Oscar Clinical Guideline: sildenafil (LiQrev, Revatio, Viagra) (PG051, Ver. 5)

sildenafil (LiQrev, Revatio, Viagra)

- Sildenafil Citrate Oral suspension [Pulmonary Hypertension] (LiQrev)
- Sildenafil Citrate Powder for oral suspension [Pulmonary Hypertension] (Revatio)
- Sildenafil Citrate Oral tablet [Pulmonary Hypertension] (Revatio)
- Sildenafil Citrate Oral tablet (Viagra)

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

Sildenafil is a selective phosphodiesterase type 5 (PDE5) inhibitor. It is administered orally for the treatment of pulmonary arterial hypertension (PAH) and male erectile dysfunction (ED). It can be administered intravenously for the treatment of PAH when the member is temporarily unable to tolerate the oral medication. There is also evidence to support the use of sildenafil in certain patients with a condition called Raynaud phenomenon (also referred to as idiopathic Raynaud phenomenon, primary Raynaud syndrome, or Raynaud disease).

Sildenafil comes in the following drug strengths and formulations: 20 mg tablets, 25 mg tablets, 50 mg tablets, 100 mg tablets, 10 mg/ml powder for suspension, 10 mg/mL oral suspension, and 10 mg/12.5 ml solution for injection.

- Sildenafil 25 mg tablets, 50 mg tablets, and 100 mg tablets are FDA indicated in the treatment of ED.
- Sildenafil 20 mg tablets, 10 mg/ml powder for suspension, 10 mg/mL oral suspension, and 10mg/12.5 ml solutions for injection are FDA indicated in the treatment of PAH.
- Sildenafil 20 mg tablets are 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 benefits policy. Please review the member's coverage benefits to determine if erectile dysfunction is a covered benefit.

Definitions

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

"Pulmonary arterial hypertension (PAH)" is a subset of pulmonary hypertension (PH), categorized into five groups based on 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 characterized by temporary narrowing of the blood vessels that supply blood to the extremities, including the fingers and toes (and sometimes the ears, lips, nipples, or tip of the nose). This leads to skin discoloration, numbness, tingling, and potentially other complications.

Clinical Indications

The Plan considers **sildenafil (LiQrev, Revatio, Viagra)** medically necessary when **ALL** the following criteria are met for the applicable indication listed below:

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

Medical Necessity Criteria for Initial Authorization

The Plan considers **sildenafil 25 mg, 50 mg, and 100 mg tablets (Viagra)** medically necessary when **ALL** of 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 documentation 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 has 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, sildenafil 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 **sildenafil 20 mg tablets, sildenafil solution, and sildenafil oral suspension (Revatio, LiQrev)** 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) $\geq$ 20 mmHg**; *and***
      ii. pulmonary capillary wedge pressure (PCWP) $\leq$ 15 mmHg**; *and***
      iii. pulmonary vascular resistance (PVR) $\geq$ 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. For sildenafil solution/suspension (Revatio, LiQrev), the member must be unable to use, or has tried and failed sildenafil 20mg tablets; ***AND***
4. Chart documentation and supporting lab work are provided for review to validate the above-listed requirements.

If the above prior authorization criteria are met, sildenafil (Revatio, LiQrev) 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 Raynaud phenomenon:

Medical Necessity Criteria for Initial Authorization

The Plan considers **sildenafil 20 mg tablets (Revatio)** 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 of 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, sildenafil 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 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

sildenafil (LiQrev, Revatio, Viagra) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

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Clinical Guideline Revision / History Information

Original Date: 08/06/2020
Reviewed/Revised: 06/24/2021, 12/01/2021, 06/23/2022, 06/29/2023