Utilization Management Policy Name: Cialis®

Restricted Product(s):	**Unrestricted Suggested Alternative(s):**
Cialis (tadalafil) Tadalafil (Cialis) (for BPH)	Doxazosin Dutasteride Finasteride Tamsulosin Viagra® (sildenafil) *benefit limitations apply*

FDA Approved Use:

Cialis is a phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of:
- erectile dysfunction (ED)
- the signs and symptoms of benign prostatic hyperplasia (BPH).
- ED and the signs and symptoms of BPH (ED/BPH).

Rationale:

Cialis can be used in attempts to treat conditions that have not been validated by the FDA. This program ensures that members are receiving this medication for conditions that have the appropriate evidence to support its use. Other products, such as doxazosin, dutasteride, finasteride, tamsulosin, or Viagra treat the same condition at a lower cost for members. Quantity limits have been added to ensure safe and effective use.

Criteria Summary:

FDA approved use/medical necessity; trial of effective and lower cost agent; exception to quantity limitation

Criteria for Approval of Restricted Product(s):

Initial Coverage

Cialis (Tadalafil) is covered for the following conditions and situations:

1. The patient has BPH symptoms that score 8 or greater on the American Urological Association Symptom Index (AUA-SI); **AND**
    a. The request is for Cialis (tadalafil) 5mg once daily tablets; **AND**
    b. The patient is ≥ 45 years of age; **AND**
    c. The patient has NOT had a total prostatectomy; **AND**
    d. The patient has tried and failed, are intolerant to, or have contraindications to both alpha blockers [Hytrin (terazosin), Cardura (doxazosin), Flomax (tamsulosin), Uroxatral (alfuzosin), Rapaflo (silodosin)] **AND** 5-alpha reductase inhibitors [ex. Proscar (finasteride), Avodart (dutasteride), Jalyn (dutasteride plus tamsulosin)]; **AND**
    e. If the request is for brand name Cialis,
        i. The patient has tried and failed tadalafil (generic Cialis) 5mg; **OR**
        ii. The patient has a clinical contraindication/intolerance to tadalafil (generic Cialis) 5mg; **OR**
2. The patient has a diagnosis of erectile dysfunction (ED); **AND**
    a. The patient has tried and failed sildenafil (generic Viagra) and tadalafil (generic Cialis); **OR**
    b. The patient has a clinical contraindication/intolerance to sildenafil (generic Viagra) and tadalafil (generic Cialis); **AND**
3. For formularies that exclude (non-formulary) the requested medication, Non-formulary Exception Criteria applies (outlined below)*

Duration of treatment for BPH: 84 days
Duration of treatment for ED: Indefinite

Continued Coverage Criteria for BPH:

1. The patient meets criteria points 1a – 1e of the initial coverage criteria; **AND**
2. The AUA-SI score is documented to have decreased after initial trial of therapy.

Duration of treatment for BPH: Indefinite

Quantity Limitations: quantity limitations apply to brand and associated generic products.

Medication	Quantity per Day (unless specified)
Cialis (tadalafil) 5 mg	1 tablet
Other strengths are subject to benefit limitations for ED	

Quantity Limit Exception Criteria:

1. The patient has been approved for coverage of Cialis for BPH; **AND**
2. The quantity (dose) requested is for documented titration purposes at the initiation of therapy (authorization for a 90 day titration period); **AND**
3. The prescribed dose cannot be achieved using a lesser quantity of a higher strength; **AND**
4. The quantity (dose) requested does not exceed the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer's product insert; **OR**
5. If the quantity (dose) requested exceeds the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer's product insert, then the prescriber must submit documentation in support of therapy with a higher dose for the intended diagnosis (submitted documentation may include medical records OR fax form which reflects medical record documentation that shows the length of time the requested dose has been used, and what other medications and doses have been tried and failed).

***Non-formulary Exception Criteria**

Non-Formulary Exception criteria applies on formularies which exclude requested product(s). Satisfactory completion of criteria points (above) may satisfy some, or all, portions of the Non-Formulary Exception Criteria. This criteria is summarized as:

a) Request must be for an FDA approved indication; **AND**
b) Patient must have a trial and failure of up to **TWO** formulary medications or a clinical contraindication/intolerance to those medications not tried.

References: all information referenced is from FDA package insert unless otherwise noted below.

Management of BPH (Revised, 2010). American Urological Association-Clinical Guidelines. http://www.auanet.org/

Policy Implementation/Update Information: Originated: December 2011; Last updated: October 2018

October 2018: Add new to market generic tadalafil to the policy; added step therapy prerequisite option of tadalafil.

May 2017: Quantity limit clarified as one 5mg tablet daily
March 2017: Reformatted criteria; annual FDA indication review; defined Restricted Access requirement of a trial of Viagra for ED; removed nitrates restriction.
October 2016: Reviewed for Essential Formulary; removal of gender specific language; added exception criteria for quantity limit exception.
August 2015: Combined Cialis BPH and ED Restricted Access criteria for Cialis
December 2011: Original utilization management criteria issued.

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- You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, Civil Rights Coordinator - Privacy, Ethics & Corporate Policy Office is available to help you.

- You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at *https://ocrportal.hhs.gov/ocr/portal/lobby.jsf,* or by mail or phone at: U.S. Department of Health and Human Services 200 Independence Avenue, SW Room 509F, HHH Building Washington, D.C. 20201 **1-800-368-1019, 800-537-7697** (TDD). Complaint forms are available at *http://www.hhs.gov/ocr/office/file/index.html*.

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1-888-206-4697. المبرقة الكاتبة: 1-800-442-7028.

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