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Clinical Guideline

Guideline Number: PG052, Ver. 4

tadalafil

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

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. There is also evidence to support the use of tadalafil in certain patients with a condition called Raynaud phenomenon (also referred to as idiopathic Raynaud phenomenon, primary Raynaud syndrome, or Raynaud disease).

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 with certain drug identifier codes.

- Tadalafil 2.5 mg and 5 mg are FDA indicated in the treatment of BPH.
- Tadalafil 20 mg is FDA indicated for the treatment of PAH.
- All strengths of tadalafil are FDA indicated in the treatment of ED.
- Tadalafil 20 mg is also used off-label for Raynaud phenomenon.

NOTE: Erectile dysfunction is an excluded benefit for certain Plans. Coverage for medications to treat sexual dysfunction, including erectile dysfunction, varies depending on a member's benefit policy. 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 prostate 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.

"**Raynaud phenomenon (RP)**" is a condition which causes the blood vessels that carry blood to the fingers and toes (sometimes even the ears, lips, nipples, and tip of the nose) to narrow for a time, leading to color changes in the skin, numbness, tingling, and other potential complications.

For the treatment of Erectile Dysfunction (if a covered benefit for the member):

Medical Necessity Criteria for Initial Authorization

The Plan considers tadalafil tablets (all strengths) medically necessary when ALL the following criteria are met:

1. the member is 18 years of age and older; ***AND***
2. the member is a male with erectile dysfunction (ED, impotence); ***AND***
3. clinical chart document is provided showing ALL of the following:
    a. a thorough medical history and physical examination has been undertaken to:
        i. support the diagnosis of erectile dysfunction**; *and***
        ii. determine potential underlying causes**; *and***
        iii. exclude potentially reversible or treatable causes (e.g., hypogonadism with inadequate testosterone replacement, hyperprolactinemia, drug-induced dysfunction, dyslipidemias, alcoholism, other substance abuse, hypertension,

thyroid disease, cardiovascular or cerebrovascular disease, neurologic disease, adrenal dysfunction, psychologic dysfunction, marital discord, smoking)**; *and***

b. a review of the patient's current drug regimens have been conducted to detect possible drug-induced ED (e.g., antidepressant, antipsychotic, certain blood pressure medications); ***AND***

4. The member will not be taking sildenafil concomitantly with ANY of the following:
    a. Guanylate Cyclase Stimulators (such as Adempas (riociguat))**; *or***
    b. Nitrates and nitrites (e.g., nitroglycerin, isosorbide dinitrate)

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

Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted if BOTH of the following are met:

1. the member still meets the applicable initial criteria; ***AND***
2. chart documentation shows the member has experienced a clinical improvement in symptoms since starting the requested medication.

For the treatment of Benign Prostatic Hyperplasia (BPH):

Medical Necessity Criteria for Initial Authorization

The Plan considers tadalafil 2.5 mg and 5 mg tablets medically necessary when ALL the following criteria are met:

1. The member is 18 years of age and older; ***AND***
2. The member has a confirmed diagnosis of BPH; ***AND***
3. The member has tried and failed, or is unable to use an alpha blocker (i.e. alfuzosin, doxazosin, tamsulosin, terazosin); ***AND***
4. The member has is unable to use, or has tried and failed a 5-alpha reductase inhibitor (i.e. dutasteride, finasteride); ***AND***
5. Chart documentation and supporting labwork are provided for review to substantiate the above listed requirements.

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

Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted if BOTH of the following are met:

1. the member still meets the applicable initial criteria; ***AND***
2. chart documentation shows the member has experienced a clinical improvement in symptoms since starting the requested medication.

For the treatment of Pulmonary Arterial Hypertension (PAH):

Medical Necessity Criteria for Initial Authorization

The Plan considers tadalafil 20 mg tablets (PAH) medically necessary when ALL of the following criteria are met:

1. The member has a diagnosis of PAH defined as WHO Group 1 class pulmonary hypertension; ***AND***
2. The diagnosis of PAH has been confirmed by ONE of the following methods:
    a. Pre-treatment right heart catheterization with ALL of the following:
        i. mean pulmonary artery pressure (mPAP) ≥ 20 mmHg**; *and***
        ii. pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg**; *and***
        iii. pulmonary vascular resistance (PVR) ≥ 3 Wood units**; *or***
    b. Doppler echocardiogram if right heart catheterization cannot be performed (e.g., 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); ***AND***
3. Chart documentation and supporting labwork are provided for review to substantiate the above listed requirements.

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

Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted if BOTH of the following are met:

1. the member still meets the applicable initial criteria**; *AND***
2. recent chart documentation shows the member experiencing therapeutic response to the requested medication as evidenced by ONE of the following:
    a. clinical improvement in symptoms since starting the requested medication**; *or***
    b. disease stability since starting the requested medication

For the treatment of of Raynaud phenomenon:

Medical Necessity Criteria for Initial Authorization

The Plan considers tadalafil 20 mg tablets medically necessary when ALL of the following criteria are met:

1. The medication is being requested for the treatment of Raynaud phenomenon (also called idiopathic Raynaud phenomenon, primary Raynaud syndrome, or Raynaud disease); ***AND***
2. The member has documented history of ONE of the following:
    a. signs of critical ischemia at the affected areas (e.g., fingers, toes, ears, lips, nipples, or the tip the nose)**; *or***

b. the quality of life of the member is affected to the degree that activities of normal living are no longer possible; ***AND***

3. The member is unable to use, or has tried and failed BOTH of the following:
    a. non-pharmacologic therapies (e.g., relaxation techniques, avoiding stressful situations, avoiding cold exposure, avoiding drugs that may precipitate RP)***; and***
    b. calcium channel blocker (e.g., amlodipine, nifedipine); ***AND***
4. Chart documentation is provided for review to substantiate the above listed requirements.

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

Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted if BOTH of the following are met:

1. the member still meets the applicable initial criteria; ***AND***
2. chart documentation shows the member has experienced a clinical improvement in symptoms, quality of life, or experienced disease stability since starting the requested medication.

Experimental or Investigational / Not Medically Necessary

Tadalafil for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

References

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Clinical Guideline Revision / History Information

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