PRIOR AUTHORIZATION POLICY

POLICY: Benign Prostatic Hyperplasia – Entadfi Prior Authorization Policy
- Entadfi™ (finasteride and tadalafil capsules – Veru)

REVIEW DATE: 12/11/2024

OVERVIEW

Entadfi, a combination of finasteride 5 mg (a 5-alpha-reductase inhibitor) and tadalafil 5 mg (a phosphodiesterase 5 inhibitor), is indicated to initiate treatment of the signs and symptoms of **benign prostatic hyperplasia** in men with an enlarged prostate for up to 26 weeks.[1]

Entadfi has a limitation of use which states the medication is not recommended for more than 26 weeks because the incremental benefit of tadalafil decreases from 4 weeks until 26 weeks, and then the incremental benefit beyond 26 weeks is unknown.[1] This is the same limitation of use included in tadalafil labeling and it applies to situations in which tadalafil is used with finasteride to initiate benign prostatic hyperplasia treatment.[2]

Guidelines

The American Urological Association guidelines on the management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (2023) note that 5-alpha reductase inhibitors (alone or in combination with an alpha blocker) are recommended as a treatment option to prevent progression of lower urinary tract symptoms/benign prostatic hyperplasia.[3] Guidelines note that clinicians may offer the combination of low-dose 5 mg tadalafil with an alpha blocker; however, there is little benefit with the combination. Regarding tadalafil, it is noted that in patients with benign prostatic hyperplasia, irrespective of a comorbid erectile dysfunction, daily 5 mg tadalafil should be discussed as a treatment option.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Entadfi. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Entadfi is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Benign Prostatic Hyperplasia.** Approve for 6 months.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Entadfi is not recommended in the following situations:

1. **Erectile Dysfunction without Benign Prostatic Hyperplasia.** Entadfi is not indicated for erectile dysfunction in patient without benign prostatic hyperplasia.[1]

2. **Alopecia.** Entadfi is not indicated for alopecia.[1] Finasteride 1 mg tablets are indicated for the treatment of male pattern hair loss (androgenetic alopecia).[4]

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Entadfi™ capsules [prescribing information]. Miami, FL: Veru; December 2021.
2. Tadalafil tablets [prescribing information]. Bedminster, NJ: Alembic; September 2024.
3. 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;211:1-8.
4. Finasteride 1 mg tablets [prescribing information]. Parsippany, NJ: Ascend Laboratories; February 2024.