PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors Preferred Specialty Management Policy

- Adcirca® (tadalafil tablets – United Therapeutics, generic)
- Alyq™ (tadalafil tablets – Teva, generic)
- Revatio® (sildenafil 20 mg tablets, oral suspension – Pfizer, generic)
- Tadliq® (tadalafil oral suspension – CMP)

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OVERVIEW

Revatio, Adcirca, Alyq, and Tadliq are phosphodiesterase type 5 inhibitors indicated for the treatment of pulmonary arterial hypertension (World Health Organization Group 1) to improve exercise ability; Alyq (20 mg tablets) is a generic product to Adcirca.[1-4] Revatio is also noted to delay clinical worsening in adults.[1]

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of Preferred Products. There are two rules were are divided into sildenafil products and tadalafil products. For all medications (Preferred and Non-Preferred), the patient is required to meet the standard *Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors Prior Authorization Policy* criteria. The program also directs the patient to try one Preferred Product prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). All approvals are provided for 1 year in duration. If the patient meets the standard *Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors Prior Authorization Policy* criteria but has not tried a Preferred Product(s), approval for the Preferred Product(s) will be authorized based on if the Non-Preferred Product requested is in the sildenafil or tadalafil grouping.

Documentation: Documentation is required for use of Revatio tablets and Adcirca tablets as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and/or other information. For criteria regarding trial of the respective generic for Revatio tablets and Adcirca tablets, verification is required as noted by **[verification required by prescriber]**.

Automation: None.

Sildenafil Products
Preferred Products: generic sildenafil tablets (20 mg)
Non-Preferred Products: Revatio tablets, Revatio suspension, sildenafil suspension

Tadalafil Products
Preferred Products: generic tadalafil tablets (20 mg), Alyq
Non-Preferred Products: Adcirca, Tadliq

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Products	Exception Criteria
Revatio tablets	**1.** Approve for 1 year if the patient meets all of the following (A, B, and C): **A)** Patient meets the standard *Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors Prior Authorization Policy* criteria; AND **B)** Patient has tried generic sildenafil 20 mg tablets **[documentation required or verification of prescription claims history required]**; AND **C)** Patient cannot continue to use generic sildenafil 20 mg tablets due to a formulation difference in the inactive ingredients(s) [e.g., differences in dyes, fillers, preservatives] between the Brand and the bioequivalent product which, per the prescriber, would result in a significant allergy or serious adverse reaction. **2.** For a patient who meets the Standard *Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors Prior Authorization Policy* criteria but has not tried the Preferred Product, approve the Preferred Sildenafil Product.
Revatio suspension	**1.** Approve for 1 year if the patient meets both of the following (A and B): **A)** Patient meets the standard *Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors Prior Authorization Policy* criteria; AND **B)** Patient meets one of the following (i, ii, or iii): **i.** Patient has tried generic sildenafil 20 mg tablets; OR **ii.** Patient cannot swallow or has difficulty swallowing generic sildenafil 20 mg tablets; OR **iii.** Patient requires administration of a dose that cannot be obtained with generic sildenafil 20 mg tablets. **2.** For a patient who meets the Standard *Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors Prior Authorization Policy* criteria but does not meet one of conditions 1Bi, 1Bii, or 1Biii, approve the Preferred Sildenafil Product.
Sildenafil suspension	**1.** Approve for 1 year if the patient meets both of the following (A and B): **A)** Patient meets the standard *Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors Prior Authorization Policy* criteria; AND **B)** Patient meets one of the following (i, ii, or iii): **i.** Patient has tried generic sildenafil 20 mg tablets; OR **ii.** Patient cannot swallow or has difficulty swallowing generic sildenafil 20 mg tablets; OR **iii.** Patient requires administration of a dose that cannot be obtained with generic sildenafil 20 mg tablets. **2.** For a patient who meets the standard *Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors Prior Authorization Policy* criteria but does not meet one of conditions 1Bi, 1Bii, or 1Biii, approve the Preferred Sildenafil Product.

Non-Preferred Products	Exception Criteria
Tadliq	**1.** Approve for 1 year if the patient meets both of the following (A and B): **A)** Patient meets the standard *Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors Prior Authorization Policy* criteria; AND **B)** Patient meets one of the following (i, ii, or iii): **i.** Patient has tried Alyq or generic tadalafil 20 mg tablets; OR **ii.** Patient cannot swallow or has difficulty swallowing Alyq, or generic tadalafil 20 mg tablets; OR **iii.** Patient requires administration of a dose that cannot be obtained with generic tadalafil 20 mg tablets. **2.** For a patient who meets the standard *Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors Prior Authorization Policy* criteria but does not meet one of conditions 1Bi, 1Bii, or 1Biii, approve the Preferred Tadalafil Products.
Adcirca tablets	**1.** Approve for 1 year if the patient meets all of the following (A, B, and C): **A)** Patient meets the standard *Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors Prior Authorization Policy* criteria; AND **B)** Patient has tried generic tadalafil 20 mg tablets **[documentation required or verification of prescription claims required]**; AND **C)** Patient cannot continue to use generic tadalafil 20 mg tablets due to a formulation difference in the inactive ingredients(s) [e.g., differences in dyes, fillers, preservatives] between the Brand and the bioequivalent product which, per the prescriber, would result in a significant allergy or serious adverse reaction. **2.** For a patient who meets the standard *Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors Prior Authorization Policy* criteria but has not tried the preferred product, approve the Preferred Tadalafil Products.

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. Tadliq® oral suspension [prescribing information]. Farmville, NC: CMP; June 2022.