STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TADALAFIL-ADCIRCA, ALYQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TADALAFIL	ADCIRCA, ALYQ, TADALAFIL		26587	GPI-14 (40143080000320)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** of the following criteria?
   - Therapy is prescribed by or in consultation with a cardiologist or pulmonologist
   - The patient is NOT concurrently or intermittently taking oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form
   - The patient is NOT concurrently taking guanylate cyclase stimulators (e.g., Adempas [riociguat])

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have documentation (e.g., chart note, lab result, diagnostic test result, etc.) confirming PAH diagnosis based on right heart catheterization with **ALL** of the following parameters?
   - Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   - Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
   - Pulmonary vascular resistance (PVR) greater than 2 Wood units

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2 per day.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TADALAFIL-ADCIRCA, ALYQ (Adcirca/Alyq)** requires the following rule(s) be met for approval:
   A. You have pulmonary arterial hypertension (PAH: type of high blood pressure that affects arteries in the lungs and in the heart) World Health Organization (WHO Group 1: a way to classify the severity of disease)
   B. Therapy is prescribed by or in consultation with a cardiologist (heart doctor) or pulmonologist (lung/breathing doctor)
   (*Initial denial text continued on the next page)*

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TADALAFIL-ADCIRCA, ALYQ

INITIAL CRITERIA (CONTINUED)

C. There is documentation (such as chart note, lab result, diagnostic test result) showing you have pulmonary arterial hypertension based on all of the following lab values by putting a catheter (narrow flexible tube) into the right side of your heart:
   1. Mean pulmonary artery pressure (PAP) greater than 20 mmHg
   2. Pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHg
   3. Pulmonary vascular resistance (PVR) greater than 2 Wood units

D. You are NOT concurrently (at the same time) or intermittently (off and on) taking oral erectile dysfunction agents (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form

E. You are NOT concurrently (at the same time) taking guanylate cyclase stimulators (drugs that also treat pulmonary hypertension such as Adempas [riociguat])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of pulmonary arterial hypertension (PAH) (WHO Group 1) and meet **ALL** the following criteria?
   - The patient is NOT concurrently or intermittently taking oral erectile dysfunction agents (e.g., Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form
   - The patient is NOT concurrently taking guanylate cyclase stimulators (e.g., Adempas [riociguat])
   - The patient has shown improvement from baseline in the 6-minute walk distance test OR remains stable from baseline in the 6-minute walk distance test with a stable or improved WHO functional class

   If yes**, approve for 12 months by GPID or GPI-14 with a quantity limit of #2 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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TADALAFIL-ADCIRCA, ALYQ

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **TADALAFIL-ADCIRCA, ALYQ (Adcirca/Alyq)** requires the following rule(s) be met for renewal:

A. You have pulmonary arterial hypertension (PAH: type of high blood pressure that affects arteries in the lungs and in the heart) World Health Organization (WHO) Group 1 (a way to classify the severity of disease)
B. You are NOT concurrently (at the same time) or intermittently (off and on) taking oral erectile dysfunction agents (such as Cialis [tadalafil], Viagra [sildenafil]) or any organic nitrates in any form
C. You are NOT concurrently (at the same time) taking guanylate cyclase stimulators (drugs that also treat pulmonary hypertension such as Adempas [riociguat])
D. You have shown improvement from baseline in the 6-minute walk distance test OR remain stable from baseline in the 6-minute walk distance test with a stable or improved World Health Organization functional class (WHO-FC: a way to classify how limited you are during physical activity)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Adcirca/Alyq.

REFERENCES

- Adcirca [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company; September 2020.
- Alyq [Prescribing Information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; September 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23
Created: 01/08
Client Approval: 05/23
P&T Approval: 04/23