

<b>Clinical Policy Title:</b>	tadalafil
<b>Policy Number:</b>	RxA.332
<b>Drug(s) Applied:</b>	Adcirca®, Alyq™, Tadliq®
<b>Original Policy Date:</b>	03/06/2020
<b>Last Review Date:</b>	10/19/2023
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. Pulmonary Arterial Hypertension (must meet all):

1. Diagnosis of PAH;
2. Prescribed by or in consultation with a cardiologist or a pulmonologist;
3. Failure of a calcium channel blocker, unless member meets one of the following (a or b):
  - a. Inadequate response or contraindication to acute vasodilator testing;
  - b. Contraindication or clinically significant adverse effects to calcium channel blockers are experienced;
4. For Tadliq® request, member is unable to swallow tablets;
5. Dose does not exceed 40 mg per day.

**Approval duration:**

**Commercial:** 6 months

**Medicaid:** 6 months

### II. Continued Therapy Approval

#### A. Pulmonary Arterial Hypertension (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria;
2. Member is responding positively to therapy;
3. For Tadliq® requests member is unable to swallow tablets;
4. If request is for a dose increase, new dose does not exceed 40 mg per day.

**Approval duration**

**Commercial:** 12 months

**Medicaid:** 12 months

## References

1. Taichman D, Ornelas J, Chung L, et. al. CHEST guideline and expert panel report: Pharmacologic therapy for pulmonary arterial hypertension in adults. Chest. 2014; 146 (2): 449-475. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137591/>. Accessed March 17, 2023.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established	01/2020	03/06/2020

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Added alternative Authorized Generic (Alyq™) to the policy.</li> <li>2. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..."</li> <li>3. Approval Duration for commercial updated to 12 months.</li> <li>4. References reviewed and updated.</li> </ol>	<p>07/09/2020</p>	<p>09/14/2020</p>
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Initial Approval Criteria and Continued Therapy Approval Criteria were updated to remove HIM approval duration.</li> <li>2. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance..."</li> <li>3. References were reviewed and updated.</li> </ol>	<p>05/28/2021</p>	<p>09/14/2021</p>
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Initial Approval Criteria I.A.4 and Continued Approval Criteria II.B.3</li> </ol>	<p>03/15/2022</p>	<p>07/18/2022</p>

<p>updated to add requirement of trial of generic tadalafil before brand Adcirca® or Alyq™, unless contraindicated or clinically significant adverse effects are experienced.</p> <p>2. References were reviewed and updated.</p>		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Clinical Policy Title, Drug(s) Applied: Updated to include new drug Tadliq®.</li> <li>2. Initial Approval Criteria, I.A.4: Updated to remove prior trial and failure criteria "If request is for brand Adcirca® or Alyq™, member must use generic tadalafil, unless contraindicated or clinically significant adverse effects are experienced."</li> <li>3. Initial Approval Criteria, I.A.4: Updated to include new drug request criteria, For Tadliq® request, member is unable to swallow tablets.</li> <li>4. Continued Therapy Approval Criteria, II.A.3: Updated to remove prior trial and failure criteria "If request is for brand Adcirca® or Alyq™, member must use generic tadalafil, unless contraindicated or clinically significant adverse effects are experienced."</li> <li>5. Continued Therapy Approval Criteria, II.A.3: Updated to include new drug request criteria, For Tadliq® request, member is unable to swallow tablets.</li> <li>6. References were reviewed and updated.</li> </ol>	<p>03/17/2023</p>	<p>04/13/2023</p>
<p>Policy was reviewed.</p>	<p>10/19/2023</p>	<p>10/19/2023</p>