

Utilization Management and Clinical Medical Policy

Policy Name: Sildenafil Citrate injection (Revatio®)	Policy Number: MP-RX-FP-172-25	Scope: <input checked="" type="checkbox"/> MMM MA <input checked="" type="checkbox"/> MMM MultiHealth	Origination Date: 8/8/2025 Last Review Date: 5/6/2026	Effective Date: 5/6/2026 Frequently Revision: Annual
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Service Category:

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| <input type="checkbox"/> Anesthesia | <input type="checkbox"/> Medicine Services and Procedures |
| <input type="checkbox"/> Surgery | <input type="checkbox"/> Evaluation and Management Services |
| <input type="checkbox"/> Radiology Procedures | <input type="checkbox"/> DME/Prosthetics or Supplies |
| <input type="checkbox"/> Pathology and Laboratory Procedures | <input checked="" type="checkbox"/> Other: Part B Drugs |

Service Description:

This document addresses the use of *Sildenafil Citrate injection (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 a phosphodiesterase-5 (PDE-5) inhibitor 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]

Sildenafil is marketed under different brand names and dosage forms that are not interchangeable because they have different FDA-approved indications, strengths, and dosing regimens. Revatio (sildenafil) is approved for pulmonary arterial hypertension (PAH; WHO Group I) and is available as oral tablets/oral suspension and as an intravenous injection; the IV formulation is typically used when oral administration is temporarily not feasible, and 10 mg IV three times daily is expected to provide an effect similar to 20 mg orally three times daily. In contrast, Viagra (sildenafil) is approved for erectile dysfunction and is supplied as oral tablets (25 mg, 50 mg, 100 mg) dosed as needed, no more than once daily. Consistent with labeling, Viagra should not be used concurrently with Revatio, and this policy covers only Revatio (sildenafil citrate) injection for its FDA-approved PAH indication; it does not provide coverage for oral sildenafil products (including Revatio tablets/oral suspension), Viagra, or other sildenafil formulations used for non-PAH indications.

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

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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]

Approved Indications

- A. Pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group I) in adults to improve exercise ability and delay clinical worsening.

Other Uses

- A. None

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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.

Revatio® (sildenafil citrate) injection

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 (Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient’s diagnosis for the drug and confirming that the patient has met **all** approval criteria.)

- i. Individual is diagnosed with Pulmonary Arterial Hypertension (PAH) (World Health Organization [WHO] Group I) confirmed by right heart catheterization; **AND**
- ii. Individual is using Revatio injection for PAH to improve exercise ability and delay clinical worsening; **AND**
- iii. Individual is 18 years of age or older; **AND**
- iv. Individual is unable or temporarily unable to use oral Revatio dosage forms (e.g., cannot take oral tablets/oral suspension due to dysphagia, NPO status, GI malabsorption, etc); **AND**
- v. Individual is not using concomitantly with organic nitrates in any form or riociguat; **AND**
- vi. Individual is not using concomitantly with other PDE-5 inhibitors (e.g., Viagra or other agents in the PDE-5 inhibitor class).

B. Criteria For Continuation of Therapy

- i. MMM considers continuation of **Sildenafil Citrate injection (Revatio)** therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval). The following documentation must be submitted:
 - A. Documentation that the individual remains temporarily unable to use oral dosage forms, and there is documentation of a clinical plan to transition to oral Revatio when feasible e.g., dysphagia, NPO status, GI malabsorption, inability to tolerate oral intake); **AND**
 - B. Documentation that the individual is not using concomitantly with organic nitrates in any form or riociguat; **AND**
 - C. Documentation that the individual is not using concomitantly with other PDE-5 inhibitors (e.g., Viagra or other agents in the PDE-5 inhibitor class); **AND**
 - D. Documentation that the patient has not experienced any unacceptable toxicity; **AND**
 - E. Documentation that the patient has demonstrated clinical improvement or stability, as evidenced by documentation of at least one of the following (as applicable): symptoms/exercise tolerance, WHO functional class, 6-minute walk distance (if measurable), PAH-related hospitalization/clinical worsening events, relevant hemodynamics, or clinician-assessed overall PAH stability.

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C. Authorization Duration

- i. Initial Approval Duration: 12 months
- ii. 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; **AND**
- ii. Requests for oral sildenafil products (including Revatio tablets/oral suspension) or Viagra are not covered under this policy; **AND**
- iii. Requests for use in pulmonary hypertension other than PAH (WHO Group I) are not covered under this policy; **AND**
- iv. Requests for concomitant use with organic nitrates, riociguat, or other PDE-5 inhibitors are not covered under this policy.

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Limits or Restrictions:

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

- i. N/A

B. 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	Dosage/Limit
Revatio (Sildenafil Citrate) injection 10mg/ 12.5mL (0.8mg/mL) single-dose vial	<ul style="list-style-type: none"> 10 mg IV administered as an intravenous bolus injection three times daily (TID) (30 mg/day). This corresponds to up to 3 single-dose vials per day.
Exceptions	
<ul style="list-style-type: none"> The dose of REVATIO injection does not need to be adjusted for body weight. A 10-mg dose of REVATIO injection is predicted to provide pharmacological effect of sildenafil and its N-desmethyl metabolite equivalent to that of a 20-mg oral dose. 	

Codes Information:

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.

ICD-10 Diagnostic Codes:

Codes	Description
I27.0	Primary pulmonary hypertension
I27.20	Pulmonary hypertension, unspecified
I27.21	Secondary pulmonary arterial hypertension
I27.29	Other secondary pulmonary hypertension

HCPCS Codes:

Codes	Description
J3490	Unclassified drugs

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Reference Information:

1. Hoepfer 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.
2. UpToDate, Inc. (n.d.). *Sildenafil: Drug information*. UpToDate. Retrieved February 16, 2026, from https://www.uptodate.com/contents/sildenafil-drug-information?search=revatio&source=panel_search_result&selectedTitle=1~134&usage_type=panel&kp_tab=drug_general&display_rank=1#F220970
3. U.S. Food and Drug Administration. (2024, December 16). *Revatio (sildenafil)* [Prescribing information]. Drugs@FDA (FDA label). Retrieved February 16, 2026, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/021845Orig1s028lbl.pdf
4. Viatrix Specialty LLC. (2024, December). *Revatio (sildenafil): Highlights of prescribing information (tablets; oral suspension; injection, for intravenous use)* [Prescribing information]. DailyMed, National Library of Medicine. Retrieved February 16, 2026, from <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=3bb9363e-b28d-4019-8aac-539233dca214&type=display>

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review	Updated the policy title to specify Revatio injection and distinguish it from oral sildenafil products. Added Approved Indications and Other Uses section. Removed pediatric criteria. Updated criteria for Continuation of Therapy, Conditions not Covered, and dosing/quantity limits table. Coding reviewed: added ICD10 code I27.0. Updated references list. Administrative update to incorporate new policy template.	5/1/2026	5/6/2026
Policy Inception	MMM Developed Medical Policy.	7/17/2025	8/8/2025