Effective Date **3/15/2025**
Coverage Policy Number **IP0519**

Entadfi (finasteride and tadalafil)

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Related Coverage Resources

Quantity Limitations

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. 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

This policy supports medical necessity review for finasteride and tadalafil (**Entadfi**™).

Medical Necessity Criteria

Finasteride and tadalafil capsule (Entadfi) is considered medically necessary when the following are met:

Benign Prostatic Hyperplasia. Individual meets the following criteria:
A. Documented inability to take single agent finasteride 5 mg and tadalafil 5 mg concurrently [may require prior authorization]

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.
Receipt of sample product does not satisfy any criteria requirements for coverage.

Reauthorization Criteria

Continuation of finasteride and tadalafil capsule (Entadfi) is considered medically necessary for Benign Prostatic Hyperplasia when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

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]

Background

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.

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.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	No criteria changes.	3/15/2025

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