Reference number(s)
83-C

Initial Prior Authorization with Quantity Limit Erectile Dysfunction (ED) – Benign Prostatic Hyperplasia (BPH) Phosphodiesterase Type 5 (PDE-5) Inhibitors

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
Chewtadzy	tadalafil	chewable tablets
Cialis	tadalafil	all
Stendra	avanafil	all
vardenafil (brand unavailable)	vardenafil	tablets
vardenafil ODT (brand unavailable)	vardenafil	orally disintegrating tablets (ODT)
Viagra	sildenafil	all

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.

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).

Limitations 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.

Stendra

Stendra is a phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of erectile dysfunction in adult males.

Vardenafil tablet

Vardenafil hydrochloride tablets are indicated for the treatment of erectile dysfunction.

Vardenafil orally disintegrating tablet

Vardenafil hydrochloride orally disintegrating tablets are indicated for the treatment of erectile dysfunction.

Viagra

Viagra is indicated for the treatment of erectile dysfunction.

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) with or without erectile dysfunction (ED) when ALL of the following criteria are met:

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

- The patient is 18 years of age or older.
- The request is for ANY of the following: Cialis (tadalafil) 2.5 mg, Cialis (tadalafil) 5 mg, Chewtadzy (tadalafil chewable tablet) 5 mg.

Erectile Dysfunction

Authorization may be granted when the requested drug is being prescribed for erectile dysfunction when the following criteria is met:

- The patient is 18 years of age or older.

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) with or without erectile dysfunction (ED) when ALL of the following criteria are met:

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

- The patient is 18 years of age or older.

- The request is for ANY of the following: Cialis (tadalafil) 2.5 mg, Cialis (tadalafil) 5 mg, Chewtadzy (tadalafil chewable tablet) 5 mg.
- The patient has achieved or maintained a positive clinical response to the requested drug.

Erectile Dysfunction

All patients (including new patients) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

Quantity Limits Apply

Quantity Limit

PLEASE NOTE: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.

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
Chewtadzy (tadalafil chewable tablets) 10 mg, 20 mg	6 tablets / 25 days	18 tablets / 75 days
Cialis (tadalafil) 2.5 mg, 5 mg	30 tablets / 25 days	90 tablets / 75 days
Cialis (tadalafil) 10 mg, 20 mg	6 tablets / 25 days	18 tablets / 75 days
Stendra (avanafil)	6 tablets / 25 days	18 tablets / 75 days
vardenafil tablets	6 tablets / 25 days	18 tablets / 75 days
vardenafil orally disintegrating tablets	6 tablets / 25 days	18 tablets / 75 days
Viagra (sildenafil)	6 tablets / 25 days	18 tablets / 75 days

Duration of Approval (DOA)

- 83-C: DOA: 36 months

References

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3. Stendra [package insert]. Freehold, NJ: Metuchen Pharmaceuticals, LLC; October 2022.
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5. Vardenafil Hydrochloride Tablet [package insert]. Congers, NY: Chartwell RX, LLC.; February 2024.
6. Vardenafil Hydrochloride Orally Disintegrating Tablet [package insert]. Bedminster, NJ: Alembic Pharmaceuticals, Inc.; September 2023.
7. Viagra [package insert]. New York, NY: Pfizer Labs; December 2017.
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16. 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.
17. 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.