Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	May 5, 2023

Entadfi™ (finasteride/tadalafil)

LENGTH OF AUTHORIZATION: Up to 26 weeks

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age.
- Patient must have a documented diagnosis of benign prostatic hyperplasia (BPH) in men with an enlarged prostate or prostate volume > 30 ml.
- Medication was prescribed to initiate treatment of the signs and symptoms of BPH. Signs/symptoms include, but are not limited to:
  - Nocturia;
  - Weak urine stream;
  - Frequent or urgent need to urinate;
  - Leaking or dribbling of urine.
- This medication will not be taken concurrently with any of the following:
  - Organic nitrates (e.g., nitroglycerin, isosorbide mononitrate, isosorbide dinitrate); **OR**
  - Guanylate cyclase stimulators (e.g., Adempas® or Verquvo™)
- The patient has tried and failed two preferred medications indicated for BPH including finasteride alone.
- Must be prescribed by or in consultation with a urologist or related specialist.

Note: Entadfi is not recommended for more than 26 weeks because the incremental benefit of tadalafil decreases from 4 weeks until 26 weeks, and the incremental benefit beyond 26 weeks is unknown.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as capsules containing finasteride (5 mg) and tadalafil (5 mg).