

Clinical Policy: Sildenafil for ED (Viagra)

Reference Number: CP.PCH.07

Effective Date: 06.01.18

Last Review Date: 05.19

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 \geq 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

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and HIM.PHAR.21 for health insurance marketplace.

II. Continued Therapy

A. Erectile Dysfunction (must meet all):

1. Currently receiving medication via Centene 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

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and HIM.PHAR.21 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.PHAR.21 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	100 mg/day (25 mg/48 hours with co-

Indication	Dosing Regimen	Maximum Dose
	Co-administration of erythromycin or strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, saquinavir): consider a starting dose of 25 mg	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 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: 10.7326/0003-4819-151-9-200911030-00151.

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; 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.	02.23.18	05.18
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

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.

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Note:

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

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