VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors Prior Authorization Policy

- Adcirca® (tadalafil tablets – Eli Lilly/United Therapeutics, generic)
- Alyq™ (tadalafil tablets – Teva, generic)
- Revatio® (sildenafil tablets and suspension – Pfizer, generic)
  Note: Revatio injection is not included in this policy

REVIEW DATE: 10/06/2021

OVERVIEW

Adcirca and Revatio and are phosphodiesterase type 5 (PDE5) inhibitors indicated for the treatment of **pulmonary arterial hypertension** (PAH).[1,2] Alyq is a generic to Adcirca.[3] Adcirca and Alyq are indicated for the treatment of PAH (WHO Group I) to improve exercise ability.[2,3] Revatio is indicated for the treatment of PAH (World Health Organization [WHO] Group I) in adults to improve exercise ability and delay clinical worsening.

Disease Overview

PAH is a serious but rare condition impacting approximately fewer than 20,000 patients in the US. It is classified within Group 1 pulmonary hypertension among the five different groups that are recognized. In this progressive disorder the small arteries in the lungs become narrowed, restricted, or blocked causing the heart to work harder to pump blood, leading to activity impairment.[4,5] In time, right-sided heart failure and/or death may occur. Common PAH symptoms include shortness of breath, fatigue, chest pain, dizziness and fainting, along with impairment in activity tolerance. It is more prevalent in women. Patients of all ages may develop the disease; however, the mean age of diagnosis typically happens between 36 to 50 years. Children may also have PAH. The condition may occur due to various underlying medical conditions or as a disease that uniquely impacts the pulmonary circulation; both genetic and environmental factors may be involved. PAH is defined as a mean pulmonary artery pressure (mPAP) $\geq$ 25 mmHg with a pulmonary capillary wedge pressure (PCWP) $\leq$ 15 mmHg measured by cardiac catheterization. The prognosis in PAH has been described as poor, with the median survival being approximately 3 years. However, primarily due to advances in pharmacological therapies, the long-term prognosis has improved. Lung transplantation may be recommended if pharmacological or medical therapies fail, based upon patient status. The WHO categorizes PAH into stages, which is also referred to as the functional class (Class I to IV) and is an adaptation of the New York Heart Association (NYHA) system to evaluate activity tolerance.

Guidelines

In 2019, an updated CHEST guideline and Expert Panel Report regarding therapy for pulmonary arterial hypertension in adults was released.[5] Evidence for use of the many medications available is also detailed. PDE5 inhibitors are a vital therapy in the management of PAH with several benefits in a variety of clinical scenarios.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Adcirca, Alyq, and Revatio (tablets and suspension only). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Adcirca, Alyq, and Revatio (tablets and suspension only), as well as the monitoring required for adverse events and long-term efficacy,

approval requires these agents to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Documentation: In the *Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors Prior Authorization Policy*, documentation is required for initiation of therapy where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes and catheterization laboratory reports. For a patient case in which the documentation requirement of the right heart catheterization upon Prior Authorization coverage review for a different medication indicated for WHO Group 1 PAH has been previously provided, the documentation requirement in this *Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors Prior Authorization Policy* is considered to be met.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Adcirca, Alyq, and Revatio is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Pulmonary Arterial Hypertension (PAH) [World Health Organization {WHO} Group 1].** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 3 years if the patient meets all of the following criteria (i, ii, and iii):
     - **i.** Patient has a diagnosis of World Health Organization (WHO) Group 1 pulmonary arterial hypertension (PAH); AND
     - **ii.** Patient meets the following criteria (a and b):
       - **a)** Patient has had a right heart catheterization **[documentation required]** (see documentation section above); AND
       - **b)** Results of the right heart catheterization confirm the diagnosis of WHO Group 1 PAH; AND
     - **iii.** The medication is prescribed by, or in consultation with, a cardiologist or a pulmonologist.
   - **B)** Patient Currently Receiving the Requested Phosphodiesterase Type 5 (PDE5) inhibitor (i.e., Adcirca, Alyq, Revatio suspension, Revatio tablets, or sildenafil suspension). Approve for 3 years if the patient meets the following criteria (i, ii, and iii):
     - **i.** Patient has a diagnosis of World Health Organization (WHO) Group 1 pulmonary arterial hypertension (PAH); AND
     - **ii.** Patient meets the following criteria (a and b):
       - **a)** Patient has had a right heart catheterization; AND
       - **b)** Results of the right heart catheterization confirm the diagnosis of WHO Group 1 PAH; AND
     - **iii.** The medication is prescribed by, or in consultation with, a cardiologist or a pulmonologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Adcirca, Alyq, and Revatio is not recommended in the following situations:

1. **Erectile Dysfunction.** Coverage is not recommended. Patients should use other phosphodiesterase type 5 (PDE5) inhibitors indicated for erectile dysfunction (i.e., Viagra® [sildenafil tablets], Cialis® [tadalafil tablets]).[6,7]

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Revatio® tablets, oral suspension, and intravenous injection [prescribing information]. New York, NY: Pfizer; February 2020.
2. Adcirca® tablets [prescribing information]. Indianapolis, IN: Eli Lilly/United Therapeutics; September 2020.
3. Alyq™ tablets [prescribing information]. North Wales, PA: Teva; January 2019.
4. McLaughlin VV, Archer SL, Badesch DB, et al; Writing committee members. 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. *Circulation*. 2009;119:2250-2294.
5. 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.
6. Viagra® tablets [prescribing information]. New York, NY: Pfizer; December 2017.
7. Cialis® tablets [prescribing information]. Indianapolis, IN: Eli Lilly; February 2018.