™) is a phosphodiesterase-5 (PDE-5) inhibitor.

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**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)

Tadalafil (Cialis) and Chewtadzy are 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 tadalafil (Cialis) and Chewtadzy are used with finasteride to initiate BPH treatment, such use is recommended for up to 26 weeks because the incremental benefit of tadalafil (Cialis) and Chewtadzy decreases from 4 weeks until 26 weeks, and the incremental benefit of tadalafil (Cialis) and Chewtadzy beyond 26 weeks is unknown.
- Chewtadzy is not indicated for once daily use for ED because dosing is not possible in such patients (the recommended dosage for this indication cannot be achieved with the lowest available strength).

## 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, Chewtadzy, and tadalafil are **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 both of the following (a and b), at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated:*
   **For Illinois HIM requests, the step therapy requirements below do not apply for formulary agents as of 1/1/2026 per IL HB 5395.*
   a. One alpha blocker (e.g., alfuzosin, doxazosin, prazosin, tamsulosin or terazosin);
   b. One 5-alpha reductase inhibitor (finasteride or dutasteride);

4. If request is for brand Cialis or Chewtadzy, member must use generic tadalafil, unless contraindicated or clinically significant adverse effects are experienced;
5. Tadalafil is not prescribed concurrently with nitrates (e.g., Nitrodur®, Nitrobid®, Nitrostat®, Isordil®, Ismo®);
6. Tadalafil is not prescribed concurrently with guanylate cyclase stimulator, such as riociguat (Adempas®);
7. Dose does not exceed both of the following (a and b):
   a. 5 mg per day;
   b. 1 tablet per day.

**Approval duration:**
**Medicaid/HIM –** 12 months
**Commercial –** 12 months or duration of request, whichever is less

**B. Erectile Dysfunction – for COMMERCIAL line of business only** (must meet all)**:***
**Cialis and Chewtadzy are not covered for this diagnosis for HIM and Medicaid.*

1. Diagnosis of ED;
2. Age ≥ 21 years;
3. Failure of generic Viagra® (sildenafil 25 mg, 50 mg, 100 mg), unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for brand Cialis or Chewtadzy, member must use generic tadalafil, unless contraindicated or clinically significant adverse effects are experienced;
5. Tadalafil is not prescribed concurrently with concomitant nitrates (e.g., Nitrodur, Nitrobid, Nitrostat, Isordil, Ismo);
6. Tadalafil is not prescribed concurrently with guanylate cyclase stimulators, such as riociguat (Adempas);
7. Dose does not exceed both of the following (a and b):
   a. 20 mg per day;
   b. Health plan-approved quantity limit.

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

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**II. Continued Therapy**

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. If request is for brand Cialis or Chewtadzy, member must use generic tadalafil, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, new dose does not exceed both of the following (a and b):
   a. 5 mg per day;
   b. 1 tablet per day.

**Approval duration:**
**Medicaid/HIM –** 12 months
**Commercial –** 12 months or duration of request, whichever is less

**B. Erectile Dysfunction – for COMMERCIAL line of business only** (must meet all)**:***
**Cialis is not covered for this diagnosis for HIM and Medicaid.*

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. If request is for brand Cialis or Chewtadzy, member must use generic tadalafil, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, new dose does not exceed both of the following (a and b):
   a. 20 mg per day;
   b. Health plan-approved quantity limit.

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

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 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.154 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):
  - Patients using nitric oxide donors, such as organic nitrates or organic nitrites in any form. Tadalafil was shown to potentiate the hypotensive effect of nitrates (e.g., Nitrodur, Nitrobid, Nitrostat, Isordil, Ismo).
  - Administration of guanylate cyclase (GC) stimulators, such riociguat (Adempas).
  - History of known serious hypersensitivity reaction to tadalafil.
- Boxed warning(s): none reported

*Appendix D: General Information*

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

## V. Dosage and Administration

| Drug Name | Indication | Dosing Regimen | Maximum Dose |
|---|---|---|---|
| Tadalafil (Cialis) | 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 |
| Chewtadzy | BPH | 5 mg PO QD | 5 mg/day |
| | ED | 10 - 20 mg PO as needed prior to sexual activity | 20 mg/dose for ED for as needed use; 5 mg/day if member has both ED and BPH |

## VI. Product Availability

| Drug Name | Availability |
|---|---|
| Tadalafil (Cialis) | Tablets: 2.5 mg, 5 mg, 10 mg, 20 mg |
| Chewtadzy | Chewable tablets: 5 mg, 10 mg, 20 mg |

## VII. References

1. Cialis Prescribing Information. Indianapolis, IN: Eli Lilly and Company; April 2023. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=bcd8f8ab-81a2-4891-83db-24a0b0e25895. Accessed April 18, 2025.
2. Chewtadzy Prescribing Information. Baudette, MN: ANI Pharmaceuticals; June 2024. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/218527s000lbl.pdf. Accessed April 18, 2025.
3. Cialis Drug Monograph. Clinical Pharmacology. Available at: https://www.clinicalkey.com/pharmacology/. Accessed May 5, 2025.

4. McVary KT, Roehrborn CG, et al. American Urological Association guideline: management of benign prostatic hyperplasia (BPH). Published 2010; Reviewed and Validity Confirmed 2014.
5. Burnett AL, Nehra A, Breau RH, et al. Erectile Dysfunction: American Urological Association Guideline 2018. Available at: https://www.auanet.org/guidelines-and-quality/guidelines/erectile-dysfunction-(ed)-guideline. Accessed May 5, 2025.
6. 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.
7. Kloner RA, Burnett AL, Miner M, et al. Princeton IV consensus guidelines: PDE5 inhibitors and cardiac health. The Journal of Sexual Medicine. February 2024; 21(2): 90–116.
8. Sandhu JS, Bixler BR, Dahm P, et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH): AUA Guideline amendment 2023. J Urol. 2023;10.1097/JU.0000000000003698. Available at: https://www.auanet.org/guidelines-and-quality/guidelines/benign-prostatic-hyperplasia-(bph)-guideline. Accessed May 14, 2024.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| 3Q 2021 annual review: no significant changes; modified HIM.PHAR.21 to HIM.PA.154; references reviewed and updated. | 04.05.21 | 08.21 |
| 3Q 2022 annual review: added requirement for generic tadalafil use for both initial and reauthorization requests; revised approval duration for Commercial line of business from length of benefit to 12 months or duration of request, whichever is less; references reviewed and updated. | 04.19.22 | 08.22 |
| Template changes applied to other diagnoses/indications and continued therapy section. | 10.03.22 | |
| 3Q 2023 annual review: revised ED age limit to 21 years or older to align with Commercial age edit; clarified for HIM PA is required for generic Viagra; references reviewed and updated. | 04.18.23 | 08.23 |
| 3Q 2024 annual review: no significant changes; for BPH split redirection and dosing limits requirement into separate requirements for added clarity; references reviewed and updated.<br>RT4: added Chewtadzy to policy. | 07.08.24 | 08.24 |
| 3Q 2025 annual review: added step therapy bypass for IL HIM per IL HB 5395; added reference to tadalafil as criteria would apply for generic requests; references reviewed and updated. | 04.18.25 | 08.25 |

**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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**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.