PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 11/16/2022

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 (2021) 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 should not offer the combination of low-dose 5 mg tadalafil with an alpha blocker because it offers no advantage in symptom improvement over either agent alone. 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 <u>without</u> 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; January 2022.
3. Management of benign prostatic hyperplasia/lower urinary tract symptoms: American Urological Association guideline 2021. Available at: Benign Prostatic Hyperplasia (BPH) Guideline - American Urological Association (auanet.org). Accessed on November 9, 2022.
4. Finasteride 1 mg tablets [prescribing information]. Parsippany, NJ: Ascend Laboratories; November 2021.