SmartPA Criteria Proposal

Drug/Drug Class:	Pulmonary Arterial Hypertension (PAH) Agents: Phosphodiesterase-5 (PDE5) and Soluble Guanylate Cyclase (SGC) Stimulators PDL Edit
First Implementation Date:	June 25, 2008
Proposed Date:	September 17, 2020
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Pulmonary arterial hypertension (PAH) is a severe, progressive, and often fatal condition that occurs idiopathically as well as in association with pulmonary, cardiac, and other thoracic conditions. Reliable estimates of the total prevalence of this condition are difficult to obtain because of the diversity of identifiable causes. PAH, formerly known as primary pulmonary hypertension, is characterized by elevations in pulmonary arterial pressure (PAP) to greater than 25 mmHg at rest and greater than 30 mmHg with exercise. The disease occurs when the PAP is abnormally elevated and forces the right side of the heart to progressively work harder when it pumps blood to the lungs. Symptoms include dyspnea, fatigue, chest pain, palpitations, syncope, and edema. Prognosis varies based on the severity of disease, whether right heart failure is present, and response to vasodilator therapy. If left untreated, the disease produces increases in PAP that may lead to right ventricular failure and death. Despite recent developments in the symptomatic treatment of PAH, there is still no cure.

PAH should be differentiated from pulmonary hypertension secondary to diseases of the heart and lung based on both pathology of the underlying disease and accepted treatments.

Why Issue Selected: Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Sildenafil Inj/Tabs (gen Revatio®) • Tadalafil Tabs (gen Adcirca®)	• Adcirca® • Adempas® • Alyq™ • Revatio® • Sildenafil Susp

Type of Criteria:	☐ **Increased risk of ADE**	☒ **Preferred Drug List**
	☒ **Appropriate Indications**	☐ **Clinical Edit**
Data Sources:	☐ **Only Administrative Databases**	☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Pulmonary Arterial Hypertension (PAH) Agents: Phosphodiesterase-5 (PDE5) and Soluble Guanylate Cyclase (SGC) Stimulators
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Documented diagnosis of pulmonary hypertension **AND**
- Documented compliance on current therapy regimen **OR**
- **For injectable Revatio: failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents, with one being generic sildenafil injection AND**
- Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents
    - Documented trial period for preferred agents **OR**
    - Documented ADE/ADR to preferred agents **OR**
- **For Adempas: documented diagnosis of chronic thromboembolic pulmonary hypertension**

Denial Criteria

- For Adempas: participant is currently pregnant
- For Revatio: history of nitrate or ritonavir (Norvir or Kaletra) therapy within the last 30 days
- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met
- Claim exceeds maximum dosing limitation for the following:

Drug Description	Generic Equivalent	Max Dosing Limitation
REVATIO 10 MG/12.5 ML VIAL	**SILDENAFIL**	**3 vials per day**
REVATIO 10 MG/ML ORAL SUSP	SILDENAFIL	6 mL per day
REVATIO 20 MG TABLET	SILDENAFIL	3 tablets per day

Required Documentation

Laboratory Results:	☐	Progress Notes:	☐
MedWatch Form:	☐	Other:	☐

Disposition of Edit

Denial: Exception Code “0160” (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

1. Evidence-Based Medicine and Fiscal Analysis: “Pulmonary Hypertension Agents, Oral – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; July 2020.
2. Evidence-Based Medicine and Fiscal Analysis: “Pulmonary Hypertension Agents: Inhaled/Injectable – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; June 2020.
3. Evidence-Based Medicine Analysis: “Primary Pulmonary Arterial Hypertension (PAH) Agents”, UMKC-DIC; June 2020.
4. Lajoie A, Bonnet S, Provencher S. Review Article: Combination Therapy in Pulmonary Arterial Hypertension: Recent accomplishments and future challenges. Pulmonary Circulation 2017; 7(2) 312–325.
5. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
6. USPDI, Micromedex; 2020.
7. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.
8. 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. 2016; 155(3): 565-586.
9. Revatio [package insert]. New York, NY: Pfizer Labs; 2020.
10. Adcirca [package insert]. Indianapolis, IN: Eli Lilly and Company; 2019.
11. Adempas [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals; 2018.