RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	avanafil
Policy Number:	RxA.471
Drug(s) Applied:	Stendra®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Avanafil (Stendra®) is a phosphodiesterase 5 (PDE5) inhibitor. It is indicated for the treatment of erectile dysfunction (ED).

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
avanafil (Stendra®)	Erectile Dysfunction	100 mg PO as early as 15 minutes prior sexual activity	200 mg/day

Dosage Forms

- Tablet: 50 mg, 100 mg, 200 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.

I. Initial Approval Criteria

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

1. Diagnosis of ED;
2. Age ≥ 18 years;
3. Stendra® is a formulary medication;
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 and guanylate cyclase stimulators;
6. Dose does not exceed 200 mg/day and plan approved quantity limit.

Approval duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

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

1. Currently receiving medication that has been authorized by RxAdvance or member has

previously 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 200 mg/day and plan approved quantity limit.

Approval duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
ED: Erectile Dysfunction
NAION: Non Arteritic Ischemic Optic Neuropathy

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):
  - Concomitant use of any form of organic nitrate is contraindicated
  - Hypersensitivity to any component of the Stendra® tablet
  - Administration with guanylate cyclase (GC) stimulators such as riociguat
- Boxed warning(s):
  - None reported

APPENDIX D: General Information
- Patients should stop Stendra® and seek medical care if a sudden loss of vision occurs in one or both eyes, which could be a sign of Non Arteritic Ischemic Optic Neuropathy (NAION). Stendra® should be used with caution, and only when the anticipated benefits outweigh the risks, in patients with a history of NAION. Patients with a "crowded" optic disc may also be at an increased risk of NAION.
- Patients should stop taking Stendra® and seek prompt medical attention in the event of sudden decrease or loss of hearing.

References
1. Stendra® Prescribing Information. Freehold, NJ: Metuchen Pharmaceuticals, LLC; September 2019. Available at: www.stendra.com. Accessed September 14, 2020.
2. 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 September 21, 2020.
3. Lue TF. Erectile dysfunction. N Engl J Med 2000;342(24):1802-1813. Accessed September 21, 2020.
4. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. September 14, 2020.
5. Avanafil, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: http://online.lexi.com. Accessed September 21, 2020.
6. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2020. Accessed with subscription at: http://www.clinicalkey.com. Updated January 14, 2020. Accessed September 21, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated: Line of business policy applies was updated to All lines of business. 2. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 3. Number of tablets was removed when referring to maximum dosing in clinical criteria. 4. Approval duration was updated from Length of benefit to 12 months for Initial and continued approval criteria. 5. Appendix A was updated: NAION was added. 6. Appendix C- contraindications were updated. "Concomitant use of any form of organic nitrate, GC and hypersensitivity to Stendra® is contraindicated." 7. Appendix D was added. 8. References were updated.	9/21/2020	12/7/2020