

STEP THERAPY CRITERIA

BRAND NAME
(generic)

CIALIS 2.5 mg, 5 mg
(tadalafil)

Status: Client Requested Criteria

Type: Initial Step Therapy; Post Step Therapy Prior Authorization

Ref # C10100-E

INITIAL STEP THERAPY for generic tadalafil 2.5 mg, 5 mg only

If the patient has filled a prescription for a 30 days supply of at least one alpha-blocker (i.e., alfuzosin, doxazosin, silodosin, tamsulosin, or terazosin), 5 alpha-reductase inhibitor (5-ARI) (e.g., dutasteride, finasteride 5 mg), or combination alpha-blocker and 5-ARI [e.g., Jalyn (dutasteride/tamsulosin)] within the past 180 days under a prescription benefit administered by CVS Caremark, then the requested generic tadalafil 2.5 mg or generic tadalafil 5 mg will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the system will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

If the patient meets the initial step therapy criteria, then the quantity for approval will be 30 tablets per month and 90 tablets per 3 months.*

*** The patient should receive only one drug from this drug class at a time.**

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

CRITERIA FOR APPROVAL

1	Does the patient require nitrate therapy on a regular or on an intermittent basis OR will the patient be taking a guanylate cyclase (GC) stimulator, such as riociguat?	Yes	No
2	Is tadalafil 2.5 mg or 5 mg being prescribed for daily use for symptomatic benign prostatic hyperplasia (BPH) in a patient that is 18 years of age or older? [Note: examples of signs and symptoms of BPH are incomplete emptying, weak stream, straining, urinary frequency, intermittency, urgency, or acute urinary retention.] [If no, then no further questions.]	Yes	No
3	Has the patient experienced an inadequate treatment response, intolerance, or contraindication to an alpha-blocker and/or a 5 alpha-reductase inhibitor (5-ARI)? [Note: Examples of trial drugs are alfuzosin, doxazosin, silodosin, tamsulosin, terazosin, dutasteride, finasteride 5mg, Jalyn.]	Yes	No
4	Is the request for brand Cialis? [If no, then no further questions]	Yes	No
5	Is treatment with brand Cialis considered medically necessary due to intolerance to the generic formulation or other medical necessity as noted by the prescriber?	Yes	No

Mapping Instructions			
	Yes	No	DENIAL REASONS
1.	Deny	Go to 2	Your plan does not cover this drug when you use nitrate drugs either daily or on occasion, or if you use a guanylate cyclase stimulator. Your request has been denied based on the information we have.
2.	Go to 3	Deny	Your plan covers this drug when you are 18 years of age or older and you have benign prostatic hyperplasia (BPH). Your request has been denied based on the information we have.
3.	Go to 4	Deny	Your plan covers this drug when you meet all of these conditions: - You are 18 years of age or older - You have benign prostatic hyperplasia (BPH) - You tried another drug for benign prostatic hyperplasia (BPH) first, and it did not work for you or you cannot take it Your request has been denied based on the information we have.
4.	Go to 5	Approve, 36 months generic tadalafil 2.5 mg or 5 mg 30 tabs/25 days* or 90 tabs/75 days*	
5.	Approve, 36 months Brand Cialis 30 tabs/25 days* or 90 tabs/75 days*	Deny	Your plan covers this drug when you meet all of these conditions: - You are 18 years of age or older - You have benign prostatic hyperplasia (BPH) - You tried another drug for benign prostatic hyperplasia (BPH) first, and it did not work for you or you cannot take it - You cannot take generic tadalafil (generic Cialis) Your request has been denied based on the information we have.

*** The patient should receive only one drug from this drug class at a time.**

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Written by: UM Development (NB)
 Date Written: 02/2017
 Revised: (JK) 10/2019 (removed brand Cialis from initial step therapy and added questions for brand medically necessary)
 Reviewed: Medical Affairs: 02/2017, 11/2019

The Participating Group signed below hereby accepts and adopts as its own the criteria for use with Prior Authorization, as administered by CVS Caremark.

Signature

Date

Client Name