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| Clinical Policy Title: | sildenafil |
| Policy Number: | RxA.547 |
| Drug(s) Applied: | Viagra® |
| Original Policy Date: | 03/06/2020 |
| Last Review Date: | 12/07/2020 |
| Line of Business Policy Applies to: | All lines of business |

Background

Sildenafil (Viagra®) 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 |
|----------------------|------------|--|--|
| Sildenafil (Viagra®) | 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). |

Dosage Forms

- Tablets: 25 mg, 50 mg, 100 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. 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.

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.

Approval duration

Commercial: 12 months

Medicaid: 12 months

HIM: 12 months

II. Continued Therapy Approval

A. Erectile Dysfunction (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance benefit 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 100 mg/day and health plan approved quantity limit.

Approval Duration

Commercial: 12 months

Medicaid: 12 months

HIM: 12 months

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 to sildenafil or any component of tablet.
- Boxed warning(s):
 - none reported.

APPENDIX D: General Information

- Not applicable

References

1. Viagra Prescribing Information. New York, NY: Pfizer Labs; December 2017. Available at <https://www.viagra.com/>. Accessed September 8, 2020.
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/Revision Date | P&T Approval Date |
|---|----------------------|-------------------|
| Policy established. | 02/2020 | 03/06/2020 |
| Policy was reviewed: <ol style="list-style-type: none"> 1. Clinical Policy Title was updated. 2. Drug(s) Applied was updated. 3. Line of Business Policy Applies to was update to all lines of business. 4. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 5. Initial Approval criteria: Commercial, Medicaid and HIM approval duration were updated from length of benefit to 12 months. 6. Continued Approval criteria: Commercial, Medicaid and HIM approval duration were updated from length of benefit to 12 months. 7. References were updated. | 09/08/2020 | 12/07/2020 |