Drug Coverage Policy

Effective Date 5/1/2024
Coverage Policy Number.....IP0099

Erectile Dysfunction – Vardenafil

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

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 and have discretion in making individual coverage determinations. 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.

Medical Necessity Criteria

Vardenafil (Levitra, Staxyn) is considered medically necessary for the treatment of erectile dysfunction. However, 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).

Coverage for vardenafil (Levitra, or Staxyn) 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.

Vardenafil (Levitra or Staxyn) for Use as Needed for Erectile Dysfunction
Where covered, a maximum quantity limitation up to 8 tablets per 30 days is allowed

When coverage requires the use of Step Therapy, there is documentation that the individual has had significant intolerance to the number of covered alternatives according to the table below:

Employer Step Therapy Criteria:

	Criteria:
Levitra or Staxyn	Trial of **vardenafil** (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

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Vardenafil (Levitra, Staxyn) is considered medically necessary when the following criteria are met:

1. **Benign Prostatic Hyperplasia.** Individual meets **ALL** of the following criteria:
   A. Documentation of **ONE** of the following:
      i. Inadequate response to **ONE** of the following:
         a. Alpha$_1$-blocker
         b. 5 alpha-reductase inhibitor
         c. 5 alpha-reductase inhibitor/alpha$_1$-blocker combination product
      ii. Failure, contraindication, intolerance to **BOTH** alpha$_1$-blockers and 5 alpha-reductase inhibitors

2. **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

3. **Raynaud's Phenomenon.** Individual meets the following criteria:
   A. Documentation of failure, contraindication, or intolerance, to **ONE** calcium channel blocker

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.

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

Reauthorization Criteria

Continuation of Vardenafil (Levitra, Staxyn) is considered medically necessary for erectile dysfunction, BPH, Raynaud's disease, or prophylaxis after radical prostatectomy when initial criteria are met AND beneficial response is demonstrated.

Authorization Duration

Initial approval duration is up to 12 months.
Reauthorization approval duration:

- Erectile Dysfunction: up to 12 months
- Benign Prostatic Hyperplasia: up to 12 months
- Raynaud's Disease: up to 12 months
- Prophylaxis After Radical Prostatectomy: not applicable for continuation beyond initial 12 months

Conditions Not Covered

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

Background

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-analysis[8], 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.

References

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

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	No criteria changes	5/1/2024

The policy effective date is in force until updated or retired.