



DRUG QUANTITY MANAGEMENT POLICY – PER RX

- POLICY:** Pulmonary Arterial Hypertension – Sildenafil Drug Quantity Management Policy – Per Rx
- LiQrev® (sildenafil oral suspension – CMP)
 - Revatio® (sildenafil tablets and powder for suspension – Pfizer, generic)

REVIEW DATE: 02/09/2024

INSTRUCTIONS FOR USE

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CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Sildenafil (Revatio, generic) and LiQrev are phosphodiesterase type 5 (PDE5) inhibitors indicated for the treatment of **pulmonary arterial hypertension** ([PAH] World Health Organization [WHO] Group I) **in adults** to improve exercise ability and delay clinical worsening.^{1,9} Sildenafil (Revatio, generic) is also indicated for **PAH** (WHO Group I) in **patients 1 to 17 years of age** to improve exercise ability and, in pediatric patients too young to perform standardized exercise testing, pulmonary hemodynamics thought to underlie improvements in exercise.¹ Due to marketing exclusivity rights, LiQrev is not labeled with information for pediatric use.⁹

Dosing

Adult Dosing

The recommended dose of sildenafil (Revatio, generic) for the treatment of PAH in adults is 20 mg three times daily (TID). The dose may be titrated to a maximum of 80 mg TID, if required, based on symptoms and tolerability. In clinical trials,

sildenafil doses of 25 mg twice daily to 100 mg five times daily have been used for PAH.²⁻⁵

The recommended dose of LiQrev for the treatment of PAH in adults is 20 mg TID.⁹

Pediatric Dosing

The recommended dose of sildenafil (Revatio, generic) for the treatment of PAH in pediatric patients is based on weight (Table 1).¹

Table 1. Sildenafil (Revatio, generic) Recommended Dosing in Pediatric Patients.¹

| Patient Weight | Recommended Dose |
|----------------|------------------------|
| ≤ 20 kg | 10 mg TID |
| 20 kg to 45 kg | 20 mg TID |
| > 45 kg | 20 mg TID ^a |

TID – Three times daily; ^a A maximum dose in pediatric patients has not been identified. In patients weighing > 45 kg, the dose may be titrated to a maximum of 40 mg three times daily, if required, based on symptoms and tolerability.

Availability

Sildenafil (Revatio, generic) is available as 20 mg tablets and as 10 mg/mL powder for oral suspension in a 112 mL bottle (after reconstitution).¹ Revatio is also available as a 10 mg/12.5 mL vial which is not targeted in this policy.

LiQrev is available as a 10 mg/mL oral suspension in bottles of 122 mL.¹⁰

Off-Label Use

Sildenafil (Revatio, generic) has some data in patients with Raynaud’s phenomenon at doses provided in strengths used for PAH.⁶⁻⁸

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of sildenafil products for PAH. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

| Product | Strength and Form | Retail Maximum Quantity per Rx | Home Delivery Maximum Quantity per Rx |
|--|---|--------------------------------|---------------------------------------|
| LiQrev® (sildenafil oral suspension) | 10 mg/mL oral suspension (122 mL) | 122 mL (1 bottle) | 366 mL (3 bottles) |
| Revatio® (sildenafil tablets and oral suspension, generic) | 20 mg tablets (bottles of 90 tablets) | 90 tablets | 270 tablets |
| | 10 mg/mL oral suspension (when reconstituted) [112 mL bottle] | 112 mL (1 bottle) | 336 mL (3 bottles) |

Pulmonary Arterial Hypertension – Sildenafil Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Sildenafil 20 mg tablets (Revatio, generic)

1. If the patient is prescribed greater than 20 mg three times daily for pulmonary arterial hypertension (PAH) or Raynaud’s phenomenon, approve a quantity sufficient for a 30-day supply at retail or a 90-day supply at home delivery.

Sildenafil 10 mg/mL oral suspension (Revatio, generic) and LiQrev 10 mg/mL oral suspension

1. Approve a quantity sufficient for a 30-day supply at retail or a 90-day supply at home delivery if the patient meets the following criteria (A, B, and C):

A) Patient meets ONE of the following (i or ii):

- i. Patient has a diagnosis of pulmonary arterial hypertension (PAH); OR
- ii. Patient has a diagnosis of Raynaud’s phenomenon; AND

B) Patient is prescribed greater than 10 mg three times daily; AND

C) Patient is unable to swallow a 20 mg sildenafil tablet (Revatio, generic).

Note: Round up to accommodate a whole package size (e.g., if the required dose is 20 mg three times daily [2 mL three times daily or 6 mL per day], 180 mL would be required for 30 days and 540 mL would be required for 90 days. Therefore, for sildenafil 10 mg/mL oral suspension [Revatio, generic], 224 mL [2 bottles] would be approved at retail or 560 mL [5 bottles] would be approved at home delivery. For LiQrev, 244 mL [2 bottles] would be approved at retail or 610 mL [5 bottles] would be approved at home delivery).

EXCLUSIONS

Approval of additional quantities of sildenafil (Revatio, generic) or LiQrev is NOT recommended in the following situations:

1. No overrides are recommended for use in erectile dysfunction or sexual dysfunction.

REFERENCES

1. Revatio tablets, oral suspension [prescribing information]. Morgantown, WV: Viartis; January 2023.
2. Vazquez ZGS, Klinger JR. Guidelines for the treatment of pulmonary arterial hypertension. *Lung*. 2020;198:581-596.
3. Ruopp NF, Cockrill BA. Diagnosis and treatment of pulmonary arterial hypertension. A review. *JAMA*. 2022;327(14):1379-1391.
4. 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.
5. Humbert M, Kovacs G, Hoeper MM, et al, for the ESC/ERS Scientific Document Group. 2022 ESC/ERS guidelines for the diagnosis and treatment of pulmonary hypertension. *Eur Heart J*. 2022;43(38):3618-3731.

6. 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 randomized trials. *Ann Rheum Dis*. 2013;72:1696-1699.
7. Fernandez-Codina A, Canas-Ruano E, Pope JE. Management of Raynaud's phenomenon in systemic sclerosis – a practical approach. *J Scleroderm Relat Disord*. 2019;4(2):102-110.
8. Hinze AM, Wigley FM. Pharmacotherapy options in the management of Raynaud's phenomenon. *Curr Treat Opt Rheumatol*. 2018;4(3):235-254.
9. LiQrev oral suspension [prescribing information]. Farmville, NC: CMP; April 2023.

HISTORY

| Type of Revision | Summary of Changes | Review Date |
|-----------------------|---|-------------|
| Early Annual Revision | <p>Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery.</p> <p>Approval duration was changed from 3 years to 1 year.</p> <p>Sildenafil 20 mg tablets (Revatio, generic): Clinical override criteria were updated to approve for a patient who is prescribed greater than 20 mg three times daily for Raynaud's phenomenon (previously only approved for a patient with pulmonary arterial hypertension).</p> <p>Sildenafil 10 mg/mL oral suspension (Revatio, generic): Clinical override criteria were updated to approve for a patient who is prescribed greater than 10 mg three times daily, is unable to swallow a 20 mg tablet, and has a diagnosis of Raynaud's phenomenon (previously only approved for a patient with a diagnosis of pulmonary arterial hypertension).</p> | 02/08/2023 |
| Update | <p>02/21/2023: No change to criteria. Policy updated to reflect expanded age indication of sildenafil (Revatio, generic) in pediatric patients.</p> | NA |
| Selected Revision | <p>LiQrev: New quantity limit added to the policy of 122 mL (1 bottle) per dispensing at retail and 366 mL (3 bottles) per dispensing at home delivery. An override to provide a quantity sufficient for a 30-day supply at home delivery or a 90-day supply at retail was added for a patient with pulmonary arterial hypertension or Raynaud's phenomenon who requires a dose greater than 10 mg three times daily and is unable to swallow a 20 mg sildenafil tablet (Revatio, generic).</p> | 05/24/2023 |
| Annual Revision | No criteria changes. | 02/09/2024 |

NA – Not applicable.

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