



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2019 P 3007- 10
Program	Step Therapy
Medication	Cialis (tadalafil) 2.5 & 5 mg
P&T Approval Date	1/10/2012, 2/2013, 2/2014, 2/2015, 2/2016, 2/2017, 2/2018, 2/2019, 8/2019
Effective Date	11/1/2019; Oxford only: N/A

1. 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.

The current standard of care includes the use of alpha-adrenergic blocking medications [e.g.: Cardura (doxazosin), Flomax (tamsulosin), Hytrin (terazosin), Rapaflo (silodosin), or Uroxatrol (alfuzosin)] in treating moderate to severe BPH with lower urinary tract symptoms (LUTS) and the use of a 5-alpha-reductase inhibitor (5-ARI) (e.g. finasteride, dutasteride) in men with an enlarged prostate.

An adequate trial of an alternative agent is defined as treatment with an alpha-adrenergic blocking medication lasting a minimum of four weeks³.

Step therapy programs are utilized to encourage use of lower cost, preferred alternatives for certain therapeutic classes. This program requires a member to try and fail an alpha-adrenergic blocking agent for the signs and symptoms of benign prostatic hyperplasia (BPH) before providing coverage for Cialis.

Members who have met the step therapy requirement as documented by claims history for qualifying medications (5-ARI or alpha-adrenergic blocking medications) will be allowed to continue on their current therapy. Members new to therapy and those members currently on therapy without a claims history for one of the qualifying medications will be required to meet the coverage criteria below.

2. Coverage Criteria^a:

A. Groups with coverage of erectile dysfunction medications as a covered benefit

1. **Cialis 2.5 mg** and **Cialis 5 mg** will be approved based on **one** of the following criteria:

a. **Both** of the following:

(1) History of failure following a trial for at least 4 weeks, contraindication or intolerance to an alpha-adrenergic blocking medication [e.g., Cardura, Flomax, Hytrin , Rapaflo or Uroxatrol]

-AND-

(2). History of trial/failure, contraindication or intolerance to tadalafil (generic Cialis)

-OR-

b. **Both** of the following:

(1) Diagnosis of erectile dysfunction without a diagnosis of benign prostatic hyperplasia

-AND-

(2) History of trial/failure, contraindication or intolerance to tadalafil (generic Cialis)

2. **tadalafil 2.5 mg and 5 mg (generic Cialis)** will be approved based on **one** of the following criteria:

a. History of failure following a trial for at least 4 weeks, contraindication or intolerance to an alpha-adrenergic blocking medication [e.g., Cardura, Flomax, Hytrin, Rapaflo, or Uroxatrol]

-OR-

b. Diagnosis of erectile dysfunction without a diagnosis of benign prostatic hyperplasia

Authorization will be issued for 12 months

B. Groups without coverage of erectile dysfunction medications as a covered benefit^b

1. **Cialis 2.5 mg and Cialis 5 mg** will be approved based on **both** of the following criteria:

a. History of failure following a trial for at least 4 weeks, contraindication or intolerance to an alpha-adrenergic blocking medication [e.g., Cardura, Flomax, Hytrin, Rapaflo, or Uroxatrol]

-AND-

b. History of trial/failure, contraindication or intolerance to tadalafil (generic Cialis)

2. **tadalafil 2.5 mg and 5 mg (generic Cialis)** will be approved based on **one** of the following criteria:

a. History of failure following a trial for at least 4 weeks, contraindication or intolerance to an alpha-adrenergic blocking medication [e.g., Cardura, Flomax, Hytrin, Rapaflo, or Uroxatrol]

Authorization will be issued for 12 months

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

^b Coverage for Cialis 2.5 & 5 mg is not provided for diagnosis of erectile dysfunction



3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Cialis [prescribing information]. Eli Lilly and Company. Indianapolis, IN. February 2018.
2. American Urological Association. Guideline on the Management of Benign Prostatic Hyperplasia (BPH). 2010, confirmed 2014.
3. Effects of Tadalafil on Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia in Men With or Without Erectile Dysfunction. Broderick, GA, et al. Urology. 2010;75; 1452-59.

Program	Cialis Step Therapy
Change Control	
Date	Change
2/2014	Administrative. References updated.
2/2015	Combined P 3007 and P 3012. No changes to criteria.
2/2016	Annual Review. Added Maryland Continuation of Care.
7/2016	Added Indiana and West Virginia coverage information.
11/2016	Administrative change. Added California coverage information.
2/2017	Annual Review. Background section updated. References updated.
2/2018	Annual Review. Updated state mandate language. References updated.
2/2019	Annual review. References updated. Step added through generic Cialis.
8/2019	Administrative changes.