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| **Clinical Policy Title:** | finasteride and tadalafil |
| **Policy Number:** | RxA.759 |
| **Drug(s) Applied:** | Entadfi™ |
| **Original Policy Date:** | 04/18/2022 |
| **Last Review Date:** | 04/18/2022 |
| **Line of Business Policy Applies to:** | All lines of business |

## Background

Entadfi™ is a combination of finasteride, a 5α-reductase inhibitor, and tadalafil, a phosphodiesterase 5 (PDE5) inhibitor, 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.

## Dosing Information

| Drug Name | Indication | Dosing Regimen | Maximum Dose |
|---|---|---|---|
| finasteride and tadalafil (Entadfi™) | Benign prostatic hyperplasia (BPH) | 1 capsule (finasteride 5 mg with tadalafil 5 mg) orally once daily without food, at the same time each day. May be taken for up to 26 weeks | 1 capsule (finasteride 5 mg with tadalafil 5 mg) orally once daily |

## Dosage Forms

- Capsules: fixed dose combination containing finasteride 5 mg and tadalafil 5 mg

## Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

**I. Initial Approval Criteria**

**A. Benign prostatic hyperplasia (BPH)** (must meet all):

1. Diagnosis of benign prostatic hyperplasia;
2. Age ≥ 18 years;
3. Trial and failure of one of the following, unless contraindicated or clinically significant adverse effects are experienced (a or b):
   a. PDE5 inhibitor (tadalafil) or;
   b. 5α-reductase inhibitor (e.g., finasteride, dutasteride);
4. Dose does not exceed 1 capsule (finasteride 5 mg with tadalafil 5 mg) orally once daily.

**Approval Duration**

**Commercial:** 6 months
**Medicaid:** 6 months

## II. Continued Therapy Approval

**A. Benign Prostatic hyperplasia (BPH)** (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not 1 capsule (finasteride 5 mg with tadalafil 5 mg) orally once daily.

**Approval Duration**
**Commercial:** 6 months
**Medicaid:** 6 months

## III. Appendices

**APPENDIX A: Abbreviation/Acronym Key**
BPH: Benign Prostatic Hyperplasia
GC: Guanylate Cyclase

**APPENDIX B: Therapeutic Alternatives**
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

| Drug Name | Dosing Regimen | Dose Limit/Maximum Dose |
|---|---|---|
| finasteride (Proscar) | 5 mg orally once daily | 5 mg/daily |
| tadalafil (Cialis) | 5 mg orally once daily | 5 mg/daily |

Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic name when the drug is available by generic only.

**APPENDIX C: Contraindications/Boxed Warnings**

- Contraindication(s):
  - Concomitant use with any form of organic nitrate, either regularly and/or intermittently. Entadfi™ can potentiate the hypotensive effect of nitrates.
  - Known hypersensitivity to Entadfi™ or any of its component.
  - Pregnancy.
  - Concomitant use with guanylate cyclase (GC) stimulators. Entadfi™ may potentiate the hypotensive effects of GC stimulators.

*Contraindications listed reflect direct statements made in the manufacturer's package insert; for additional uses, warnings, and precautions, please refer to clinical guidelines.

- Boxed Warning(s):
  - None reported.

**APPENDIX D: General Information**

- Renal Impairment: Creatinine clearance less than 50 mL/min or hemodialysis: Use is not recommended.
- CYP3A4 inducers: Concomitant use may increase tadalafil exposure. Use is not recommended.

**References**


1. Entadfi™ Prescribing Information. Veru Inc., Miami, FL; December 2021. Available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=112bf653-8322-4444-8d4d-03234b11c38c&type=display#section-11.1 . Accessed April 18, 2022.
2. Clinical Pharmacology. Tampa, FL: Gold Standard, Inc.; 2022. Available at: http://www.clinicalpharmacology-ip.com/. Accessed April 18, 2022.
3. Finasteride and tadalafil, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Accessed April 18, 2022.
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5. Yunuo Wu PDCPRCUSof Pand HPMHD. Guidelines for the treatment of benign prostatic hyperplasia. U.S. Pharmacist – The Leading Journal in Pharmacy. https://www.uspharmacist.com/article/guidelines-for-the-treatment-of-benign-prostatic-hyperplasia. Published August 18, 2016. Accessed April 19, 2022.
6. Management of Benign Prostatic Hyperplasia/ Lower Urinary Tract Symptoms: AUA Guideline 2021. Benign prostatic hyperplasia (BPH) guideline - american urological association. Available at: https://www.auanet.org/guidelines/guidelines/benign-prostatic-hyperplasia-(bph)-guideline. Accessed April 19, 2022.


| Review/Revision History | Review/Revision Date | P&T Approval Date |
|---|---|---|
| Policy was established. | 04/18/2022 | 04/18/2022 |