Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Sildenafil Citrate (Revatio)	MP-RX-FP-172-25	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

Service Description

This document addresses the use of *Sildenafil Citrate (Revatio)* , a drug approved by the Food and Drug Administration (FDA) for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group I) in adults to improve exercise ability and delay clinical worsening.

Background Information
Revatio (sildenafil citrate) injection is indicated for the treatment of **pulmonary arterial hypertension (PAH) (World Health Organization Group I) in adults to improve exercise ability and delay clinical worsening**. The recommended adult intravenous dosage is 10 mg three times a day as a bolus injection; oral dosing is 20 mg three times a day, titratable up to 80 mg three times a day based on symptoms and tolerability, though higher doses have not shown additional benefit in short-term studies.[1]

Clinical trials demonstrated that sildenafil significantly improves exercise capacity, as measured by the 6-minute walk distance. In one study, the mean placebo-corrected increase in walk distance at 12 weeks was 45–50 meters, with no additional benefit at doses higher than 20 mg three times daily.[1] Another study showed a 26-meter adjusted treatment difference at 16 weeks ($p = 0.0009$).[1] Sildenafil also produced a statistically significant reduction in mean pulmonary arterial pressure (mPAP) compared to placebo (mean treatment effect: -3.9 mmHg; 95% CI: -5.7, -2.1; $p = 0.00003$).[1]

Importantly, sildenafil delayed time to clinical worsening, with placebo-treated patients being three times more likely to experience a clinical worsening event than those treated with sildenafil ($p = 0.0074$).[1] These findings support its use as a disease-modifying therapy in PAH (WHO Group I) in adults.[1]

Recent randomized controlled trial data have clarified optimal dosing. A 2024 multicenter trial demonstrated that higher doses of sildenafil (up to 80 mg three times daily) were noninferior to lower doses (5 mg three times daily) for all-cause mortality, and higher doses were associated with improved time to clinical worsening and 6MWD. However, the 20 mg three times daily dose remains the standard, with titration up to 80 mg three times daily now permitted if clinically indicated, as reflected in updated regulatory guidance.[2]

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Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J3490	Unclassified drugs

ICD-10	Description
I27.20	Pulmonary hypertension, unspecified
I27.21	Secondary pulmonary arterial hypertension
I27.29	Other secondary pulmonary hypertension

Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Sildenafil Citrate (Revatio)

Note: This document addresses the clinical criteria regarding the use of sildenafil citrate injection, for intravenous use only and no other dosage forms for this drug.

A. Criteria For Initial Approval

i. Individual is diagnosed with Pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group I) confirmed by right hearth catheterization to improve exercise ability and delay clinical worsening; **AND**
ii. Individual is 18 years of age or older; **AND**
iii. Individual is unable to use oral dosage forms; **AND**
iv. Individual is not using concomitantly with organic nitrates in any form or riociguat;

OR

v. Individual is diagnosed with Pulmonary arterial hypertension (PAH) (WHO Group I) to improve exercise ability; **AND**
vi. Individual is between the ages 1-17 years old; **AND**
vii. Individual is too young to perform standard exercise testing, pulmonary hemodynamics thought to underline improvements in exercises; **AND**
viii. Individual is unable to use oral dosage forms; **AND**
ix. Individual is not using concomitantly with organic nitrates in any form or riociguat.

B. Criteria For Continuation of Therapy

i. MMM considers continuation of **Sildenafil Citrate (Revatio)** therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when there is no evidence of an unacceptable toxicity or disease progression while on the current regimen.
    a. *Doctors must provide attestation that the patient has not experienced any unacceptable toxicity, and the patient has improved clinically.*

C. Authorization Duration

a. Initial Approval Duration: 12 months
b. Reauthorization Approval Duration: 12 months

D. **Conditions Not Covered**

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

i. Requests for **Sildenafil Citrate (Revatio)** may not be approved when the above criteria (Section A: Criteria for Initial Approval) are not met and for all other indications.

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Limits or Restrictions

A. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Limit
Revatio (Sildenafil Citrate)	10mg/ 12.5mL single-use vial.
Exceptions	
Describe any exceptions, such as limits applicable to loading doses or starter packs.	

Reference Information

1. Revatio. FDA Drug Label.
2. Hoeper MM, Ewert R, Jansa P, Sirenko Y, Skride A, Balagtas C, Hackley S, Vogt S, Abreu P, Haughie S, Hassan T, Oudiz RJ. Randomized, Multicenter Study to Assess the Effects of Different Doses of Sildenafil on Mortality in Adults With Pulmonary Arterial Hypertension. Circulation. 2024 Jun 18;149(25):1949-1959. doi: 10.1161/CIRCULATIONAHA.123.068107. Epub 2024 May 16. PMID: 38752352.

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Policy Inception 6/10/2025	MMM Developed Medical Policy.	7/17/2025	8/8/2025