Clinical Policy Title:	avanafil
Policy Number:	RxA.471
Drug(s) Applied:	Stendra®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2021
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 orally as early as 15 minutes prior sexual activity; The dose may be increased up to 200 mg orally, approximately 15 minutes before sexual activity or decreased to 50 mg orally approximately 30 minutes before sexual activity.	200 mg/day; 50 mg/day when given with moderate CYP3A4 inhibitors

* Renal Impairment: No dose adjustment is necessary for mild to moderate renal impairment. Avoid use in patients with severe renal impairment or renal failure, since no data available.
Hepatic Impairment: No dose adjustments necessary for mild to moderate hepatic impairment (Child Pugh Class A or B). Avoid use in patients with severe hepatic impairment, since no data available.

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. The provision of provider samples does not guarantee coverage under the terms 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. 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. 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 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
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
sildenafil (Viagra®)	50 mg orally 1 hour (0.5 - 4 hours) before sexual activity	100 mg/day
tadalafil (Cialis®)	10 mg orally, taken prior to anticipated sexual activity; 2.5 mg orally once daily at about the same time each day without regard to timing of sexual activity	20 mg/dose orally for erectile dysfunction for as needed use; 5 mg/day orally for erectile dysfunction for once daily use
vardenafil	10 mg orally approximately 60 minutes before sexual activity	20 mg/day

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

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 August 30, 2021.
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. Available at: https://www.endocrinepractice.org/article/S1530-891X(20)40332-5/fulltext. Accessed August 30, 2021.
3. Lue TF. Erectile dysfunction. N Engl J Med 2000;342(24):1802-1813. Available at: https://www.nejm.org/doi/10.1056/NEJM200006153422407. Accessed August 30, 2021.
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5. Avanafil, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: http://online.lexi.com. Accessed August 30, 2021.
6. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2020. Accessed with subscription at: http://www.clinicalkey.com. Updated 2021. Accessed August 30, 2021.

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	9/21/2020	12/7/2020

organic nitrate, GC and hypersensitivity to Stendra® is contraindicated." 7. Appendix D was added. 8. References were updated.		
Policy was reviewed: 1. Dosing information was updated from "100 mg orally as early as 15 minutes prior sexual activity" to "100 mg orally as early as 15 minutes prior sexual activity; the dose may be increased up to 200 mg orally, approximately 15 minutes before sexual activity or decreased to 50 mg orally approximately 30 minutes before sexual activity", for better precision. 2. Dosing information was updated from maximum dose "200 mg/day" to maximum dose "200 mg/day; 50 mg/day when given with moderate CYP3A4 inhibitors" for better precision. 3. Dosing information was updated to include hepatic and renal impairment doses adjustment. 4. Statement about provider sample "The provision of provider samples does not guarantee coverage…" was added to Clinical Policy. 5. Continued Therapy Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 6. Therapeutic Alternative verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..". 7. Appendix B was updated to include "tadalafil (Cialis®)" & "vardenafil" as therapeutic alternatives. 8. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 9. References were reviewed and updated.	08/30/2021	12/07/2021