sildenafil (Revatio)

Commercial Medical Benefit Drug Policy

Place of Service
Home Infusion
Hospital Administration
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: RESPIRATORY TRACT/PULMONARY AGENTS
Mechanism of Action: A synthetic analog of prostacyclin
HCPCS:
C9399, J3490:sildenafil (Revatio)
How Supplied:
10 mg/12.5 mL in a single use vial

Condition(s) listed in policy *(see coverage criteria for details)*

- Pulmonary Arterial Hypertension WHO Group I

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Pulmonary Arterial Hypertension WHO Group I
Meets medical necessity if all the following are met:

1. Patient is receiving oral sildenafil
2. Patient is temporarily unable to take oral medication due to a documented medical reason

Covered Doses:
10 mg (corresponding to 12.5 ml) given intravenously three times a day

Coverage Period:
Dependent on patient's situation

ICD-10:
I27.0, I27.2, I27.89

Additional Information

Clinical classification of pulmonary hypertension (6th World Symposium on Pulmonary Hypertension)

1 PAH
1.1 Idiopathic PAH
1.2 Heritable PAH
1.3 Drug- and toxin-induced PAH
1.4 PAH associated with:
1.4.1 Connective tissue disease
1.4.2 HIV infection
1.4.3 Portal hypertension
1.4.4 Congenital heart disease
1.4.5 Schistosomiasis
1.5 PAH long-term responders to calcium channel blockers
1.6 PAH with overt features of venous/capillaries (PVOD/PCH) involvement
1.7 Persistent PH of the newborn syndrome
2 PH due to left heart disease
2.1 PH due to heart failure with preserved LVEF
2.2 PH due to heart failure with reduced LVEF
2.3 Valvular heart disease
2.4 Congenital/acquired cardiovascular conditions leading to post-capillary PH
3 PH due to lung diseases and/or hypoxia
3.1 Obstructive lung disease
3.2 Restrictive lung disease
3.3 Other lung disease with mixed restrictive/obstructive pattern
3.4 Hypoxia without lung disease
3.5 Developmental lung disorders
4 PH due to pulmonary artery obstructions
4.1 Chronic thromboembolic PH
4.2 Other pulmonary artery obstructions
5 PH with unclear and/or multifactorial mechanisms
5.1 Haematological disorders
5.2 Systemic and metabolic disorders
5.3 Others
5.4 Complex congenital heart disease

References

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3. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch

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5. Belch, J, Carlizza A, *et al.* ESVM guidelines-the diagnosis and management of Raynaud's phenomenon. *Vasa* 2017; 46 (6), 413-423. https://doi.org/10.1024/0301-1526/a000661
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8. Roustit M, Blaise S, Allanore Y, et al: Phosphodiesterase-5 inhibitors for the treatment of secondary Raynaud's phenomenon: systematic review and meta-analysis of randomised trials. Ann Rheum Dis 2013; 72(10):1696-1699. https://pubmed.ncbi.nlm.nih.gov/23426043/
9. Simonneau G, Montani D, Celermajer DS, *et al.* Haemodynamic definitions and updated clinical classification of pulmonary hypertension. *European Respiratory Journal* 2019; 53: 1801913 [https://doi.org/ 10.1183/13993003.01913-2018].

Review History

Date of Last Annual Review: 3Q2025

Changes from previous policy version:

- No clinical changes following annual review.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee