

Clinical Policy Title:	varденаfil
Policy Number:	RxA.200
Drug(s) Applied:	Levitra®, Staxyn®
Original Policy Date:	02/07/2020
Last Review Date:	06/10/2021
Line of Business Policy Applies to:	All lines of business

Background

Levitra®, Staxyn® is a phosphodiesterase-5 inhibitor. Levitra® and Staxyn® are indicated for the treatment of erectile dysfunction (ED).

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
varденаfil (Levitra®, Staxyn®)	ED	10 mg by mouth 60 minutes before sexual activity	Staxyn®: 10 mg/day Levitra®: 20mg/day

Dosage Forms

- vardenafil (Levitra®): Tablet: 2.5 mg, 5 mg, 10 mg, 20 mg
- vardenafil (Staxyn®): Orally disintegrating tablet: 10 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the provisions of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Erectile Dysfunction (must meet all):

1. Diagnosis of ED;
2. Age ≥ 18 years;
3. Requested agent is on the formulary;
4. Failure of generic Viagra® (sildenafil 25 mg, 50 mg, 100 mg) unless contraindicated or clinically significant adverse effects are experienced;
5. Member is not on nitrates or guanylate cyclase stimulators;
6. Dose does not exceed health plan approved quantity limit and the following:
 - a. Levitra®: 20 mg/day (1 tablet);
 - b. Staxyn®: 10 mg/day (1 tablet).

Approval Duration

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

Commercial: 12 months

Medicaid: 12 months

II. Continued Therapy Approval

A. Erectile Dysfunction (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed health plan approved quantity limit and the following:
 - a. Levitra®: 20 mg/day (1 tablet);
 - b. Staxyn®: 10 mg/day (1 tablet).

Approval Duration

Commercial: 12 months

Medicaid: 12 months

B. Appendices

APPENDIX A: Abbreviation/Acronym Key

ED: Erectile dysfunction

FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
sildenafil (Viagra®)	50 mg by mouth 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 as Adempas® (riociguat).
- **Boxed Warning(s):**
 - None reported

APPENDIX D: General Information

- **Diagnoses/Indications for which coverage is NOT authorized:**
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

References

1. Staxyn® Prescribing Information. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc. Co; August 2017. Available at www.staxyn.com. Accessed February 18, 2021.
2. Levitra® Prescribing Information. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc. Co; August 2017. Available at: www.levitra.com. Accessed February 18, 2021.
3. Guay, AT, Spark RF, Bansal S, 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. Accessed February 18, 2021.
4. Lue TF. Drug therapy: Erectile dysfunction. N Engl J Med 2000;342(24):1802-13. Accessed July 09,2020.
 5. Bella AJ, Shamloul R. Psychotropics and sexual dysfunction. Cent European J Urol. 2014;66(4):466-71. Accessed February 18, 2021.
 6. Burnett AL, Nehra A, Breau RH, et al. Erectile Dysfunction: American Urological Association Guideline 2018. Available at: [https://www.auanet.org/guidelines/erectile-dysfunction-\(ed\)-guideline](https://www.auanet.org/guidelines/erectile-dysfunction-(ed)-guideline). Accessed February 18, 2021.
 7. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2020. Accessed with subscription at: <http://www.clinicalkey.com>. Updated January 14, 2020. Accessed February 18, 2021.
 8. Vardenafil, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: <http://online.lexi.com>. Accessed February 18, 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Policy title table was updated: Clinical Policy Title was updated to " vardenafil". Drug(s) Applied was updated to "Levitra®, Staxyn®". Line of Business Policy Applies to was updated to "All" 2. Clinical policy was updated: Approval duration was updated for both Initial and Continued Approval Criteria; Continued Approval was rephrased to "Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy" 3. References were updated.	07/10/2020	09/14/2020
Policy was reviewed: 1. Last review date was updated. 2. Clinical policy verbiage added " The provision of provider samples does not guarantee...". 3. Continued Therapy criteria II.A.1 was rephrased from 4. "Currently receiving medication that has been authorized by RxAdvance..." 5. Appendix B: "Therapeutic alternatives verbiage was	02/18/2021	06/10/2021

<p>updated to below are suggested therapeutic alternatives based on clinical guidance...."</p> <p>6. References were reviewed and updated.</p>		
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