Clinical Policy: Sildenafil for ED (Viagra, Vybrique)

Reference Number: CP.PCH.07
Effective Date: 06.01.18
Last Review Date: 05.26
Line of Business: Commercial, HIM/ICHRA

Revision Log

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

Description

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

FDA Approved Indication(s)

Viagra and Vybrique are 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 sildenafil (Viagra, Vybrique) 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 or Vybrique^ 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.*
   ^For Illinois HIM requests, the step therapy requirements above do not apply for Vybrique as of 1/1/2026 per IL HB 5395
4. Sildenafil (Viagra, Vybrique) is NOT prescribed concurrently with nitrates or guanylate cyclase stimulators;
5. Dose does not exceed both of the following (a and b):
   a. 100 mg per day;
   b. Health plan approved quantity limit.

Approval duration:
HIM/ICHRA – 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/ICHRA) 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/ICHRA; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) 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/ICHRA; 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/ICHRA.

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 or Vybrique^ 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.*
   ^For Illinois HIM requests, the step therapy requirements below do not apply for Vybrique as of 1/1/2026 per IL HB 5395
4. Sildenafil (Viagra, Vybrique) is NOT prescribed concurrently with nitrates or guanylate cyclase stimulators;
5. If request is for a dose increase, new dose does not exceed both of the following (a and b):
   a. 100 mg per day;
   b. Health plan approved quantity limit.

Approval duration:
HIM/ICHRA – 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/ICHRA) 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/ICHRA; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) 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/ICHRA; 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/ICHRA.

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/ICHRA 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 The maximum recommended dosing frequency is once per day	100 mg/day (25 mg/48 hours with co-administration of ritonavir)

VI. Product Availability

Drug Name	Availability
Sildenafil (Viagra)	Tablets: 25 mg, 50 mg, 100 mg
Sildenafil (Vybrique)	Oral film: 25 mg, 50 mg, 75 mg, 100 mg

VII. References

1. Viagra Prescribing Information. New York, NY: Pfizer Labs; November 2023. Available at https://www.viagra.com/. Accessed January 14, 2026.
2. Vybrique Prescribing Information. Parsippany, NJ: IBSA Pharma Inc; December 2025. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/210858s000lbl.pdf. Accessed January 14, 2026.
3. 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.
4. 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.
5. Köhler TS, Kloner RA, Rosen RC, et al. The Princeton IV consensus recommendations for the management of erectile dysfunction and cardiovascular disease. Mayo Clin Proc. 2024 Sep;99(9):1500-1517.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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 other diagnoses/indications and continued therapy section.	09.29.22	
2Q 2023 annual review: no significant changes; references reviewed and updated.	01.31.23	05.23
2Q 2024 annual review: no significant changes; references reviewed and updated.	01.08.24	05.24
2Q 2025 annual review: no significant changes; in policy/criteria description added reference to generic sildenafil as criteria would also apply; references reviewed and updated.	01.15.25	05.25
2Q 2026 annual review: no significant changes; added to continued therapy "Sildenafil (Viagra, Vybrique) is NOT prescribed concurrently with nitrates or guanylate cyclase stimulators"; references reviewed and updated. RT4: added Vybrique to criteria; references reviewed and updated. Added ICHRA line of business.	04.21.26	05.26

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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