

Clinical Policy Title:	finasteride and tadalafil
Policy Number:	RxA.759
Drug(s) Applied:	Entadfi™
Original Policy Date:	04/18/2022
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

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. alpha-blocker (e.g., alfuzosin, doxazosin, tamsulosin, terazosin, silodosin)
 - c. 5α-reductase inhibitor (e.g., finasteride, dutasteride);
4. Medical justification as to why individual agents cannot be given.
5. 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

References

1. 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](https://www.auanet.org/guidelines/guidelines/benign-prostatic-hyperplasia-(bph)-guideline). Accessed March 31, 2023.

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy was established.	04/18/2022	04/18/2022
Policy was reviewed: 1. Initial Approval Criteria I.A.3: Updated to add alpha-blockers as one of trial and failure options. 2. Initial Approval Criteria I.A.4: Updated to add Medical justification as to why individual agents cannot be given. 3. References were reviewed and updated.	03/31/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023