Original Effective Date: 09/01/2014
Current Effective Date: 04/11/2025
Last P&T Approval/Version: 01/29/2025
Next Review Due By: 01/2026
Policy Number: C6121-C

Tadalafil and Combinations

PRODUCTS AFFECTED

Cialis (tadalafil) 2.5mg and 5mg, Entadfi (finasteride/tadalafil), tadalafil 2.5mg and 5mg

FOR TADALAFIL FOR PULMONARY HYPERTENSION PLEASE REFER TO PULMONARY ARTERIAL HYPERTENSION (PAH) CRITERIA C9837-A

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Benign prostatic hyperplasia (BPH)

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. BENIGN PROSTATIC HYPERPLASIA (BPH):
1. Documentation of a diagnosis of benign prostatic hyperplasia (BPH)
   AND
2. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to tadalafil include: use with any form of organic nitrate, either regularly and/or intermittently, known hypersensitivity to tadalafil, concomitant use with guanylate cyclase (GC) stimulators such as riociguat. Additional contraindications to Entadfi (tadalafil/finasteride) include: pregnancy.]
   AND
3. Prescriber attests that tadalafil or Entadfi (finasteride/tadalafil) is being prescribed for daily use for symptomatic benign prostatic hyperplasia (BPH) in a male that is 18 years of age or older. *[NOTE: Examples of signs and symptoms are incomplete emptying, weak stream, straining, urinary frequency, intermittency, urgency, or acute urinary retention.] [Cialis (tadalafil) is NOT covered when prescribed for sexual or erectile dysfunction]*
   AND
4. FOR TADALAFIL REQUESTS: Documentation the member had a trial (at least 4 weeks) and failure or FDA labeled contraindication to BOTH a formulary alpha-1 blocker AND a formulary 5-alpha reductase inhibitor
   AND
5. FOR ENTADFI REQUESTS: Documentation of ALL of the following:
   (a) Member has had a trial (at least 4 weeks) and failure or FDA labeled contraindication to ALL of the following: a formulary alpha-1 blocker AND a formulary 5-alpha reductase inhibitor AND a phosphodiesterase 5 inhibitor
   AND
   (b) Member has had a trial (at least 7 days) and failure of any of the therapies above used in combination concurrently.

CONTINUATION OF THERAPY:

A. BENIGN PROSTATIC HYPERPLASIA (BPH) [TADALAFIL ONLY]:
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
   AND
2. Documented improvement in baseline symptoms
   AND
3. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:

Tadalafil Initial authorization: 12 months, Continuation of therapy: 12 months
Entadfi (finasteride and tadalafil) Initial authorization: 26 weeks, Continuation of therapy: N/A

PRESCRIBER REQUIREMENTS:

No requirements

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:

1 tablet per day

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Selective cGMP Phosphodiesterase Type 5 Inhibitors, Prostatic Hypertrophy Agent Combinations

FDA-APPROVED USES:
Tadalafil (Cialis): indicated for the treatment of erectile dysfunction (ED) and for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) and indicated for the treatment of ED and the signs and symptoms of BPH (ED/BPH).

Entadfi (finasteride and tadalafil): 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.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Cialis is a phosphodiesterase 5 (PDE-5) inhibitor, indicated for the treatment of erectile dysfunction, the signs and symptoms of BPH, and the combination of erectile dysfunction and the signs and symptoms of BPH. This prior authorization is for plans who do not cover Cialis for erectile dysfunction.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Cialis (tadalafil) are considered experimental/investigational or are not a covered benefit and therefore, will follow Molina's Off-Label policy. Contraindications to tadalafil include: use with any form of organic nitrate, either regularly and/or intermittently, known hypersensitivity to tadalafil, concomitant use with guanylate cyclase (GC) stimulators such as riociguat. Additional contraindications to Entadfi (tadalafil/finasteride) include: pregnancy.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover*

claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Cialis TABS 2.5MG
Cialis TABS 5MG
Entadfi CAPS 5-5MG
Tadalafil TABS 2.5MG
Tadalafil TABS 5MG

REFERENCES

1. Cialis (tadalafil) [prescribing information]. Indianapolis, IN: Lilly USA LLC; April 2023
2. Entadfi (finasteride and tadalafil) [prescribing information]. Miami, FL: Veru Inc; December 2021.
3. Lerner LB, McVary, KT, Barry MJ et al: Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA Guideline part I, initial work-up and medical management. J Urol 2021; 206: 806.
4. Broderick GA, Brock GB, Roehrorn CG, et al. Effects of Tadalafil on Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia in Men with or without Erectile Dysfunction. Urology. 2010; 75: 1452-1459.
5. Roehrorn CG, Kaminetsky JC, Auerbach SM, et al. Changes in peak urinary flow and voiding efficiency in men with signs and symptoms of benign prostatic hyperplasia during once daily tadalfil treatment. BJUI. 2009;105: 502-507.
6. Porst H, McVary KT, Montorsi F, et al. Effects of Once daily Tadalfil on Erectile Function in Menwith Erectile Dysfunction and Signs and Symptoms of Benign Prostatic Hyperplasia. European Urology. 2009; 56: 727-736.
7. Hatzimouratidis K, A review of the use of tadalafil in the treatment of benign prostatic hyperplasia in men with and without erectile dysfunction. Ther Adv Urol. 2014 Aug; 6(4): 135–147.
8. 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;10.1097/JU.0000000000003698. https://doi.org/10.1097/JU.0000000000003698

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Drug Class	Q1 2025
REVISION- Notable revisions: Products Affected Required Medical Information Continuation of Therapy Available Dosage Forms References	Q1 2024
REVISION- Notable revisions: Diagnosis Required Medical Information Continuation of Therapy Duration of Approval Contraindications/Exclusions/Discontinuation References	Q1 2023

REVISION- Notable revisions: Required Medical Information Duration of Approval FDA Approved Uses References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file