

PREFERRED SPECIALTY MANAGEMENT (PSM) POLICY

POLICY: Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors
Preferred Specialty Management (PSM)

DATE REVIEWED: 09/25/2019; selected revision 06/03/2020

DRUGS AFFECTED:

- Adcirca[®] (tadalafil 20 mg tablets – United Therapeutics [generic])
- Alyq[™] (tadalafil tablets – Teva)
- Revatio[®] (sildenafil 20 mg tablets, oral suspension – Pfizer [generics for tablets and suspension])

OVERVIEW

Revatio, Adcirca, and Alyq are phosphodiesterase type 5 (PDE5) inhibitors indicated for the treatment of pulmonary arterial hypertension (PAH) [World Health Organization {WHO} Group 1] to improve exercise ability; Alyq is a generic product to Adcirca.¹⁻³ Revatio is also noted to delay clinical worsening in adults.¹ Use of Revatio, especially chronic use, is not recommended in children. In a long-term trial involving pediatric patients (aged 1 to 17 years) with PAH, an increase in mortality was noted with increasing Revatio doses. The recommended dose of Revatio tablets and oral suspension is 5 mg or 20 mg three times daily, 4 to 6 hours apart. Revatio is available as 20 mg tablets and as an oral suspension (10 mg/mL when reconstituted). Adcirca and Alyq are dosed as 40 mg once daily and are available as 20 mg tablets. This policy involves the use of these products.¹⁻³ For more information on criteria within a Prior Authorization (PA) program by specific condition refer to the *Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors Prior Authorization Policy*.³

POLICY STATEMENT

This program requires the patient to meet ESI Standard Prior Authorization criteria and requires the patient to try the Preferred Product (generic sildenafil 20 mg tablets, Alyq or generic tadalafil 20 mg tablets), when clinically appropriate, prior to the approval of a Non-Preferred Product (Revatio tablets, Revatio suspension, sildenafil suspension, and Adcirca). Of note, this policy does not include Revatio injection. Patients meeting the prior authorization criteria for a Non-Preferred Product who have not tried the Preferred Product will receive authorization for a Preferred Product, if clinically appropriate. All approvals for Preferred and Non-Preferred Products are provided for 1 year in duration unless noted otherwise below.

Automation: None

Preferred Products: generic sildenafil tablets (20 mg), Alyq, generic tadalafil tablets (20 mg)

Non-Preferred Products: Adcirca, Revatio tablets, Revatio suspension, sildenafil suspension

Recommended Exception Criteria

Trade Name	Exception
Revatio tablets	<ol style="list-style-type: none"> 1. Approve if the patient meets the ESI Standard <i>Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors Prior Authorization Policy</i> criteria and the patient meets both of the following (A and B): <ol style="list-style-type: none"> A) The patient has tried generic sildenafil 20 mg tablets [documentation required or verification of prescription claims history required]; AND B) The patient cannot take generic sildenafil 20 mg tablets (due to a formulation difference in the inactive ingredients between brand and generic tablets) as identified by the prescribing physician. 2. For patients who meet the ESI Standard <i>Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors Prior Authorization Policy</i> criteria but have not tried the Preferred Product, approve the Preferred Products (generic sildenafil 20 mg tablets, Alyq, or generic tadalafil 20 mg tablets).
Revatio suspension	<ol style="list-style-type: none"> 1. Approve if the patient meets the ESI Standard <i>Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors Prior Authorization Policy</i> criteria and the patient meets one of the following criteria (A, B, <u>or</u> C): <ol style="list-style-type: none"> A) The patient has tried generic sildenafil 20 mg tablets, Alyq, or generic tadalafil 20 mg tablets; OR B) The patient cannot swallow or has difficulty swallowing generic sildenafil 20 mg tablets, Alyq, or generic tadalafil 20 mg tablets; OR C) The patient requires administration of a dose that cannot be obtained with generic sildenafil 20 mg tablets. 2. For patients who meet the ESI Standard <i>Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors Prior Authorization Policy</i> criteria but do not meet one of conditions 1A, 1B, or 1C, approve the Preferred Products (generic sildenafil 20 mg tablets, Alyq, or generic tadalafil 20 mg tablets)
Sildenafil suspension	<ol style="list-style-type: none"> 1. Approve if the patient meets the ESI Standard <i>Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors Prior Authorization Policy</i> criteria and the patient meets one of the following criteria (A, B, <u>or</u> C): <ol style="list-style-type: none"> A) The patient has tried generic sildenafil 20 mg tablets, Alyq, or generic tadalafil 20 mg tablets; OR B) The patient cannot swallow or has difficulty swallowing generic sildenafil 20 mg tablets, Alyq, or generic tadalafil 20 mg tablets; OR C) The patient requires administration of a dose that cannot be obtained with generic sildenafil 20 mg tablets. 2. For patients who meet the ESI Standard <i>Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors Prior Authorization Policy</i> criteria but do not meet one of conditions 1A, 1B, or 1C, approve the Preferred Products (generic sildenafil 20 mg tablets, Alyq, or generic tadalafil 20 mg tablets)
Adcirca tablets	<ol style="list-style-type: none"> 1. Approve if the patient meets the ESI Standard <i>Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors Prior Authorization Policy</i> criteria and the patient meets both of the following (A and B): <ol style="list-style-type: none"> A) The patient has tried generic tadalafil 20 mg tablets [documentation required or verification of prescription claims history required]; AND B) The patient cannot take generic tadalafil 20 mg tablets or Alyq (due to a formulation difference in the inactive ingredients between brand and generic tablets) as identified by the prescribing physician. 2. For patients who meet the ESI Standard <i>Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors Prior Authorization Policy</i> criteria but have not tried the preferred product, approve the Preferred Products (generic sildenafil 20 mg tablets, Alyq, or generic tadalafil 20 mg tablets).

REFERENCES

1. Revatio® tablets, suspension, and injection [prescribing information]. New York, NY: Pfizer; January 2019.
2. Adcirca® tablets [prescribing information]. Indianapolis, IN: Eli Lilly (marketed by United Therapeutics); August 2017.
3. Alyq™ tablets [prescribing information]. North Wales PA: Teva Pharmaceuticals; January 2019.
4. *Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors Prior Authorization Policy*. Express Scripts, Inc. Updated 09/18/2019.