RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title: **Sildenafil for ED (Viagra)**
Policy Number: **RxA.547**
Drug(s) Applied: **Sildenafil (Viagra®)**
Last Review Date: **01/2020**
Line of Business: **Commercial, HIM**

Background

Sildenafil (Viagra®) is a phosphodiesterase-5 (PDE5) inhibitor.
It is indicated for the treatment of erectile dysfunction (ED).

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.

Indication	Dosing Regimen	Maximum Dose
ED	50 mg orally 1 hour (0.5 - 4 hours) before sexual activity Co-administration of erythromycin or strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, saquinavir): consider a starting dose of 25 mg	100 mg/day (25 mg/48 hours with co-administration of ritonavir)

Tablets: 25 mg, 50 mg, 100 mg

I. Initial Approval Criteria

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

1. Diagnosis of ED;
2. Age ≥ 18 years;
3. Viagra or its generic version is a formulary medication;
4. For brand Viagra, medical justification supports inability to use generic Viagra (sildenafil 25 mg, 50 mg, 100 mg), such as contraindication or intolerance to the excipients in the generic formulation;
   **Therapeutic failure does not constitute acceptable medical justification.*
5. Member is NOT on nitrates and guanylate cyclase stimulators;
6. Dose does not exceed 100 mg/day and health plan approved quantity limit.

Approval duration:
HIM – 12 months
Commercial – Length of Benefit

II. Continued Therapy

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

1. Currently receiving medication via RxAdvance benefit or member has previously met initial approval criteria;

2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 100 mg/day and health plan approved quantity limit.

Approval duration:
HIM – 12 months
Commercial – Length of Benefit

III. Appendices

Appendix A: Abbreviation/Acronym Key
ED: erectile dysfunction
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): patients using nitric oxide donors (e.g., organic nitrates or organic nitrites in any form); administration with guanylate cyclase (GC) stimulators (e.g., Adempas (riociguat)); hypersensitivity
- Boxed warning(s): none reported

References

1. Viagra Prescribing Information. New York, NY: Pfizer Labs; December 2017. Available at https://www.viagra.com/. Accessed February 4, 2019.
2. Montague DK, Jarow JP, Broderick GA et al. Chapter 1: The management of erectile dysfunction: an AUA update. J Urol. 2005 Jul;174(1):230-9.
3. Qaseem A, Snow V, Denberg TD et al. Hormonal testing and pharmacologic treatment of erectile dysfunction: a clinical practice guideline from the American College of Physicians. Ann Intern Med. 2009 Nov 3;151(9):639-49. doi: 10.7326/0003-4819-151-9-20091103000151.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	03/06/2020