

## DRUG QUANTITY MANAGEMENT POLICY - PER RX

**POLICY:** sildenafil tablets and powder for suspension (Revatio® – Pfizer, generics [tablets]) Dispensing Limit

**DATE REVIEWED:** 12/31/2019

### DESCRIPTION

**Revatio 20 mg tablets (generic)** Maximum quantity per RX = 90 tablets

**Revatio for oral suspension 10 mg/mL (112 mL bottle)** Maximum quantity per RX = 1 bottle (112 mL)

Revatio is available as 20 mg tablets and as 10 mg/mL powder for suspension.<sup>1</sup> The recommended dose for the treatment of pulmonary arterial hypertension (PAH) is 5 mg or 20 mg three times daily (TID). In a clinical trial comparing doses of 1 mg, 5 mg, and 20 mg of Revatio three times daily, patients taking 5 mg and 20 mg had similar increases in the primary efficacy endpoint: change from baseline to 12 weeks in the 6 minute walk distance. The increases in 6 minute walk distance were significantly better than for the patients taking the 1 mg dose. Per manufacturer prescribing information, doses higher than 20 mg three times daily are not recommended as no greater efficacy was achieved with higher doses in clinical trials. However, sildenafil doses of 25 mg twice daily to 100 mg five times daily have been used for PAH.<sup>2-14</sup>

Therefore, 90 tablets would supply enough drug for 30 days of therapy and one bottle of suspension provides sufficient medication for doses up to 10 mg three times per day (90 mL). Exceptions can be made for patients who require the liquid dosage form and/or for those who have been titrated to higher doses.

### CRITERIA

All approvals are provided for 3 years in duration unless otherwise noted below.

#### *Revatio (sildenafil) tablets*

1. **Pulmonary arterial hypertension (PAH).** Exceptions can be made for patients taking *greater than* 20 mg three times daily, if there is documentation that the patient has been receiving 20 mg three times daily and the dose is being titrated or the patient is already on greater than 20 mg three times daily. Authorize the requested quantity to allow for a 30 day supply per dispensing.
2. **Erectile dysfunction or sexual dysfunction.** No overrides recommended.
3. Any other indications: No overrides recommended.

**For Raynaud disease, refer to Viagra.**

#### *Revatio for oral suspension*

1. **Pulmonary arterial hypertension (PAH).**
  - a. Exceptions can be made for patients taking *greater than* 10 mg three times daily, if there is documentation that the patient has been receiving 10 mg three times daily and the dose is being titrated or the patient is already on greater than 10 mg three times daily; AND
  - b. Patient is unable to swallow a 20 mg tablet. Approve an adequate quantity for a 30-day supply per dispensing. NOTE: Round up to accommodate a whole package size. For *example*, if the

required dose is 20 mg three times daily (2 mL TID), 180 mL would be required for 30 days; approve two 112 mL bottles (total 224 mL).

2. **Erectile dysfunction or sexual dysfunction.** No overrides recommended.
3. **Any other indications:** No overrides recommended.

**For Raynaud disease, refer to Viagra.**

## REFERENCES

1. Revatio tablets, oral suspension [prescribing information]. New York, NY: Pfizer Labs; January 2019.
2. Watanabe H, Ohashi K, Takeuchi K, et al. Sildenafil for primary and secondary pulmonary hypertension. *Clin Pharmacol Ther.* 2002;71:398-402.
3. Jackson G, Chambers J. Sildenafil for primary pulmonary hypertension: short and long-term symptomatic benefit. *Int J Clin Pract.* 2002;56:397-398.
4. Prasad S, Wilkinson J, Gatzoulis MA. Sildenafil in primary pulmonary hypertension. *N Engl J Med.* 2000;343:1342.
5. Sayin T, Ozenci M. Sildenafil in primary pulmonary hypertension – is there a subset of patients who respond favourably. *Can J Cardiol.* 2002;18:676-678.
6. Abrams D, Schulze-Neick I, et al. Sildenafil as a selective pulmonary vasodilator in childhood primary pulmonary hypertension. *Heart.* 2000;84:e4.
7. Sastry BKS, Narasimhan C, Reddy NK, et al. Clinical efficacy of sildenafil in primary pulmonary hypertension. *J Am Coll Cardiol.* 2004;43:1149-1153.
8. Garg N, Sharma MK, Sinha N. Role of oral sildenafil in severe pulmonary arterial hypertension: clinical efficacy and dose response relationship. *Int J Cardiol.* 2007;120:306-313.
9. Galie N, Ghofrani H, Torbicki A, et al. Sildenafil citrate therapy for pulmonary arterial hypertension. *N Engl J Med.* 2005;353:2148-2157.
10. Singh TP, Rohit M, Grover A, et al. A randomized, placebo-controlled, double-blind, crossover study to evaluate the efficacy of oral sildenafil therapy in severe pulmonary artery hypertension. *Am Heart J.* 2006;151:851.e1-5.
11. Wort SJ. Sildenafil in Eisenmenger syndrome: safety first. *Int J Cardiol.* 2007;120:314-316.
12. Lim ZS, Salmon AP, Vettukattil JJ, et al. Sildenafil therapy for pulmonary arterial hypertension associated with atrial septal defects. *Int J Cardiol.* 2007;118:178-182.
13. Chau EM, Fan KY, Chow WH. Effects of chronic sildenafil in patients with Eisenmenger syndrome versus idiopathic pulmonary arterial hypertension. *Int J Cardiol.* 2007;120:301-305.
14. Simonneau G, Rubin KJ, Galie N, et al, for the PACES Study Group. Addition of sildenafil to long-term intravenous epoprostenol therapy in patients with pulmonary arterial hypertension. A randomized trial. *Ann Intern Med.* 2008;149:521-530.