Drug Coverage Policy

Effective Date.....3/1/2026
Coverage Policy Number.....IP0519
Policy Title.....Entadfi

Benign Prostatic Hyperplasia – Entadfi

- Entadfi™ (finasteride and tadalafil capsules – Veru)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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]

Limitation of Use: Entadfi 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.

Coverage Policy

POLICY STATEMENT
Prior Authorization is required for benefit coverage of Entadfi. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

Entadfi is considered medically necessary when the following are met:

FDA-Approved Indication

Benign Prostatic Hyperplasia. Approve for 6 months if the patient meets the following criteria:
A. Preferred product criteria are met for the product(s) as listed in the below table(s)

Employer Plans:

Product	Criteria
Entadfi (finasteride and tadalafil capsules – Veru)	According to the prescriber, the patient has a clinical reason they cannot take finasteride 5 mg and tadalafil 5 mg as separate agents **[may require prior authorization]**.

Individual and Family Plans:

Product	Criteria
Entadfi (finasteride and tadalafil capsules – Veru)	According to the prescriber, the patient has a clinical reason they cannot take finasteride 5 mg and tadalafil 5 mg as separate agents **[may require prior authorization]**.

Conditions Not Covered

Entadfi for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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]

References

1. Entadfi™ capsules [prescribing information]. Miami, FL: Veru; December 2021.
2. Tadalafil tablets [prescribing information]. Bedminster, NJ: Alembic; February 2025.
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; January 2025.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	No criteria changes.	3/15/2025
Annual Revision	**Updated** policy title **from** "Entadfi (finasteride and tadalafil)" **to** "Benign Prostatic Hyperplasia – Entadfi" **Updated** approval duration from 12 months to 6 months. **Updated** preferred product table language from "Documented inability to take single agent finasteride 5 mg and tadalafil 5 mg concurrently [may require prior authorization]" **to** "According to the prescriber, the patient has a clinical reason they cannot take finasteride 5 mg and tadalafil 5 mg as separate agents **[may require prior authorization]**."	3/1/2026

The policy effective date is in force until updated or retired.