

Clinical Policy: Sildenafil (Revatio)

Reference Number: IL.PHAR.197

Effective Date: 03.16

Last Review Date: 3.29.23

Line of Business: YouthCare HealthChoice Illinois

[Coding Implications](#)
[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Sildenafil (Revatio[®]) is a phosphodiesterase-5 inhibitor.

FDA Approved Indication(s)

Revatio is indicated:

- For the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1) in adults to improve exercise ability and delay clinical worsening.
- In pediatric patients 1 to 17 years old for the treatment of PAH (WHO Group 1) to improve exercise ability and, in pediatric patients too young to perform standard exercise testing, pulmonary hemodynamics thought to underly improvements in exercise.

Policy/Criteria

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

It is the policy of health plans affiliated with Centene Corporation[®] that sildenafil is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Pulmonary Arterial Hypertension (must meet all):

1. Diagnosis of PAH;
2. Prescribed by or in consultation with a cardiologist or pulmonologist;
3. Age \geq 1 year
4. Failure of a calcium channel blocker (*see Appendix B*), unless member meets one of the following (a or b):
 - a. Inadequate response or contraindication to acute vasodilator testing;
 - b. Contraindication or clinically significant adverse effects to calcium channel blockers are experienced;
5. Request is for sildenafil 20mg tablet
**Prior authorization may be required for Revatio 10mg/mL oral susp, sildenafil 20mg tablet*
6. If request is for Revatio[®] 10mg/mL oral susp, member must be unable to ingest a solid dosage form by meeting a, b or c
 - a. Documentation why member cannot take solid dosage form (age, g-tube, etc)
 - b. Oral-motor difficulties
 - c. Dysphagia
**Prior authorization may be required for Revatio 10mg/mL oral susp, sildenafil 20mg tablet*

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7. If request is for brand Revatio® 10mg/12.5mL vial, brand Revatio® 20mg tablet, sildenafil 10mg/12.5mL vial, or sildenafil 10mg/mL oral susp there must be evidence of failure of one of the PDL drugs, used for ≥ 3 consecutive months, unless contraindicated or clinically significant adverse effects are experienced brand
8. Dose does not exceed the following (a or b):
 - a. Adult: one of the following in divided doses (i or ii):
 - i. 240 mg per day (oral formulations);
 - ii. 30 mg per day (intravenous formulations);
 - b. Pediatric: one of the following in divided doses (i, ii, iii):
 - i. Body weight ≤ 20 kg: 30 mg per day (oral formulation);
 - ii. Body weight > 20 kg to < 45 kg: 60 mg per day (oral formulation);
 - iii. Body weight ≥ 45 kg: 120 mg per day (oral formulation).

Approval duration:

Medicaid– 6 months

B. Other diagnoses/indications

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid

II. Continued Therapy

A. Pulmonary Arterial Hypertension (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, dose does not exceed the following (a and b):
 - a. Adult: one of the following in divided doses (i or ii):
 - i. 240 mg per day (oral formulations);
 - ii. 30 mg per day (intravenous formulations);
 - b. Pediatric: one of the following in divided doses (i, ii, iii):
 - i. Body weight ≤ 20 kg: 30 mg per day (oral formulation);
 - ii. Body weight > 20 kg to < 45 kg: 60 mg per day (oral formulation);
 - iii. Body weight ≥ 45 kg: 120 mg per day (oral formulation).

Approval duration:

Medicaid – 12 months

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B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FC: functional class	PAH: pulmonary arterial hypertension
FDA: Food and Drug Administration	PH: pulmonary hypertension
NYHA: New York Heart Association	WHO: World Health Organization

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
nifedipine (Adalat [®] CC, Afeditab [®] CR, Procardia [®] , Procardia XL [®])	<u>Adult:</u> 30 mg PO QD; may increase to 60 to 120 mg BID <u>Pediatric:</u> 0.3 to 0.6 mg/kg/dose PO QD; may increase to 2 to 3 mg/kg/day	<u>Adult:</u> 240 mg/day <u>Pediatric:</u> 180 mg/day
diltiazem (Dilt-XR [®] , Cardizem [®] CD, Cartia XT [®] , Tiazac [®] , Taztia XT [®] , Cardizem [®] LA, Matzim [®] LA)	<u>Adult:</u> 60 mg PO BID; may increase to 120 to 360 mg BID <u>Pediatric:</u> 0.75 mg/kg/dose PO BID; may increase to 3 to 5 mg/kg/day	<u>Adult:</u> 720 mg/day <u>Pediatric:</u> 360 mg/day

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Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
amlodipine (Norvasc [®])	<u>Adult:</u> 5 mg PO QD; may increase to 15 to 30 mg/day <u>Pediatric:</u> 0.1 to 0.3 mg/kg/dose PO QD; may increase to 2.5 to 7.5 mg/day	<u>Adult:</u> 30 mg/day <u>Pediatric:</u> 10 mg/day

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
 - Use with organic nitrates or riociguat
 - History of hypersensitivity reaction to sildenafil or any component of the tablet, injection, or oral suspension
- Boxed warning(s): none reported

Appendix D: Pulmonary Hypertension: WHO Classification

- Group 1: PAH (pulmonary arterial hypertension)
- Group 2: PH due to left heart disease
- Group 3: PH due to lung disease and/or hypoxemia
- Group 4: CTEPH (chronic thromboembolic pulmonary hypertension)
- Group 5: PH due to unclear multifactorial mechanisms

Appendix E: Pulmonary Hypertension: WHO/NYHA Functional Classes (FC)

Treatment Approach*	FC	Status at Rest	Tolerance of Physical Activity (PA)	PA Limitations	Heart Failure
Monitoring for progression of PH and treatment of co-existing conditions	I	Comfortable at rest	No limitation	Ordinary PA does not cause undue dyspnea or fatigue, chest pain, or near syncope.	
Advanced treatment of PH with PH-targeted therapy - see Appendix F**	II	Comfortable at rest	Slight limitation	Ordinary PA causes undue dyspnea or fatigue, chest pain, or near syncope.	
	III	Comfortable at rest	Marked limitation	Less than ordinary PA causes undue dyspnea or fatigue, chest pain, or near syncope.	

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Treatment Approach*	FC	Status at Rest	Tolerance of Physical Activity (PA)	PA Limitations	Heart Failure
	IV	Dyspnea or fatigue may be present at rest	Inability to carry out any PA without symptoms	Discomfort is increased by any PA.	Signs of right heart failure

*PH supportive measures may include diuretics, oxygen therapy, anticoagulation, digoxin, exercise, pneumococcal vaccination. **Advanced treatment options also include calcium channel blockers.

Appendix F: Pulmonary Hypertension: Targeted Therapies

Mechanism of Action	Drug Class	Drug Subclass	Drug	Brand/Generic Formulations	
Reduction of pulmonary arterial pressure through vasodilation	Prostacyclin* pathway agonist <i>*Member of the prostanoid class of fatty acid derivatives.</i>	Prostacyclin	Epoprostenol	Velettri (IV) Flolan (IV) Flolan generic (IV)	
		Synthetic prostacyclin analog	Treprostinil	Orenitram (oral tablet) Remodulin (IV) Tyvaso (inhalation)	
			Iloprost	Ventavis (inhalation)	
	Endothelin receptor antagonist (ETRA)	Non-prostanoid prostacyclin receptor (IP receptor) agonist	Selexipag	Uptravi (oral tablet)	
			Selective receptor antagonist	Ambrisentan	Letairis (oral tablet)
				Nonselective dual action receptor antagonist	Bosentan
		Macitentan	Opsumit (oral tablet)		
	Nitric oxide-cyclic guanosine monophosphate enhancer	Phosphodiesterase type 5 (PDE5) inhibitor	Sildenafil	Revatio (IV, oral tablet, oral suspension)	
			Tadalafil	Adcirca (oral tablet)	
			Guanylate cyclase stimulant (sGC)	Riociguat	Adempas (oral tablet)

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
PAH	<u>Adult:</u> Tablet and oral suspension: 20 mg to 80 mg PO TID	<u>Adult:</u>

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Indication	Dosing Regimen	Maximum Dose
	Injection: 10 mg TID as an IV bolus <u>Pediatric:</u> Tablet and oral suspension: Body weight ≤ 20 kg: 10 mg PO TID Body weight > 20 kg to < 45 kg: 20 mg PO TID Body weight ≥ 45 kg: 20 mg to 40 PO TID	Tablet and oral suspension: 240 mg/day Injection: 30 mg/day <u>Pediatric:</u> See dosing regimen

VI. Product Availability

- Tablet: 20 mg
- Oral suspension: 10 mg/mL
- Single-use vial: 10 mg/12.5 mL

VII. References

1. Revatio Prescribing Information. New York, NY: Pfizer Inc.; January 2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/021845s0251bl.pdf . Accessed February 28, 2023..
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3. Klinger JR, Elliott CG, Levine DJ, et al. Therapy for pulmonary arterial hypertension in adults: update of the CHEST guideline and expert panel report. *CHEST*. 2019;155(3):565-586. doi: <https://doi.org/10.1016/j.chest.2018.11.030>.
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6. Galiè N, Humbert M, Vachiary JL, et al. 2015 ESC/ERS Guidelines for the diagnosis and treatment of Pulmonary Hypertension. *European Heart Journal*. Doi:10.1093/eurheartj/ehv317.
7. Simmonneau G, Montani D, Celermajer D, et al. Haemodynamic definitions and updated clinical classification of pulmonary hypertension. *Eur Respir J*. 2019; 53:1801913.
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9. Yaghi S, Novikov A, Trandafirescu T. Clinical update on pulmonary hypertension. *J Investig Med*. 2020; 0:1-7. doi:10.1136/jim-2020-001291.

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Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3490	Unclassified drugs
J8499	Prescription drug, oral, non-chemotherapeutic, Not Otherwise Specified
C9399	Unclassified drug or biologicals

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created, adapted CP.PHAR.197 Sildenafil (Revatio) policy.	9.1.2022	
Annual Review: Template changes applied; references reviewed and updated.	2.28.2023	
RT4: updated PAH criteria to include newly FDA approved pediatric age expansion; updated adult PAH dosing per revised PI; updated HCPCS codes and Appendix B.	3.29.23	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a

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discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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