PRIOR AUTHORIZATION POLICY

POLICY: Benign Prostatic Hyperplasia – Entadfi Prior Authorization Policy
- Entadfi™ (finasteride and tadalafil capsules – Veru)

REVIEW DATE: 12/11/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Entadfi, a combination of finasteride 5 mg (a 5-alpha-reductase inhibitor) and tadalafil 5 mg (a phosphodiesterase 5 inhibitor), is indicated to initiate treatment of the signs and symptoms of **benign prostatic hyperplasia** in men with an enlarged prostate for up to 26 weeks.[1]

Entadfi has a limitation of use which states the medication is not recommended for more than 26 weeks because the incremental benefit of tadalafil decreases from 4 weeks until 26 weeks, and then the incremental benefit beyond 26 weeks is unknown.[1] This is the same limitation of use included in tadalafil labeling and it applies to situations in which tadalafil is used with finasteride to initiate benign prostatic hyperplasia treatment.[2]

Guidelines

The American Urological Association guidelines on the management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (2023) note that 5-alpha reductase inhibitors (alone or in combination with an alpha blocker) are recommended as a treatment option to prevent progression of lower urinary tract symptoms/benign prostatic hyperplasia.[3] Guidelines note that clinicians may offer the combination of low-dose 5 mg tadalafil with an alpha blocker; however, there is

little benefit with the combination. Regarding tadalafil, it is noted that in patients with benign prostatic hyperplasia, irrespective of a comorbid erectile dysfunction, daily 5 mg tadalafil should be discussed as a treatment option.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Entadfi. All approvals are provided for the duration noted below.

- **Entadfi™ (finasteride and tadalafil capsules - Veru)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Benign Prostatic Hyperplasia.** Approve for 6 months.

CONDITIONS NOT COVERED

- **Entadfi™ (finasteride and tadalafil capsules - Veru)**

is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Erectile Dysfunction <u>without</u> Benign Prostatic Hyperplasia.** Entadfi is not indicated for erectile dysfunction in patient without benign prostatic hyperplasia.[1]

2. **Alopecia.** Entadfi is not indicated for alopecia.[1] Finasteride 1 mg tablets are indicated for the treatment of male pattern hair loss (androgenetic alopecia).[4]

REFERENCES

1. Entadfi™ capsules [prescribing information]. Miami, FL: Veru; December 2021.
2. Tadalafil tablets [prescribing information]. Bedminster, NJ: Alembic; September 2024.
3. Sandhu JS, Bixler BR, Dahm P, et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH): AUA Guideline amendment 2023. *J Urol*. 2023;211:1-8.
4. Finasteride 1 mg tablets [prescribing information]. Parsippany, NJ: Ascend Laboratories; February 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	11/29/2023
Annual Revision	No criteria changes.	12/11/2024