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)
- LiQrev® (sildenafil oral suspension – CMP)
- Revatio® (sildenafil tablets, oral suspension – Pfizer, generic)
- Tadliq® (tadalafil oral suspension – CMP)

REVIEW DATE: 10/11/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Adcirca, Alyq, LiQrev, Revatio, and Tadliq are phosphodiesterase type 5 (PDE5) inhibitors indicated for the treatment of **pulmonary arterial hypertension** (PAH).[1-5] Alyq is a generic to Adcirca.[3]

- Adcirca, Alyq, and Tadliq are indicated for the treatment of PAH (World Health Organization [WHO] Group I) to improve exercise ability.[2-4]
- Liqrev and Revatio are indicated for the treatment of PAH (WHO Group I) in adults to improve exercise ability and delay clinical worsening.[1,5]
- Revatio is also indicated in pediatric patients 1 to 17 years old for the treatment of PAH to improve exercise ability and in pediatric patients too young to perform standard exercise testing, pulmonary hemodynamics thought to underly improvements in exercise.[1]

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of Preferred Products. There are two rules 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]**.

Sildenafil Products

Preferred Products: generic sildenafil tablets (20 mg)

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

Tadalafil Products

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

Non-Preferred Products: Adcirca, Tadliq

Pulmonary Arterial Hypertension – Phosphodiesterase Type 5 Inhibitors non-preferred product(s) is(are) covered as medically necessary when the following non-preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.

NON-PREFERRED PRODUCT 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, LiQrev suspension, 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 Alyq or generic tadalafil 20 mg tablets **[documentation required or verification of prescription claims history 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; January 2023.
2. Adcirca® tablets [prescribing information]. Indianapolis, IN: Eli Lilly/United Therapeutics; September 2020.
3. Alyq™ tablets [prescribing information]. North Wales, PA: Teva; September 2021.
4. Tadliq® oral suspension [prescribing information]. Farmville, NC: CMP; June 2022.
5. Liqrev® suspension [prescribing information]. Farmville, NC: CMP; April 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	10/12/2022
Selected Revision	Tadliq was added as a Non-Preferred Product with exception criteria developed.	11/30/2022
Selected Revision	The Preferred Products and Non-Preferred Products are now divided into two rules, Sildenafil Products and Tadalafil Products. In the Sildenafil Products Grouping, Preferred Products are generic sildenafil tablets (20 mg); Non-Preferred Products are Revatio (sildenafil) tablets, Revatio suspension, and sildenafil suspension. In the Tadalafil Products Grouping, generic tadalafil products (20 mg) and Alyq (tadalafil 20 mg tablets) are Preferred Products; Adcirca (tadalafil) and Tadliq (tadalafil oral suspension) are Non-Preferred Products. The criteria for Revatio suspension, sildenafil suspension, and Tadliq, were changed to direct a patient to try the Preferred Product(s). Criteria for all Non-Preferred Products now specify auto-approvals to be within the designated Preferred Product(s) grouping. There were no other criteria changes.	02/01/2023
Annual Revision	Added Liqrev to the policy as a Non-Preferred sildenafil product with exception criteria developed.	10/11/2023