

## sildenafil

### 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. 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/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, and 10mg/12.5 ml solutions for injection are FDA indicated in the treatment of PAH. 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

"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.

For the treatment of Erectile Dysfunction:

**Medical Necessity Criteria for Initial Authorization**

The Plan considers sildenafil 25 mg, 50 mg, and 100 mg tablets medically necessary when ALL of the following criteria are met:

1. The member is 18 years of age and older; *and*
2. Erectile dysfunction is a covered benefit on the member’s plan.
3. Clinical 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 the member still meets the applicable initial criteria and has chart documentation demonstrating the following:

1. The member has shown 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 and sildenafil solution 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. Pretreatment right heart catheterization with ALL of the following:
    - i. mean pulmonary artery pressure (mPAP)  $\geq$  20 mmHg,
    - ii. pulmonary capillary wedge pressure (PCWP)  $\leq$  15 mmHg,
    - iii. pulmonary vascular resistance (PVR)  $\geq$  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. Doppler echocardiogram if right heart catheterization cannot be performed.
3. Chart documentation and supporting labwork are 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 the member still meets the initial criteria and has chart documentation demonstrating ONE of the following:

1. The member has shown a clinical improvement in symptoms since starting the requested medication.
2. The member has experienced disease stability since starting the requested medication.

### Experimental or Investigational / Not Medically Necessary

Sildenafil 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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