

PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 11/06/2024

OVERVIEW

Vardenafil tablets (Levitra, generic) and vardenafil orally disintegrating tablets (Staxyn, generic), phosphodiesterase type 5 inhibitors, 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 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.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.

Automation: When available, the ICD-10 codes for male erectile dysfunction (ICD-10: N52.*) will be used for automation to allow approval of the requested medication. This automation is gender-selective and is not applicable for women; approval for use in women is always determined by Prior Authorization criteria.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of vardenafil is recommended in those who meet one of the following criteria:

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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 (α 1) blocker; OR

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

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

Note: Examples of 5 α -reductase inhibitor includes 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 RECOMMENDED FOR APPROVAL

Coverage of vardenafil is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

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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.

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