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5.40.031

Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Cardiovascular Agents	**Original Policy Date:**	January 21, 2022
Subject:	Entadfi	**Page:**	1 of 4

Last Review Date: March 7, 2025

Entadfi

Description

Entadfi (finasteride and tadalafil)

Background
Entadfi is a combination of finasteride, a 5α-reductase inhibitor, and tadalafil, a phosphodiesterase 5 (PDE5) inhibitor. It is used to treat the signs and symptoms of benign prostatic hyperplasia (BPH), a condition in which the prostate gland becomes enlarged. Common symptoms of BPH include difficulty in starting urination, weak urine stream; sudden urge to urinate; and more frequent urination at night (1).

Regulatory Status
FDA-approved indication: Entadfi is a combination of finasteride, a 5-alpha reductase inhibitor, and tadalafil, a phosphodiesterase 5 (PDE5) inhibitor, and, indicated to initiate treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in men with an enlarged prostate for up to 26 weeks (1).

The recommended dose of Entadfi is one capsule (containing finasteride 5 mg and tadalafil 5 mg) orally once daily at approximately the same time every day for up to 26 weeks (1).

Administration of Entadfi to patients who are using any form of organic nitrate, either regularly and/or intermittently, is contraindicated. Entadfi can potentiate the hypotensive effect of nitrates. Entadfi is also contraindicated with guanylate cyclase (GC) stimulators, such as riociguat (1).

Patients should stop Entadfi and seek medical care if a sudden loss of vision occurs in one or both eyes, which could be a sign of non-arteritic anterior ischemic optic neuropathy (NAION). Patients should also stop Entadfi and seek prompt medical attention in the event of sudden decrease or loss of hearing (1).

The safety and effectiveness in pediatric patients less than 18 years of age have not been established (1).

Related policies
Cialis

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Entadfi may be considered **medically necessary** if the conditions indicated below are met.

Entadfi may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

1. Benign Prostatic Hyperplasia / Hypertrophy (BPH)

AND ALL of the following:

1. Actively symptomatic
    a. Including **one or more** of the following:
        i. Dribbling at the end of urinating
        ii. Inability to urinate (urinary retention)
        iii. Incomplete emptying of bladder
        iv. Incontinence
        v. Nocturia - needing to urinate two or more times per night
        vi. Pain with urination or bloody urine
        vii. Slowed or delayed start of the urinary stream

viii. Straining to urine
ix. Strong and sudden urge to urinate
x. Weak urine stream

2. Inadequate treatment response, intolerance, or contraindication to **BOTH** of the following:
    a. Alpha blocker
    b. 5-alpha reductase inhibitor

AND NONE of the following:

1. Concurrent therapy with any nitrates (in any form)
2. Concurrent therapy with a guanylate cyclase (GC) stimulator

Prior – Approval *Renewal* Requirements

None

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 182 capsules (1 capsule per day for up to 26 weeks)

Duration 12 months

Prior – Approval *Renewal* Limits

None

Rationale

Summary

Entadfi (finasteride and tadalafil) is used to treat the signs and symptoms of benign prostatic hyperplasia (BPH) in patients 18 years of age or older that are actively symptomatic. Therapy is limited to up to 26 weeks. Entadfi is contraindicated in patients who are using any form of organic nitrate or a guanylate cyclase (GC) stimulator (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Entadfi while maintaining optimal therapeutic outcomes.

References

1. Entadfi [package Insert]. Miami, FL: Very Inc.; December 2021.

Policy History

Date	Action
January 2022	Addition to PA
March 2022	Annual review
December 2022	Annual review. Changed policy number to 5.40.031
March 2023	Annual review
June 2023	Annual review
March 2024	Annual review
June 2024	Annual review
March 2025	Annual review. Per SME, changed the t/f requirement to both Alpha blocker and 5-alpha reductase inhibitor

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.