Clinical Policy Title:	sildenafil
Policy Number:	RxA.467
Drug(s) Applied:	Revatio®, Liqrev®, sildenafil (PAH)
Original Policy Date:	03/06/2020
Last Review Date:	11/30/2023
Line of Business Policy Applies to:	All lines of business
Criteria	

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Pulmonary Arterial Hypertension (must meet all):

1. Diagnosis of pulmonary arterial hypertension;
2. Prescribed by or in consultation with a cardiologist or a pulmonologist;
3. Trial and 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;

Approval duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy

A. Pulmonary Arterial Hypertension (must meet all):

1. Member is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples.

Approval duration

All Lines of Business (except Medicare): 12 months

References

1. McLaughlin VV, Archer SL, Badesch DB, et al. ACCF/AHA 2009 expert consensus document on pulmonary hypertension: A report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents and the American Heart Association: developed in collaboration with the American College of Chest Physicians, American Thoracic Society, Inc., and the Pulmonary Hypertension Association. J Am Coll Cardiol. 2009; 53(17): 1573:1619. Available at: https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.109.192230. Accessed June 26, 2023.
2. Taichman D, Ornelas J, Chung L, et. al. CHEST guideline and expert panel report: Pharmacologic therapy for pulmonary arterial hypertension in adults. Chest. 2014; 146 (2): 449:475. Available at: https://pubmed.ncbi.nlm.nih.gov/24937180/. Accessed June 26, 2023.

3. Abman SH, Hansmann G, Archer SL, et al. Pediatric pulmonary hypertension: Guidelines from the American Heart Association and American Thoracic Society. Circulation. 2015 Nov 24; 132(21): 2037:99. Available at: https://www.ahajournals.org/doi/10.1161/CIR.0000000000000329. Accessed June 26, 2023.
4. Kim NH, Delcroix M, Jenkins DP, et al. Chronic thromboembolic pulmonary hypertension. J Am Coll Cardiol 2013; 62(25): Suppl D92:99. Available at: https://pubmed.ncbi.nlm.nih.gov/24355646/. Accessed June 26, 2023.
5. Humbert M, Kovacs G, Hoeper MM, et al. 2022 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension. European Heart Journal. 2022;43(38):3618-3731. doi:10.1093/eurheartj/ehac237. Available at: https://academic.oup.com/eurheartj/article/43/38/3618/6673929. Accessed June 26, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated. 2. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 3. Appendices B and F were updated. 4. References were updated.	09/01/2020	12/07/2020
Policy was reviewed: 1. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 2. Continued Therapy Criteria II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance…”. 3. Therapeutic Alternatives verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..". 4. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 5. References were reviewed and updated.	08/28/2021	12/7/2021
Policy was reviewed: 1. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been	04/01/2022	07/18/2022

authorized by RxAdvance...". 2. Appendix B, Dosing Regimen, nifedipine (Adalat® CC, Procardia, Procardia XL®): Updated dosing information from “60 mg orally once daily; may increase to 120 to 240 mg/day” to “For Adalat® CC: Initial, 30 mg orally once daily, maintenance, 30 to 60 mg once daily For Procardia XL®: Initial, 30 or 60 mg orally once daily” for indication PAH. 3. Appendix B, Maximum Dose, nifedipine (Adalat® CC, Procardia, Procardia XL®): Updated maximum dose information from 240 mg/day to For Adalat® CC: 90 mg/day For Procardia XL®: 120 mg/day. 4. Appendix B, Dosing Regimen, diltiazem (Dilt-XR®, Cardizem® CD, Cartia XT®, Tiazac®, Taztia XT®, Cardizem® LA, Matzim® LA): Updated dosing information from 720 to 960 mg orally once daily to For Tiazac®, Taztia XT®: 120 to 240 mg once daily, For Dilt-XR®, Cardizem® CD, Cartia XT®, Cardizem® LA, Matzim® LA: 180 to 240 mg once daily for indication PAH. 5. Appendix B, Maximum Dose, diltiazem (Dilt-XR®, Cardizem® CD, Cartia XT®, Tiazac®, Taztia XT®, Cardizem® LA, Matzim® LA): Updated maximum dose information from 960 mg/day to For Tiazac®, Taztia XT®: 540 mg /day, For Dilt-XR®, Cardizem® CD, Cartia XT®, Cardizem® LA, Matzim® LA: 480 mg once daily for indication PAH. 6. Appendix B, Dosing Regimen, amlodipine (Norvasc®): Updated dosing information from Initial: 2.5 mg orally once daily; increase cautiously and progressively up to the maximum tolerated dose to Adult starting dose: 5 mg once daily, Pediatric starting dose: 2.5 mg to 5 mg once daily for indication PAH. 7. Appendix B, Maximum Dose, amlodipine (Norvasc®): Updated maximum dose information from 20 mg/day to Adult: 10 mg/day, Pediatric starting dose: 5 mg/day for indication PAH. 8. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package		

insert..." was added to Appendix C. 9. References were reviewed and updated.		
Policy was reviewed: 1. Background: Updated to remove detail pertaining to indication pulmonary arterial hypertension (PAH), "The delay in clinical worsening was demonstrated when Revatio® was added to background epoprostenol therapy. Studies establishing effectiveness were short-term (12 to 16 weeks) and included predominately patients with New York Heart Association (NYHA) Functional Class II-III symptoms and idiopathic etiology (71%) or associated with connective tissue disease (25%)." 2. Background: Updated to remove limitation(s) of use, “Limitation(s) of use: Adding sildenafil to bosentan therapy does not result in any beneficial effect on exercise capacity.” 3. Background: Updated to include new information regarding Pediatric Patients (1 to 17 years old), "Sildenafil (Revatio®) is indicated in pediatric patients 1 to 17 years old for the treatment of pulmonary arterial hypertension (PAH) (WHO Group I) to improve exercise ability and, in pediatric patients too young to perform standard exercise testing, pulmonary hemodynamics thought to underly improvements in exercise." 4. Dosing Information, Dosing Regimen, sildenafil (Revatio®): Updated dosing information from Tablet and oral suspension: 5 mg or 20 mg Orally three times a day, 4-6 hours apart Injection: 2.5 mg or 10 mg three times a day as an Intravenous bolus to Adults: Tablet and oral suspension: 20 mg orally three times a day Injection: 10 mg three times a day as an Intravenous bolus for indication Pulmonary arterial hypertension. 5. Dosing Information, Maximum Dose, sildenafil (Revatio®): Updated to maximum dosing information from Tablet/oral suspension: 60 mg/day to Tablet/oral suspension: 240 mg/day for indication	03/23/2023	04/13/2023

Pulmonary arterial hypertension. 6. Dosing Information, Dosing Regimen and Maximum Dose, sildenafil (Revatio®): Updated to include dosing information for ages Pediatrics (1 to 17 years old) for indication Pulmonary arterial hypertension. 7. Initial Approval Criteria, I.A.4: Updated dosing criteria from Dose does not exceed 60 mg per day (oral formulations) or 30 mg per day (intravenous formulations) in divided doses to Dose does not exceed any one of the following (a, b or c): a. For adults (orally): 80 mg/day three times a day; b. For adults (Intravenously): 30 mg/day; c. Pediatrics weight-based dose (1 to 17 years old): i. Weighing ≤ 20 kg: 10 mg three times a day; ii. Weighing 20 kg to 45 kg: 20 mg three times a day; iii. Weighing > 45 kg: 40 mg three times a day. 8. Continued Therapy Approval Criteria, II.A.3: Updated dosing criteria from If request is for a dose increase, new dose does not exceed 60 mg per day (oral formulations) or 30 mg per day (intravenous formulations) in divided doses to Dose does not exceed any one of the following (a, b or c): a. For adults (orally): 80 mg/day three times a day; b. For adults (Intravenously): 30 mg/day; c. Pediatrics weight-based dose (1 to 17 years old): i. Weighing ≤20 kg: 10 mg three times a day; ii. Weighing 20 kg to 45 kg: 20 mg three times a day; iii. Weighing >45 kg: 40 mg three times a day. 9. Appendix A: Updated to remove abbreviations FDA. 10. Appendix B: Updated to remove brands Adalat CC and Procardia due to discontinuation.		

11. References were reviewed and updated.		
Policy was reviewed: 1. Clinical Policy Title, Drug(s) Applied: Updated to include new drug Liqrev®. 2. Background: Updated to include new drug Liqrev®. 3. Dosing Information, Drug Name: Updated to include new drug Liqrev®. 4. Dosage Forms: Updated to include new dosage form for Liqrev®. 5. Initial Approval Criteria, I.A.3: Updated to include new age criteria "Meets any one of the followings: (a or b) a. For Liqrev®: Age ≥ 18 years; b. For Revatio®: Age ≥ 1 years; 6. Appendix B, Dosing Regimen, diltiazem (Dilt-XR®, Cardizem® CD, Cartia XT®, Tiazac®, Taztia XT®, Cardizem® LA, Matzim® LA): Updated dosing information from For Tiazac®, Taztia XT®: 120 to 240 mg once daily For Dilt-XR®, Cardizem® CD, Cartia XT®, Cardizem® LA, Matzim® LA: 180 to 240 mg once daily to Adult: 60 mg orally twice daily; may increase to 120 to 360 mg twice daily. Pediatric: 0.75 mg/kg/dose orally twice daily; may increase to 3 to 5 mg/kg/day. 7. Appendix B, Maximum Dose, diltiazem (Dilt-XR®, Cardizem® CD, Cartia XT®, Tiazac®, Taztia XT®, Cardizem® LA, Matzim® LA) Updated maximum dose information from For Tiazac®, Taztia XT®: 540 mg/day, For Dilt-XR®, Cardizem® CD, Cartia XT®, Cardizem® LA, Matzim® LA: 480 mg/day to Adult: 720 mg/day, Pediatric: 360 mg/day to Adult: 720 mg/day, Pediatric: 360 mg/day. 8. References were reviewed and updated	06/26/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023