

Entadfi™ (finasteride and tadalafil)

Policy # 00815

Original Effective Date: 12/12/2022

Current Effective Date: 12/01/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider Entadfi™‡ (finasteride and tadalafil) to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Entadfi (finasteride and tadalafil) will be considered when the following patient selection criteria are met:

- Patient has a diagnosis of benign prostatic hyperplasia with an enlarged prostate; AND
- Patient is experiencing one or more symptoms of benign prostatic hyperplasia (for example, urinary frequency, urinary urgency, nocturia, incontinence, slow urinary stream, straining to void, urinary hesitancy, or terminal dribbling); AND
- Patient is 18 years of age or older; AND
- Patient has tried and failed (e.g., intolerance or inadequate response) generic finasteride 5 mg in combination with generic tadalafil 5 mg for at least 6 months of therapy unless there is clinical evidence or patient history that suggests the use of these agents will be ineffective or cause an adverse reaction to the patient; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient has tried and failed (e.g., intolerance or inadequate response) at least one generic alpha-1 adrenergic receptor antagonist (for example, alfuzosin, silodosin, tamsulosin, terazosin, or doxazosin) for at least 4 weeks of therapy unless there is clinical evidence or patient history that suggests the use of an alpha-1 adrenergic receptor antagonist will be ineffective or cause an adverse reaction to the patient; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Entadfi will not be used in combination with an alpha-1 adrenergic receptor antagonist (for example, alfuzosin, silodosin, tamsulosin, terazosin, or doxazosin); AND
- Treatment with Entadfi will not exceed 26 weeks of therapy.

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Entadfi (finasteride and tadalafil) when the patient has not tried and failed generic finasteride 5 mg in combination with generic tadalafil 5 mg for at least 6 months of therapy to be **not medically necessary**.**

Based on review of available data, the Company considers the use of Entadfi (finasteride and tadalafil) when the patient has not tried and failed at least one generic alpha-1 adrenergic receptor antagonist for at least 4 weeks of therapy to be **not medically necessary**.**

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Entadfi (finasteride and tadalafil) for any indication other than benign prostatic hyperplasia to be **investigational**.*

Based on review of available data, the Company considers the use of Entadfi (finasteride and tadalafil) when the patient selection criteria are not met (EXCEPT those denoted as **not medically necessary*****) to be **investigational**.*

Background/Overview

Entadfi is a combination of finasteride, a 5 alpha-reductase inhibitor, and tadalafil, a phosphodiesterase 5 (PDE 5) inhibitor, indicated to initiate treatment of the signs and symptoms of benign prostatic hyperplasia in men with an enlarged prostate for up to 26 weeks. It is available as a fixed dose combination of 5 mg of finasteride and 5 mg of tadalafil and should be taken once daily at approximately the same time. Finasteride and tadalafil are both available as generic agents, and because Entadfi's study criteria was based on the co-administration of these two generic agents, it cannot be said that Entadfi provides any additional benefit over the generics. The generically available agents offer a more cost-effective treatment option, while also providing equally efficacious treatment.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Entadfi 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.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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The purpose of this policy is to ensure that the requested drug is used per the FDA approved indication and that the most efficacious and cost-effective regimens are used for the requested condition.

References

1. Entadfi [package insert]. Veru, Inc. Miami, Florida. Updated December 2021.

Policy History

Original Effective Date: 12/12/2022

Current Effective Date: 12/01/2025

11/03/2022 Medical Policy Committee review

11/09/2022 Medical Policy Implementation Committee approval. New policy.

11/02/2023 Medical Policy Committee review

11/08/2023 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

11/07/2024 Medical Policy Committee review

11/13/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

11/06/2025 Medical Policy Committee review

11/12/2025 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 11/2026

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

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****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.