

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[®], Staxyn[®]) 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[®] 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[®] (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

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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/ Maximum Dose
Sildenafil (Viagra)	50 mg PO 1 hour (0.5 – 4 hours) before sexual activity	100 mg/day

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) 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[®] (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 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

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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. 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. Accessed May 2, 2024.
3. Guay, AT, et al. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for the Evaluation and Treatment of Male Sexual Dysfunction: A Couple’s Problem-2003 Update. Endocrine Practice, 2003; 9(1): 77-95
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

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standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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