BlueCross BlueShield
Federal Employee Program

ENTADFI
(finasteride and tadalafil)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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.