

## PRIOR AUTHORIZATION POLICY

**POLICY:** Erectile Dysfunction – Vardenafil (Levitra, Staxyn) Prior Authorization Policy

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

**REVIEW DATE:** 10/13/2021

---

### OVERVIEW

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

Vardenafil has been studied for other indications:

- **Benign Prostatic Hyperplasia.** Vardenafil has been studied in benign prostatic hyperplasia.<sup>5,6</sup> The European Association of Urology guidelines (2021) 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 benefits the most from phosphodiesterase type 5 inhibitors.
- **Prophylaxis after Radical Prostatectomy.** Vardenafil was studied in men following bilateral nerve-sparing radical prostatectomy.<sup>9</sup>
- **Raynaud Phenomenon.** Vardenafil has been studied in patients with Raynaud phenomenon.<sup>3,4</sup> Levitra improved digital blood flow and decreased the number of Raynaud's attacks.

### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of vardenafil tablets (Levitra, generic) and vardenafil orally disintegrating tablets (Staxyn, generic). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with vardenafil tablets (Levitra, generic) and vardenafil orally disintegrating tablets (Staxyn, generic) as well as the monitoring required for adverse events and long-term efficacy, some approvals require vardenafil tablets (Levitra, generic) and vardenafil orally disintegrating tablets (Staxyn, generic) 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.

**Note:** Phosphodiesterase type 5 inhibitors should not be administered, either regularly or intermittently, with concomitant nitrate therapy. Patients will be informed of the consequences should they initiate nitrate therapy while taking a phosphodiesterase type 5 inhibitor.

---

### RECOMMENDED AUTHORIZATION CRITERIA

Coverage of vardenafil tablets (Levitra, generic) or vardenafil orally disintegrating tablet (Staxyn, generic) is recommended in those who meet one of the following criteria:

#### 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 criteria (A or B):

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

- A) Patient has tried an  $\alpha_1$ -blocker; OR

Note: Examples of  $\alpha_1$ -blockers include doxazosin, terazosin, tamsulosin, alfuzosin.

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

Note: Examples of  $5\alpha$ -reductase inhibitor includes finasteride, dutasteride.

3. **Prophylaxis After Radical Prostatectomy (Early Penile Rehabilitation).** Approve for 1 year in patients who meet the following criteria (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 criteria (A or B):

- A) Patient has tried at least two of the following therapies: calcium channel blockers,  $\alpha$ -adrenergic blockers, nitroglycerin, losartan fluoxetine, or angiotensin converting enzyme (ACE) inhibitors; OR

Note: Examples of calcium channel blockers include amlodipine, felodipine, nifedipine. Examples of  $\alpha$ -adrenergic blockers include prazosin, doxazosin. Examples of ACE inhibitors include lisinopril, benazepril, captopril, enalapril.

- B) Patient has tried one vasodilator.

Note: Examples of vasodilators include Flolan (epoprostenol for injection), Edex (alprostadil for injection), Tracleer (bosentan tablets).

### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of vardenafil (Levitra, generic) or vardenafil orally disintegrating tablets (Staxyn, generic) 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

1. Vardenafil hydrochloride tablet tablets [prescribing information]. Bridgewater, NJ: Alembic Pharmaceuticals Limited; November 2020.
  2. Vardenafil orally disintegrating tablets [prescribing information]. Bridgewater, NJ: Alembic Pharmaceuticals Limited; October 2019.
  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. Gravas S, Cornu JN, Gacci C, et al. Management of non-neurogenic male lower urinary tract symptoms (LUTS). © European Association of Urology 2021. Available at: <http://uroweb.org/guideline/treatment-of-non-neurogenic-male-luts/> Accessed on September 8, 2021.
  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.
-