

Drug Policy

Policy: Impacted Drugs:	Erectile Dysfunction (Oral Agents) Preferred Step Therapy Policy Cialis (tadalafil tablets) Levitra (vardenafil tablets) Sildenafil (tablets) Staxyn (vardenafil orally disintegrating tablets) Stendra (avanafil tablets) Tadalafil (tablets) Vardenafil (tablets) Viagra (sildenafil tablets)	Annual Review Date: 06/20/2024 Last Revised Date: 06/20/2024
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OVERVIEW

Viagra (sildenafil citrate), Cialis, Stendra, and Levitra/Staxyn are selective inhibitors of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5). All agents are indicated for the treatment of erectile dysfunction (ED). Cialis is also indicated for the treatment of signs and symptoms of benign prostatic hyperplasia (BPH), and for the treatment of ED and the signs and symptoms of BPH (ED/BPH).

POLICY STATEMENT

A preferred step therapy program has been developed to encourage the use of a preferred product prior to the use of a non-preferred product. If the preferred step therapy rule is not met for a non-preferred agent at the point of service, coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 1 year in duration.

Preferred Medications

- Sildenafil citrate (tablets)
- Tadalafil (tablets)

Non-Preferred Medications

- Levitra® (vardenafil tablets)
- Staxyn™ (vardenafil orally disintegrating tablets)
- Stendra™ (avanafil tablets)
- Viagra® (sildenafil citrate tablets)
- Cialis® (tadalafil tablets)
- Vardenafil (tablets)

CRITERIA

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1. If the patient has tried a preferred medication, then authorization for a non-preferred medication may be given.
2. Exceptions allowed for Staxyn if the patient cannot swallow or has difficulty swallowing tablets.

Initial Approval/ Extended Approval.

A) *Initial Approval:* 1 year (365 days)

B) *Extended Approval:* 1 year (365 days)

Step Therapy Exception Criteria

In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

- A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics **[documentation required]**; **OR**
- B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent **[documentation required]**; **OR**
- C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
 1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); **OR**
 2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as **[documentation required]**. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a

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pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Viagra® tablets [prescribing information]. New York, NY: Pfizer Labs; August 2017.
2. Levitra® tablets [prescribing information]. West Haven, CT: Bayer Pharmaceuticals; August 2017.
3. Staxyn® orally disintegrating tablets [prescribing information]. Wayne, NJ: Bayer; August 2017.
4. Cialis® tablets [prescribing information]. Indianapolis, IN: Eli Lilly and Company; May 2017.
5. Stendra™ tablets [prescribing information]. Mountain View, CA: Vivus, Inc; October 2017.
6. Sildenafil. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 06 June 2019. Accessed on 18 June 2019.
7. Vardenafil. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 29 April 2019. Accessed on 18 June 2019.
8. Avanafil. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 22 February 2019. Accessed on 18 June 2019.
9. Tadalafil. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 20 May 2019. Accessed on 18 June 2019.