LOUISIANA BLUE

Cialis® 5 mg, generics (tadalafil)

Policy # 00388
Original Effective Date: 09/18/2013
Current Effective Date: 01/13/2025

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.

Note: Other strengths of Cialis® and tadalafil tablets (2.5 mg, 10 mg, and 20 mg) are addressed separately in medical policy 00726 Select Erectile Dysfunction Medications.

Note: The generic equivalent of Adcirca® (tadalafil 20 mg, Alyq) is addressed separately in medical policy 00215 Advanced Therapies for Pharmacological Treatment of Pulmonary Hypertension.

Note: Tadalafil oral suspension (Tadliq®) is addressed separately in medical policy 00215 Advanced Therapies for Pharmacological Treatment of Pulmonary Hypertension.

Note: This policy pertains to the pharmacy benefit ONLY.

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.*

Benign Prostatic Hyperplasia

Based on review of available data, the Company may consider brand and generic Cialis®‡ 5 mg (tadalafil) tablets for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) to be **eligible for coverage**** when the following patient selection criteria are met:

Patient Selection Criteria

Coverage eligibility will be considered for brand and generic Cialis 5 mg (tadalafil) tablets for the treatment of the signs and symptoms of BPH when the following criteria are met:

- Patient has a diagnosis of benign prostatic hyperplasia (BPH); AND
- Patient is 18 years of age and older; AND
- Patient is exhibiting signs and symptoms of BPH prior to initiating brand or generic Cialis 5 mg (tadalafil) tablets, as documented in clinical records; AND

- Patient has tried and failed (e.g., intolerance or inadequate response) either two single entity medications for BPH OR a combination product containing two medications for BPH unless there is clinical evidence or patient history that suggests these products will be ineffective or cause an adverse reaction to the patient. Each medication ingredient should come from a different therapeutic class (e.g., alpha blockers, 5-alpha reductase inhibitors); 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.)*
- If the request is for brand Cialis 5 mg (tadalafil) tablets ONLY: Patient has tried and failed (e.g., intolerance or inadequate response) the generic equivalent tadalafil 5 mg tablets unless there is clinical evidence or patient history that suggests the use of the generic equivalent will be ineffective or cause an adverse reaction to the patient.
  *(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.)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of brand or generic Cialis 5 mg (tadalafil) tablets when the patient has NOT tried and failed either two single entity medications for the treatment of the signs and symptoms of BPH OR a combination product containing two medications for the treatment of the signs and symptoms of BPH to be **not medically necessary.****

Based on review of available data, the Company considers the use of brand Cialis 5 mg (tadalafil) tablets for the treatment of the signs and symptoms of BPH when the patient has NOT tried and failed the generic equivalent tadalafil 5 mg tablets 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 brand and generic Cialis 5 mg (tadalafil) tablets for any other indication besides treating the signs and symptoms of BPH, (excluding erectile dysfunction which is **not covered**** for most contracts) to be **investigational.*** Based on review of available data, the Company considers the use of brand and generic Cialis 5 mg (tadalafil) tablets for the treatment of the signs and symptoms of BPH in patients under 18 years of age to be **investigational.***

Cialis® 5 mg, generics (tadalafil)

Policy # 00388
Original Effective Date: 09/18/2013
Current Effective Date: 01/13/2025

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.*

Erectile Dysfunction

Based on review of available data, the Company may consider brand and generic Cialis 5 mg (tadalafil) tablets for the treatment of erectile dysfunction to be **eligible for coverage**** when the following patient selection criteria are met:

Patient Selection Criteria

Coverage eligibility will be considered for brand and generic Cialis 5 mg (tadalafil) tablets for the treatment of erectile dysfunction when the following criteria are met:

- Patient has a diagnosis of erectile dysfunction; AND
- Patient is 18 years of age and older; AND
  *(Note: This specific patient selection criterion is a contractual requirement for coverage eligibility and will be considered not covered** if not met.)*
- If the request is for brand Cialis 5 mg (tadalafil) tablets ONLY:
  - Patient has tried and failed (e.g., intolerance or inadequate response) generic sildenafil (25 mg, 50 mg, or 100 mg) tablets unless there is clinical evidence or patient history that suggests the use of these products 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) generic tadalafil tablets unless there is clinical evidence or patient history that suggests the use of these products 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) generic vardenafil tablets (film coated or ODT) unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.
    *(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.)*

Cialis® 5 mg, generics (tadalafil)

Policy # 00388
Original Effective Date: 09/18/2013
Current Effective Date: 01/13/2025

When Services Are Not Covered

Based on review of available data, the Company considers the use of brand and generic Cialis 5 mg (tadalafil) tablets for the treatment of erectile dysfunction in members under 18 years of age to be **not covered.****

Based on review of available data, the Company considers the use of brand and generic Cialis 5 mg (tadalafil) tablets for the treatment of erectile dysfunction for members whose contracts exclude coverage for erectile dysfunction to be **not covered.****

Note: The treatment of erectile dysfunction is considered an exclusion in most member contracts.

Background/Overview

Cialis (tadalafil) is a phosphodiesterase 5 (PDE5) inhibitor indicated to treat erectile dysfunction, the signs and symptoms of BPH, and erectile dysfunction occurring in combination with the signs and symptoms of BPH. Only the 5 mg strength is approved for the treatment of BPH. All strengths of Cialis are approved by the FDA for use in erectile dysfunction. Cialis is now available as a generic product, which gives a more economical option as compared to the brand product.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Cialis (tadalafil) is a phosphodiesterase 5 (PDE5) inhibitor indicated to treat erectile dysfunction, the signs and symptoms of BPH, and erectile dysfunction occurring in combination with the signs and symptoms of BPH.

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.

The purpose of this policy is to limit the use of brand and generic Cialis 5 mg (tadalafil) tablets to those patients experiencing signs and symptoms of BPH (as documented in clinical records) and have failed other medications for their condition. The policy also provides criteria for coverage for the treatment of erectile dysfunction for members whose contracts allow such coverage. Within the criteria of both indications, members are driven to use generic products, which offer a more economical option for treatment.

Cialis® 5 mg, generics (tadalafil)

Policy # 00388
Original Effective Date: 09/18/2013
Current Effective Date: 01/13/2025

References

1. Cialis [package insert]. Indianapolis, IN: Lilly USA, LLC; February 2018.

Policy History

Original Effective Date: 09/18/2013
Current Effective Date: 01/13/2025

09/05/2013	Medical Policy Committee review
09/18/2013	Medical Policy Implementation Committee approval. New policy.
09/04/2014	Medical Policy Committee review
09/17/2014	Medical Policy Implementation Committee approval. No change to coverage.
09/03/2015	Medical Policy Committee review
09/23/2015	Medical Policy Implementation Committee approval. No change to coverage.
05/05/2016	Medical Policy Committee review
05/18/2016	Medical Policy Implementation Committee approval. Clarified that the patient must be exhibiting signs and symptoms of benign prostatic hyperplasia prior to starting Cialis.
05/04/2017	Medical Policy Committee review
05/17/2017	Medical Policy Implementation Committee approval. No change to coverage.
10/05/2017	Medical Policy Committee review
10/18/2017	Medical Policy Implementation Committee approval. Added "as documented in clinical records" as part of the criteria for the signs and symptoms of BPH.
10/04/2018	Medical Policy Committee review
10/17/2018	Medical Policy Implementation Committee approval. No change to coverage.
10/03/2019	Medical Policy Committee review
10/09/2019	Medical Policy Implementation Committee approval. No change to coverage.
12/03/2020	Medical Policy Committee review
12/09/2020	Medical Policy Implementation Committee approval. Added a new section for the treatment of erectile dysfunction. Clarified that BPH members need to be 18 years of age or older. Updated relevant background information. Added "5 mg, generics" to the title. Added new notes regarding other policies.
12/02/2021	Medical Policy Committee review
12/08/2021	Medical Policy Implementation Committee approval. No change to coverage.
12/01/2022	Medical Policy Committee review
12/14/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Added new note stating that Tadliq is referred to in another policy.
12/07/2023	Medical Policy Committee review
12/13/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Cialis® 5 mg, generics (tadalafil)

Policy # 00388
Original Effective Date: 09/18/2013
Current Effective Date: 01/13/2025

12/05/2024 Medical Policy Committee review
12/11/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 12/2025

*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.

**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.

Cialis® 5 mg, generics (tadalafil)

Policy # 00388
Original Effective Date: 09/18/2013
Current Effective Date: 01/13/2025

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.