

Drug and Biologic Coverage Policy



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Sildenafil (Viagra®)

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Related Coverage Resources

[Male Sexual Dysfunction Treatment: Non-pharmacologic](#)
[Pulmonary Hypertension \(PH\) Therapy](#)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for sildenafil (**Viagra®**).

The use of sildenafil (Revatio®) for pulmonary hypertension is addressed in a separate coverage policy. Please refer to the related coverage policy link above.

Coverage for brand Viagra varies across plans and may require the use of Step Therapy in accordance with benefit plan specifications. Refer to the customer's benefit plan document for coverage details.

For plans that do NOT include coverage for sexual dysfunction, medical necessity review may be required in addition to the Step Therapy requirements for non-sexual dysfunction uses. Refer to the customer's benefit plan document for coverage details.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Sildenafil (Viagra) is considered medically necessary when the individual meets **ONE** of the following:

1. Treatment of Erectile Dysfunction.

Erectile Dysfunction therapy is specifically excluded under many benefit plans [both Employer Groups and Individual and Family Plans]. Please refer to the applicable benefit plan document to determine benefit availability and the terms and conditions of coverage (for example, quantity limitations).

Sildenafil (Viagra) for Use as Needed for Erectile Dysfunction

Where covered, a maximum quantity limitation up to 8 tablets per 30 days is allowed

Employer Group Non-Covered Products and Criteria:

Non-Covered Product	Criteria
Viagra (sildenafil)	Trial of sildenafil (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction

2. Treatment of Benign Prostatic Hyperplasia (BPH). Individual meets the following criteria:

A. Documentation of failure, contraindication, or intolerance to **ONE** of the following:

- i. Alpha1-blocker
- ii. 5 alpha-reductase inhibitor
- iii. 5 alpha-reductase inhibitor/alpha1-blocker combination product

3. Treatment of Raynaud's Phenomenon. Individual meets the following criteria:

A. Documentation of failure, contraindication, or intolerance to **ONE** calcium channel blocker

4. Prophylaxis after Radical Prostatectomy (Early Penile Rehabilitation). Individual meets **ALL** of the following criteria:

- A. Documentation of radical prostatectomy within the previous 12 months
- B. Medication is prescribed by, or in consultation with, an urologist

5. Prevention or Treatment of High-Altitude Pulmonary Edema (HAPE). Individual meets **ALL** of the following criteria:

- A. Documented diagnosis of HAPE or history of HAPE
- B. Documentation of failure, contraindication, or intolerance to **ONE** other pharmacologic therapy for the treatment or prevention of HAPE

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of sildenafil (Viagra) is considered medically necessary when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months.

Reauthorization approval duration:

- 1. Erectile Dysfunction: up to 12 months

2. Benign Prostatic Hyperplasia: up to 12 months
3. Raynaud's Disease: up to 12 months
4. Prophylaxis After Radical Prostatectomy: not applicable for continuation beyond initial 12 months
5. High-altitude Pulmonary Edema (HAPE): not applicable for continuation beyond initial 12 months

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven.

Background

OVERVIEW

Sildenafil (Viagra, generic) are indicated for the treatment of **erectile dysfunction**.¹

Sildenafil has been studied for other indications.

- **Benign Prostatic Hyperplasia.** The European Association of Urology guidelines (2022) note that phosphodiesterase type 5 inhibitors can be used in men with moderate-to-severe lower urinary tract symptoms with or without erectile dysfunction.⁹ The guidelines add that based on the results from a meta-analysis⁸, younger men with lower body mass index and more severe lower urinary tract symptoms benefit the most from phosphodiesterase type 5 inhibitors.
- **High-Altitude Pulmonary Edema.** Published guidelines for the prevention of high-altitude pulmonary edema recommend nifedipine as the preferred pharmacologic treatment option.¹² Other pharmacologic therapies include salmeterol, tadalafil, sildenafil, dexamethasone, or acetazolamide.
- **Prophylaxis after Radical Prostatectomy.** Viagra given on a daily basis has been used to improve the return of normal spontaneous erectile function, improve tissue oxygenation, and prevent penile fibrosis after nerve-sparing radical prostatectomy.^{10,11} It is better to initiate a penile rehabilitation program as soon as possible after surgery in order to limit and prevent postoperative local hypoxxygenation and fibrosis.
- **Pulmonary Arterial Hypertension.** Sildenafil tablets (Revatio[®]) are approved for pulmonary arterial hypertension.² Sildenafil (Viagra, generics) are available in 25 mg, 50 mg, and 100 mg tablets, and Revatio is available as 20 mg tablets. Viagra has been used for this diagnosis.^{3,4} Doses of Viagra that were used in these reports ranged from 25 mg twice daily to 100 mg five times daily. Patients will have usually been started on Revatio 20 mg three times daily.
- **Raynaud's Phenomenon.** There are studies which show sildenafil has been beneficial in patients with Raynaud's phenomenon.^{5,6} Guidelines from the European League against Rheumatism (EULAR) on the treatment of systemic sclerosis (2023) recommend considering dihydropyridine calcium channel blockers (CCBs), usually oral nifedipine, for first-line therapy of Raynaud's phenomenon in patients with systemic sclerosis.⁷ Phosphodiesterase type 5 inhibitors should also be considered in such clinical scenarios.

References

1. Viagra tablets [prescribing information]. New York, NY: Pfizer; December 2017.
2. Revatio[®] tablets [prescribing information]. New York, NY: Pfizer; January 2023.
3. Garg N, Sharma MK, Sinha N. Role of oral sildenafil in severe pulmonary arterial hypertension: Clinical efficacy and dose response relationship. *Int J Cardiol.* 2007;120:306-313.
4. Galié N, Ghofrani HA, Torbicki A, et al; Sildenafil Use in Pulmonary Arterial Hypertension (SUPER) Study Group. Sildenafil citrate therapy for pulmonary arterial hypertension. *N Engl J Med.* 2005;353:2148-2157.
5. Fernandez-Codina A, Canas-Ruano E, Pope JE. Management of Raynaud's phenomenon in systemic sclerosis-a practical approach. *J Scleroderm Relat Disord.* 2019;4(2):102-110.
6. Hinze AM, Wigley FM. Pharmacotherapy options in the management of Raynaud's phenomenon. *Curr Treat Opt Rheumatol.* 2018;4(3):235-254.
7. Del Galdo F, Lescoat A, Conaghan PG, et al. 2023 Update of EULAR recommendations for the treatment of systemic sclerosis. *Ann Rheum Dis.* 2023;82:154-155.

8. Gacci M, Corona G, Salvi M, et al. A systematic review and meta-analysis on the use of phosphodiesterase 5 inhibitors alone or in combination with α -blockers for lower urinary tract symptoms due to benign prostatic hyperplasia. *Eur. Urol.* 2012;61:994-1003.
9. Gravas S, Cornu JN, Gacci C, et al. Management of non-neurogenic male lower urinary tract symptoms (LUTS). © European Association of Urology 2022. Available at: <http://uroweb.org/guideline/treatment-of-non-neurogenic-male-luts/> Accessed on October 26, 2023.
10. Bannowsky A, Schulze H, van der Horst C, et al. Recovery of erectile function after nerve-sparing radical prostatectomy: improvement with nightly low-dose sildenafil. *BJU Int.* 2008;101:1279-1283.
11. Bratu O, Oprea I, Marcu D, et al. Erectile dysfunction post-radical prostatectomy- a challenge for both patient and physician. *J Med Life.* 2017;10(1):13-18.
12. Luks AM, Auerbach PS, Freer L, et al. Wilderness Medical Society Consensus Guidelines for the Prevention and Treatment of Acute Altitude Illness: 2019 Update. Available at: [https://www.wemjournal.org/article/S1080-6032\(19\)30090-0/fulltext](https://www.wemjournal.org/article/S1080-6032(19)30090-0/fulltext). Accessed on October 26, 2023.

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