



PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 11/01/2023

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CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Vardenafil (Levitra, generic) and vardenafil orally disintegrating tablets (Staxyn, generic) are indicated for the treatment of **erectile dysfunction**.^{1,2}

Vardenafil has been studied for other indications:

- **Benign Prostatic Hyperplasia.** Vardenafil has been studied in benign prostatic hyperplasia.^{5,6} 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.⁷ 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 benefits the most from phosphodiesterase type 5 inhibitors.
- **Prophylaxis after Radical Prostatectomy.** Vardenafil was studied in men following bilateral nerve-sparing radical prostatectomy.⁹
- **Raynaud's Phenomenon.** Vardenafil has been studied in patients with Raynaud's phenomenon.^{3,4} 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.¹⁰ 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 Indications

- 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 (α 1) blocker; OR

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

B) Patient has tried a 5 α -reductase inhibitor.

Note: Examples of 5 α -reductase inhibitor includes finasteride, dutasteride.

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

Approve for 1 year in patients who meet the following (A and B):

A) Patient had radical prostatectomy within the previous 12 months; AND

B) The medication is prescribed by or in consultation with an urologist.

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

A) Patient has tried one calcium channel blocker; OR

Note: Examples of calcium channel blockers include amlodipine, felodipine, nifedipine.

B) According to the prescriber, use of a calcium channel blocker is contraindicated.

Note: Examples of reasons a patient cannot take calcium channel blocker therapy include right heart failure or decreased cardiac output.

CONDITIONS NOT COVERED

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

is(are) considered experimental, investigational or unproven for ANY other use(s).

REFERENCES

1. Vardenafil hydrochloride tablet tablets [prescribing information]. Bridgewater, NJ: Alembic Pharmaceuticals; March 2023.
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HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Raynaud's Phenomenon: Updated criteria to require a trial of one calcium channel blocker unless, according to the prescriber, use of a calcium channel is contraindicated. Previously a trial of at least two of the following therapies were needed: calcium channel blocker, alpha-adrenergic blockers, nitroglycerin, losartan, fluoxetine, or angiotensin-converting enzyme inhibitors OR a trial of one vasodilator.	10/12/2022

Annual Revision	No criteria changes.	11/01/2023
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