

**Clinical Policy: Vardenafil (Levitra, Staxyn)**

Reference Number: CP.CPA.324

Effective Date: 06.01.18

Last Review Date: 08.24

Line of Business: Commercial

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

**Description**

Vardenafil (Levitra<sup>®</sup>, Staxyn<sup>®</sup>) is a phosphodiesterase-5 inhibitor.

**FDA Approved Indication(s)**

Levitra and Staxyn are indicated for the treatment of erectile dysfunction (ED).

**Policy/Criteria**

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Levitra and Staxyn are **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria****A. Erectile Dysfunction** (must meet all):

1. Diagnosis of ED;
2. Age  $\geq$  21 years;
3. Failure of generic Viagra<sup>®</sup> (sildenafil 25 mg, 50 mg, 100 mg) unless contraindicated or clinically significant adverse effects are experienced;
4. One of the following (a or b):
  - a. For Levitra requests, member must use generic vardenafil tablet, unless contraindicated or clinically significant adverse effects are experienced;
  - b. For Staxyn requests, member must use generic vardenafil orally disintegrating tablet, unless contraindicated or clinically significant adverse effects are experienced;
5. Levitra and Staxyn are not prescribed concurrently with nitrates (e.g., Nitrodur, Nitrobid, Nitrostat, Isordil, Ismo);
6. Levitra and Staxyn are not prescribed concurrently with guanylate cyclase stimulators, such as riociguat (Adempas);
7. Dose does not exceed health plan approved quantity limit and both of the following (a and b):
  - a. One tablet per day;
  - b. One of the following (i or ii):
    - i. Levitra: 20 mg per day;
    - ii. Staxyn: 10 mg per day.

**Approval duration: Benefit Renewal Date (quantity limits are plan specific)**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial; or
  - b. For drugs NOT on the formulary (commercial), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial.

**II. Continued Therapy**

**A. Erectile Dysfunction (must meet all):**

1. Member meets one of the following (a or b):
  - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
  - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member is responding positively to therapy;
3. One of the following (a or b):
  - a. For Levitra requests, member must use generic vardenafil tablet, unless contraindicated or clinically significant adverse effects are experienced;
  - b. For Staxyn requests, member must use generic vardenafil orally disintegrating tablet, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, new dose does not exceed health plan approved quantity limit and both of the following (a and b):
  - a. One tablet per day;
  - b. One of the following (i or ii):
    - i. Levitra: 20 mg per day;
    - ii. Staxyn: 10 mg per day.

**Approval duration: Benefit Renewal Date (quantity limits are plan specific)**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial; or
  - b. For drugs NOT on the formulary (commercial), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

ED: erectile dysfunction

FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

| Drug Name              | Dosing Regimen                                         | Dose Limit/<br>Maximum Dose |
|------------------------|--------------------------------------------------------|-----------------------------|
| Sildenafil<br>(Viagra) | 50 mg PO 1 hour (0.5 – 4 hours) before sexual activity | 100 mg/day                  |

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): administration with nitrates, nitric oxide donors, or guanylate cyclase (GC) stimulators, such Adempas<sup>®</sup> (riociguat)
- Boxed warning(s): none reported

**V. Dosage and Administration**

| Indication | Dosing Regimen                             | Maximum Dose                           |
|------------|--------------------------------------------|----------------------------------------|
| ED         | 10 mg PO 60 minutes before sexual activity | Staxyn: 10 mg/day<br>Levitra: 20mg/day |

**VI. Product Availability**

| Drug Name            | Availability                        |
|----------------------|-------------------------------------|
| Vardenafil (Levitra) | Tablet: 2.5 mg, 5 mg, 10 mg, 20 mg  |
| Vardenafil (Staxyn)  | Orally disintegrating tablet: 10 mg |

## VII. References

1. Staxyn Prescribing Information. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc. Co; April 2023. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2023/200179s007lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/200179s007lbl.pdf). Accessed May 2, 2024.
2. Levitra Prescribing Information. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc. Co; March 2023. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2023/021400s023lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/021400s023lbl.pdf). Accessed May 2, 2024.
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4. Lue TF. Drug therapy: Erectile dysfunction. N Engl J Med 2000;342:1802.
5. Steele, D. Drugs causing sexual dysfunction and their alternatives: A Reference Tool. Urol Nurs. 1989 Oct-Dec;9(6):10-12.
6. Burnett AL, Nehra A, Breau RH, et al. Erectile Dysfunction: American Urological Association Guideline 2018. Available at: [https://www.auanet.org/guidelines-and-quality/guidelines/erectile-dysfunction-\(ed\)-guideline](https://www.auanet.org/guidelines-and-quality/guidelines/erectile-dysfunction-(ed)-guideline). Accessed April 25, 2023.
7. Kloner RA, Burnett AL, Miner M, et al. Princeton IV consensus guidelines: PDE5 inhibitors and cardiac health. The Journal of Sexual Medicine. February 2024; 21(2): 90–116.

| Reviews, Revisions, and Approvals                                                                                                                                                                                                                                                        | Date     | P&T Approval Date |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|-------------------|
| 3Q 2020 annual review: revise approval duration from length of benefit to “Benefit Renewal Date (quantity limits are plan specific)”; removed criteria requiring request for formulary product as criteria would also apply for non-formulary requests; references reviewed and updated. | 04.22.20 | 08.20             |
| 3Q 2021 annual review: modified minimum age from 18 to 21 years per age limit programming; references reviewed and updated.                                                                                                                                                              | 04.06.21 | 08.21             |
| 3Q 2022 annual review: added requirement for generic vardenafil use for both initial and reauthorization requests; references reviewed and updated.                                                                                                                                      | 04.19.22 | 08.22             |
| Template changes applied to other diagnoses/indications and continued therapy section.                                                                                                                                                                                                   | 09.23.22 |                   |
| 3Q 2023 annual review: no significant changes; references reviewed and updated.                                                                                                                                                                                                          | 04.14.23 | 08.23             |
| 3Q 2024 annual review: no significant changes; references reviewed and updated.                                                                                                                                                                                                          | 05.02.24 | 08.24             |

## **Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted

## CLINICAL POLICY

### Vardenafil

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