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| <b>Clinical Policy Title:</b>              | Tadalafil, Sildenafil  |
| <b>Policy Number:</b>                      | RxA.332  |
| <b>Drug(s) Applied:</b>                    | Tadalafil: Alyq™, Tadliq®<br>Sildenafil: Liqrev®, sildenafil (PAH) |
| <b>Original Policy Date:</b>               | 03/06/2020   |
| <b>Last Review Date:</b>                   | 12/11/2025   |
| <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 symptomatic PAH;
2. Trial and failure of a calcium channel blocker, unless contraindicated or clinically significant adverse effects are experienced;
3. If request is for Alyq or Tadliq: trial and failure or intolerance to generic tadalafil.
4. If request is for Liqrev: trial and failure or intolerance to generic sildenafil.

#### Approval duration:

**All Lines of Business (except Medicare):** 12 months

### II. Continued Therapy Approval

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

1. Member is currently receiving medication in the past 120 days that has been authorized by RxAdvance or the member has met initial approval criteria.

#### Approval duration

**All Lines of Business (except Medicare):** 12 months

## References

1. Marc Humbert, Gabor Kovacs, Marius et.al. 2022 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension: Developed by the task force for the diagnosis and treatment of pulmonary hypertension of the European Society of Cardiology (ESC) and the European Respiratory Society (ERS). Endorsed by the International Society for Heart and Lung Transplantation (ISHLT) and the European Reference Network on rare respiratory diseases (ERN-LUNG)., European Heart Journal, Volume 43, Issue 38, 7 October 2022, Pages 3618–3731. Available at: <https://academic.oup.com/eurheartj/article/43/38/3618/6673929>. Accessed March 24, 2025.

| Review/Revision History | Review/Revised Date | P&T Approval Date |
|-------------------------|---------------------|-------------------|
| Policy established      | 01/2020             | 03/06/2020        |
| Policy was reviewed:    | 07/09/2020          | 09/14/2020        |

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.

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| <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>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>  | 05/28/2021 | 09/14/2021 |
| <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 updated to add requirement of trial of generic tadalafil before brand Adcirca® or Alyq™, unless contraindicated or clinically significant adverse effects are experienced.</li> <li>2. References were reviewed and updated.</li> </ol>  | 03/15/2022 | 07/18/2022 |
| <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</li> </ol> | 03/17/2023 | 04/13/2023 |

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| <p>failure criteria "If request is for brand Adcirca® or Alyq™, member must use generic tadalafil, unless contraindicated or clinically significant adverse effects are experienced."</p> <p>5. Continued Therapy Approval Criteria, II.A.3: Updated to include new drug request criteria, For Tadliq® request, member is unable to swallow tablets.</p> <p>6. References were reviewed and updated.</p> |            |            |
| Policy was reviewed.   | 10/19/2023 | 10/19/2023 |
| <p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1) Removed dosing criteria.</li> <li>2) Removed reauthorization requirement for positive response to therapy.</li> <li>3) Updated the initial approval coverage duration to 12 months.</li> <li>4) References were reviewed and updated.</li> <li>5) Added trial and failure of generic tadalafil or sildenafil</li> </ol>            | 4/1/2024   |            |
| <p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1) Removed prescriber criteria.</li> <li>2) Updated continuation of therapy language.</li> <li>3) Updated approval duration verbiage.</li> <li>4) References were reviewed and updated.</li> </ol>  | 03/24/2025 | 04/10/2025 |
| Policy was reviewed:   | 12/11/2025 | 12/11/2025 |