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| Reference number(s) |
| 865-C |

Initial Prior Authorization with Quantity Limit Benign Prostatic Hyperplasia (BPH) Chewtadzy 5 mg, Cialis 2.5 mg, 5 mg

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name | Dosage Form | Strength |
|------------|--------------|------------------|--------------|
| Chewtadzy | tadalafil | chewable tablets | 5 mg |
| Cialis | tadalafil | all | 2.5 mg, 5 mg |

Indications

FDA-approved Indications

Chewtadzy

Erectile Dysfunction

Chewtadzy is indicated for the treatment of erectile dysfunction (ED) in adult males.

Benign Prostatic Hyperplasia

Chewtadzy is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in adult males.

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Erectile Dysfunction and Benign Prostatic Hyperplasia

Chewtadzy is indicated for the treatment of ED and the signs and symptoms of BPH (ED/BPH) in adult males.

Limitations of Use

If Chewtadzy is used with finasteride to initiate BPH treatment, such use is recommended for up to 26 weeks because the incremental benefit of tadalafil decreases from 4 weeks until 26 weeks, and the incremental benefit of tadalafil 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).

Cialis

Erectile Dysfunction

Cialis is indicated for the treatment of erectile dysfunction (ED).

Benign Prostatic Hyperplasia

Cialis is indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH).

Erectile Dysfunction and Benign Prostatic Hyperplasia

Cialis is indicated for the treatment of ED and the signs and symptoms of BPH (ED/BPH).

Limitation 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.

Coverage Criteria

Benign Prostatic Hyperplasia (BPH)

Authorization may be granted when the requested drug is being prescribed for daily use for symptomatic benign prostatic hyperplasia (BPH).

[NOTE: Examples of signs and symptoms of BPH are incomplete emptying, weak stream, straining, urinary frequency, intermittency, or urgency.]

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Continuation of Therapy

Benign Prostatic Hyperplasia (BPH)

Authorization may be granted when the requested drug is being prescribed for daily use for symptomatic benign prostatic hyperplasia (BPH) when the following criteria is met:

[NOTE: Examples of signs and symptoms of BPH are incomplete emptying, weak stream, straining, urinary frequency, intermittency, or urgency.]

- The patient has achieved or maintained a positive clinical response to the requested drug.

Quantity Limits Apply

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

| Drug | 1 Month Limit | 3 Month Limit |
|---|----------------------|----------------------|
| Chewtadzy (tadalafil chewable tablets) 5 mg | 30 tablets / 25 days | 90 tablets / 75 days |
| Cialis (tadalafil) 2.5 mg, 5 mg | 30 tablets / 25 days | 90 tablets / 75 days |

Duration of Approval (DOA)

- 865-C: DOA: 36 months

References

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3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed February 25, 2025.
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5. 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(4):806-817.
6. 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;211(1):11-19.
7. Burnett AL, Nehra A, Breau RH, et al. Erectile Dysfunction: AUA Guideline. J Urol. 2018;200:633-641.

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8. Ueda P, Mercer CH, Ghaznavi C, et al. Trends in Frequency of Sexual Activity and Number of Sexual Partners Among Adults Aged 18-44 Years in the US, 2000-2018. JAMA Network Open. 2020;3(6): e203833.
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10. Mark KP, Arenella K, Girard A, et al. Erectile dysfunction in the United States: report from the 2021 National Survey of Sexual Wellbeing. J Sex Med. 2024;21(4):296-303.