

PRIOR AUTHORIZATION CRITERIA

BRAND NAME (generic)

**CHEWTADZY 5 mg
(tadalafil chewable tablets)**

**CIALIS 2.5 mg, 5 mg
(tadalafil)**

Status: CVS Caremark® Criteria

Type: Initial Prior Authorization with Quantity Limit

POLICY

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.

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

BPH Chewtadzy 5mg, Cialis 2.5mg, 5mg PA with Limit Policy UDR 05-2024 v2.docx

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

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

30 tablets per 25 days* or 90 tablets per 75 days*

**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*

DURATION OF APPROVAL (DOA)

- 865-C: DOA: 36 months

REFERENCES

1. Chewtadzy [package insert]. Baudette, MN: ANI Pharmaceuticals, Inc. June 2024.
2. Cialis [package insert]. Indianapolis, IN: Eli Lilly and Company; April 2023.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed March 27, 2024.
4. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 03/27/2024).
5. 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.