



## PRIOR AUTHORIZATION POLICY

- POLICY:** Erectile Dysfunction – Vardenafil Prior Authorization Policy
- Levitra® (vardenafil tablets – GlaxoSmithKline, generic)
  - Staxyn™ (vardenafil orally disintegrating tablet – GlaxoSmithKline, generic)

**REVIEW DATE:** 11/12/2025

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### **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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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.

### **CIGNA NATIONAL FORMULARY COVERAGE:**

#### **OVERVIEW**

Vardenafil tablets (Levitra, generic) and vardenafil orally disintegrating tablets (Staxyn, generic), phosphodiesterase type 5 inhibitors, are indicated for the treatment of **erectile dysfunction**.<sup>1,2</sup>

Vardenafil has been studied for other uses.

- **Benign Prostatic Hyperplasia.** Vardenafil has been studied in benign prostatic hyperplasia.<sup>5,6</sup> The European Association of Urology guidelines (2024) note that phosphodiesterase type 5 inhibitors can be used in men with moderate-to-severe lower urinary tract symptoms with or without erectile dysfunction.<sup>7</sup> The guidelines add that based on the results from a meta-analysis<sup>8</sup>, younger men with lower body mass index and more severe

lower urinary tract symptoms benefit the most from treatment with phosphodiesterase type 5 inhibitors.

- **Prophylaxis after Radical Prostatectomy.** Vardenafil was studied in men following bilateral nerve-sparing radical prostatectomy.<sup>9</sup>
- **Raynaud's Phenomenon.** Vardenafil has been studied in patients with Raynaud's phenomenon.<sup>3,4</sup> Vardenafil improved digital blood flow and decreased the number of Raynaud's attacks. 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.<sup>10</sup> Phosphodiesterase type 5 inhibitors should also be considered in such clinical scenarios.

## **POLICY STATEMENT**

Prior Authorization is recommended for prescription benefit coverage of vardenafil tablets and vardenafil orally disintegrating tablets. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with vardenafil as well as the monitoring required for adverse events and long-term efficacy, some approvals require vardenafil to be prescribed by or in consultation with a physician who specializes in the condition being treated.

- **Levitra® (vardenafil tablets - GlaxoSmithKline, generic)**
- **Staxyn™ (vardenafil orally disintegrating tablet - GlaxoSmithKline, generic)**

**is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):**

### **FDA-Approved Indication**

- 1. Erectile Dysfunction.** Approve for 1 year.

### **Other Uses with Supportive Evidence**

- 2. Benign Prostatic Hyperplasia.** Approve for 1 year if the patient meets ONE of the following (A or B):

Note: For men with erectile dysfunction and benign prostatic hyperplasia, use criterion 1 above.

**A)** Patient has tried an alpha-1 ( $\alpha$ 1) blocker; OR

Note: Examples of alpha-1 ( $\alpha$ 1) blockers include doxazosin, terazosin, tamsulosin, and alfuzosin.

**B)** Patient has tried a 5 $\alpha$ -reductase inhibitor.

Note: Examples of 5 $\alpha$ -reductase inhibitor include finasteride and dutasteride.

- 3. Prophylaxis After Radical Prostatectomy (Early Penile Rehabilitation).**

Approve for 1 year if the patient meets BOTH of the following (A and B):

- A) Patient had a radical prostatectomy within the previous 12 months; AND
- B) The medication is prescribed by or in consultation with a urologist.

**4. Raynaud's Phenomenon.** Approve for 1 year if the patient meets ONE of the following (A or B):

- A) Patient has tried at least one calcium channel blocker; OR  
Note: Examples of calcium channel blockers include amlodipine, felodipine, and nifedipine.
- B) According to the prescriber, use of a calcium channel blocker is contraindicated.  
Note: Examples of reasons a patient cannot take a calcium channel blocker include right heart failure and decreased cardiac output.

### CONDITIONS NOT COVERED

- **Levitra® (vardenafil tablets - GlaxoSmithKline, generic)**
- **Staxyn™ (vardenafil orally disintegrating tablet - GlaxoSmithKline, generic)**

**is(are) considered not medically necessary for ANY other use(s); criteria will be updated as new published data are available.**

### REFERENCES

1. Vardenafil hydrochloride tablet tablets [prescribing information]. Bridgewater, NJ: Alembic; March 2023.
2. Vardenafil orally disintegrating tablets [prescribing information]. Bridgewater, NJ: Alembic; September 2023.
3. Caglayan E, Huntgeburth M, Karasch T, et al. Phosphodiesterase type 5 inhibition is a novel therapeutic option in Raynaud disease. *Arch Intern Med.* 2006;166:231-233.
4. Caglayan E, Axmann S, Hellmich M, et al. Research Letter. Vardenafil for the treatment of Raynaud Phenomenon: a randomized, double-blind, placebo-controlled crossover study. *Arch Intern Med.* 2012;172:1182-1184.
5. Stief CG, Porst H, Neuser D, et al. A randomised, placebo-controlled study to assess the efficacy of twice-daily vardenafil in the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia. *Eur Urol.* 2008;53:1236-1244.
6. Gacci M, Vittori G, Tosi N, et al. A randomized, placebo-controlled study to assess safety and efficacy of vardenafil 10 mg and tamsulosin 0.4 mg vs. tamsulosin 0.4 mg alone in the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia. *J Sex Med.* 2012;9:1624-1633.
7. Cornu JH, Gacci M, Hashim H, et al. Guidelines on the management of non-neurogenic male lower urinary tract symptoms (LUTS). © European Association of Urology 2024. Available at: <https://uroweb.org/guidelines/management-of-non-neurogenic-male-luts>. Accessed on November 6, 2025.
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  $\alpha$ -blockers for lower urinary tract symptoms due to benign prostatic hyperplasia. *Eur. Urol.* 2012;61:994-1003.
9. Montorsi F, Brock G, Lee J, et al. Effect of nightly versus on-demand vardenafil on recovery of erectile function in men following bilateral nerve-sparing radical prostatectomy. *Eur Urol.* 2008;54:924-931.
10. 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.

## HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	11/01/2023
Annual Revision	No criteria changes.	11/06/2024
Annual Revision	No criteria changes.	11/12/2025

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