Clinical Policy: Sildenafil for ED (Viagra)

Reference Number: CP.PCH.07
Effective Date: 06.01.18
Last Review Date: 05.22
Line of Business: Commercial, HIM

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Sildenafil (Viagra®) is a phosphodiesterase-5 (PDE5) inhibitor.

FDA Approved Indication(s)

Viagra is indicated for the treatment of erectile dysfunction (ED).

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Viagra is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of ED;
2. Age ≥ 18 years;
3. If brand Viagra is requested, member must use generic Viagra (sildenafil 25 mg, 50 mg, 100 mg), unless contraindicated or clinically significant adverse effects are experienced;
   **Therapeutic failure does not constitute acceptable medical justification.*
4. Sildenafil (Viagra) is NOT prescribed concurrently with nitrates or guanylate cyclase stimulators;
5. Dose does not exceed 100 mg per day and health plan approved quantity limit.

Approval duration:
HIM – 12 months
Commercial – Benefit Renewal Date (quantity limits are plan specific)

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial and HIM.PA.33 for health insurance marketplace; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business:

CP.CPA.190 for commercial and HIM.PA.103 for health insurance marketplace; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial and HIM.PA.154 for health insurance marketplace.

II. Continued Therapy

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy;
3. If brand Viagra is requested, member must use generic Viagra (sildenafil 25 mg, 50 mg, 100 mg), unless contraindicated or clinically significant adverse effects are experienced;
   **Therapeutic failure does not constitute acceptable medical justification.*
4. If request is for a dose increase, new dose does not exceed 100 mg per day and health plan approved quantity limit.

Approval duration:
HIM – 12 months
Commercial – Benefit Renewal Date (quantity limits are plan specific)

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial and HIM.PA.33 for health insurance marketplace; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial and HIM.PA.103 for health insurance marketplace; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial and HIM.PA.154 for health insurance marketplace.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. 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 – CP.CPA.09 for commercial and HIM.PA.154 for health insurance marketplace or evidence of coverage documents.

IV. Appendices/General Information

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

V. Dosage and Administration

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)

VI. Product Availability

Tablets: 25 mg, 50 mg, 100 mg

VII. References

1. Viagra Prescribing Information. New York, NY: Pfizer Labs; December 2017. Available at https://www.viagra.com/. Accessed February 21, 2022.
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: 10.7326/0003-4819-151-9-200911030-00151.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy: no significant changes from previously approved corporate policy; polices combined for HIM and Commercial;	02.23.18	05.18

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Commercial: policy split from CP.CPA.277 phosphodiesterase-5 inhibitor; removed requirement that member is male as this is implied; added age; modified redirection to formulary phosphodiesterase-5 inhibitor to require that the agent being requested is a formulary agent as most formulary agent require PA, references reviewed and updated.		
Added redirection to sildenafil (generic Viagra). Modified Commercial approval duration to length of benefit.	05.23.18	08.18
2Q 2019 annual review: No clinical changes; generalized continued approval dose limit to reference health plan approved QL; references reviewed and updated.	02.04.19	05.19
2Q 2020 annual review: no significant changes; updated to template language; references reviewed and updated.	02.12.20	05.20
For Commercial ED criteria set, revised approval duration from length of benefit to "Benefit Renewal Date (quantity limits are plan specific)"; removed criteria requiring request for formulary product as criteria would also apply for non-formulary requests.	06.03.20	08.20
2Q 2021 annual review: revised medical justification language to state 'member must use'; revised reference to HIM off-label use policy from HIM.PHAR.21 to HIM.PA.154; references reviewed and updated.	01.14.21	05.21
2Q 2022 annual review: added generic redirection to Section II for continuation of therapy requests; references reviewed and updated.	02.21.22	05.22
Template changes applied to continued therapy section.	09.29.22	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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