BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Cialis® (tadalafil)

Policy # 00388
Original Effective Date: 09/18/2013
Current Effective Date: 09/17/2014

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 Cialis®‡ (tadalafil) for the treatment 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 Cialis (tadalafil) when all of the following criteria are met:

- The patient has a diagnosis of benign prostatic hyperplasia (BPH); and
- The patient has tried and failed either two single entity medications for benign prostatic hyperplasia (BPH) OR a combination product containing two medications for benign prostatic hyperplasia (BPH). Each medication ingredient should come from a different therapeutic class (e.g. alpha blockers, 5-alpha reductase inhibitors).
  *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

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 Cialis (tadalafil) for any other indication besides benign prostatic hyperplasia ([BPH], excluding erectile dysfunction which is **not covered**) to be **investigational.***

When Services Are Considered Not Medically Necessary
Based on review on available data, the Company considers the use of Cialis (tadalafil) when the patient has not tried and failed either two single entity medications for benign prostatic hyperplasia (BPH) OR a combination product containing two medications for benign prostatic hyperplasia (BPH) to be **not medically necessary.****

When Services Are Not Covered
The use of Cialis (tadalafil) for the treatment of erectile dysfunction is a contract exclusion and is therefore **not covered.**

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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.

Rationale/Source

The purpose of this policy is to limit the use of Cialis (tadalafil) to those patients experiencing signs and symptoms of BPH and have failed other medications for their condition. The use of Cialis (tadalafil) for the treatment of erectile dysfunction is a contract exclusion and is therefore not covered.

References

1. Cialis® [package insert]. Indianapolis, IN: Lilly USA, LLC; October 2011.

Policy History

Original Effective Date:	09/18/2013
Current Effective Date:	09/17/2014
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.
Next Scheduled Review Date:	09/2015

*****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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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.

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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.

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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.