Clinical Guideline

Guideline Number: PG052, Ver. 1

tadalafil

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Oscar may delegate utilization management decisions of certain services to third-party delegates who may develop and adopt their own clinical criteria.

The clinical guidelines are applicable to all commercial plans. Services are subject to the terms, conditions, limitations of a member's plan contracts, state laws, and federal laws. Please reference the member's plan contracts (e.g., Certificate/Evidence of Coverage, Summary/Schedule of Benefits) or contact Oscar at 855-672-2755 to confirm coverage and benefit conditions.

Summary

Tadalafil is a selective phosphodiesterase type 5 (PDE5) inhibitor. It is administered orally for the treatment of pulmonary arterial hypertension (PAH), male erectile dysfunction (ED), benign prostatic hyperplasia (BPH), or the concurrent treatment of ED and BPH. Taladfil comes in the following drug strengths: 2.5 mg tablets, 5 mg tablets, 10 mg tablets, and 20 mg tablets. There are specific formulations of tadafi 20 mg tablets for the treatment of PAH including Adcirca (brand), Alyq (generic), and tadalafil 20 mg. Tadalafil 20 mg tablets for the treatment of PAH are specifically labeled as such and include the following NDCs: 27241-0123-02, 65862-0880-60, 42291-0804-60, 31722-0647-30, 69097-0526-03, 43598-0578-60, 00378-6976-91, and 13668-0581-30. Tadalafil 20 mg tablets for the treatment of PAH has the following GPI: 401430800003**.

Tadalafil 2.5 mg and 5 mg are FDA indicated in the treatment of BPH. All strengths of tadalafil are FDA indicated in the treatment of ED. Tadalafil 20 mg is FDA indicated for the treatment of PAH (see specific NDCs and GPI above). Erectile dysfunction is an excluded benefit in certain states. Please review the member's coverage benefits to determine if erectile dysfunction is a covered benefit.

Definitions

"Benign prostatic hyperplasia (BPH)" is a histologic diagnosis that refers to the proliferation of glandular epithelial tissue, smooth muscle, and connective tissue within the prostatic transition zone.

"Erectile Dysfunction" is the consistent or recurrent inability to acquire or sustain an erection of sufficient rigidity and duration for sexual intercourse.

"Pulmonary arterial hypertension (PAH)" is a subset of pulmonary hypertension (PH). Pulmonary hypertension is classified into five groups based upon etiology. Patients in the first group are considered to have PAH, whereas patients in the remaining four groups are considered to have PH.

Erectile Dysfunction:

Medical Necessity Criteria for Initial Authorization

Oscar covers tadalafil tablets (all strengths) when ALL of the following criteria are met:

1. Member is 18 years of age and older; *and*
2. Erectile dysfunction is a covered benefit on the member's plan.

If the above prior authorization criteria are met, the requested medication will be approved for 12 months.

Medical Necessity Criteria for Reauthorization:

Oscar covers tadalafil tablets (all strengths) when ALL of the following criteria are met:

1. Initial Authorization requirements are met.

If the above prior authorization criteria is met, the requested medication will be approved for 12 months.

Benign prostatic hyperplasia (BPH):

Medical Necessity Criteria for Initial Authorization

Oscar covers tadalafil 2.5 mg and 5 mg tablets when ALL of the following criteria are met:

1. Member is 18 years of age and older; *and*
2. Member has a diagnosis of BPH; *and*
3. Member has tried and failed or has a contraindication or intolerance to an alpha blocker (i.e. alfuzosin, doxazosin, tamsulosin, terazosin); *and*
4. Member has tried and failed or has a contraindication or intolerance to a 5-alpha reductase inhibitor (i.e. dutasteride, finasteride).

If the above prior authorization criteria are met, the requested medication will be approved for 12 months.

Medical Necessity Criteria for Reauthorization:

Oscar covers tadalafil 2.5 mg and 5 mg tablets when ALL of the following criteria are met:

1. Documentation of clinical benefit on the medication.

If the above prior authorization criteria is met, the requested medication will be approved for 12 months.

Pulmonary Arterial Hypertension (PAH):

Medical Necessity Criteria for Initial Authorization

Oscar covers tadalafil 20 mg tablets (PAH) when ALL of the following criteria are met:

1. Member has PAH defined as WHO Group 1 class of of pulmonary hypertension; *and*
2. PAH confirmed by ONE of the following:
    a. Pretreatment right heart catheterization with ALL of the following: mean pulmonary artery pressure (mPAP) $\geq$ 25 mmHg, pulmonary capillary wedge pressure (PCWP) $\leq$ 15 mmHg, pulmonary vascular resistance (PVR) > 3 Wood units
    b. For infants less than one year of age with post cardiac surgery, chronic heart disease, chronic lung disease associated with prematurity, or congenital diaphragmatic hernia:
        i. PAH was confirmed by Doppler echocardiogram if right heart catheterization cannot be performed

If the above prior authorization criteria are met, the requested medication will be approved for 12 months.

Medical Necessity Criteria for Reauthorization:

Oscar covers tadalafil 20 mg tablets (PAH) when ALL of the following criteria are met:

1. Documentation of clinical benefit as evidenced by disease stability or disease improvement.

If the above prior authorization criteria is met, the requested medication will be approved for 12 months.

Experimental or Investigational / Not Medically Necessary

Tadalafil for any other indication is *not covered* by Oscar as it is considered experimental, investigational, or unproven.

References

1. Adcirca (tadalafil) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; December 2019.
2. Black L, Naslund MJ, Gilbert TD Jr, et al. An examination of treatment patterns and costs of care among patients with benign prostatic hyperplasia. Am J Manag Care 2006; 12:S99.
3. Cialis (tadalafil) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; February 2018.
4. Nickel JC, Gilling P, Tammela TL, et al. Comparison of dutasteride and finasteride for treating benign prostatic hyperplasia: the Enlarged Prostate International Comparator Study (EPICS). BJU Int 2011; 108:388.
5. Roehrborn CG, Nuckolls JG, Wei JT, et al. The benign prostatic hyperplasia registry and patient survey: study design, methods and patient baseline characteristics. BJU Int 2007; 100:813.
6. Wei JT, Calhoun E, Jacobsen SJ. Urologic diseases in America project: benign prostatic hyperplasia. J Urol 2005; 173:1256.

Clinical Guideline Revision / History Information

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