

Pulmonary Arterial Hypertension (PAH) Oral Agents and Winrevair Drug Use Criteria

Created: 6/2026

Applies To:

Preferred Oral PAH Agents

- Revatio (sildenafil)
- Adcirca (tadalafil)
- Letairis (ambrisentan)

Non-Preferred Oral PAH Agents

- Tracleer (bosentan)
- Opsumit (macitentan)
- Adempas (riociguat)
- Uptravi (selexipag)

High-Cost Add-On Therapy

- Winrevair (sotatercept-csrk)

Initial Request:

1. Is the requested medication being used for erectile dysfunction, sexual dysfunction, infertility, or another non-covered indication?
 - a. If yes, deny as not meeting criteria
 - b. If no, go to 2
2. Does the member have one of the following diagnoses?
 - WHO Group 1 Pulmonary Arterial Hypertension (PAH)
 - OR
 - WHO Group 4 Chronic Thromboembolic Pulmonary Hypertension (CTEPH) and request is for Adempas (riociguat)
 - a. If yes, go to 3
 - b. If no, deny as not meeting criteria

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3. Has the diagnosis been confirmed by right heart catheterization?
 - a. If yes, go to 4
 - b. If no, deny as not meeting criteria
 4. If requesting Adempas (riociguat) for CTEPH, does documentation support inoperable CTEPH or persistent/recurrent CTEPH following surgical treatment?
 - a. If yes, go to 5
 - b. If no, deny as not meeting criteria
 - c. If not applicable, go to 5
 5. Does documentation support WHO Functional Class II, III, or IV symptoms?
 - a. If yes, go to 6
 - b. If no, deny as not meeting criteria
 6. Is the medication prescribed by or in consultation with a pulmonologist, cardiologist, or pulmonary hypertension specialist?
 - a. If yes, go to 7
 - b. If no, deny as not meeting criteria
 7. Is the requested medication FDA approved or supported by nationally recognized treatment guidelines for the requested diagnosis?
 - a. If yes, go to 8
 - b. If no, deny as not meeting criteria
 8. Is the requested dose consistent with treatment of pulmonary hypertension and not erectile dysfunction dosing?
 - a. If yes, go to 9
 - b. If no, deny as not meeting criteria
 9. Is the request for Revatio (sildenafil), Adcirca (tadalafil), or Letairis (ambrisentan)?
 - a. If yes, approve for up to 12 months
 - b. If no, go to 10

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10. Is the request for Tracleer (bosentan) or Opsumit (macitentan)?
- If yes, go to 11
 - If no, go to 12
11. Has the member completed an adequate trial of Letairis (ambrisentan) for at least 90 days unless contraindicated, not tolerated, or clinically inappropriate?
- If yes, approve for up to 12 months
 - If no, deny as not meeting criteria
12. Is the request for Adempas (riociguat) or Uptravi (selexipag)?
- If yes, go to 13
 - If no, go to 14
13. Has the member completed BOTH of the following unless contraindicated, not tolerated, or clinically inappropriate?
- Revatio (sildenafil) or Adcirca (tadalafil) for at least 90 days
AND
 - Letairis (ambrisentan) for at least 90 days
- If yes, approve for up to 12 months
 - If no, deny as not meeting criteria
14. Is the request for Winrevair (sotatercept-csrk)?
- If yes, go to 15
 - If no, deny as not meeting criteria
15. Does documentation support WHO Functional Class II or III disease?
- If yes, go to 16
 - If no, deny as not meeting criteria
16. Has the member completed BOTH of the following unless contraindicated, not tolerated, or clinically inappropriate?
- Revatio (sildenafil) or Adcirca (tadalafil) for at least 90 days
AND
 - Letairis (ambrisentan), Tracleer (bosentan), or Opsumit (macitentan) for at least 90 days
- If yes, go to 17
 - If no, deny as not meeting criteria

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17. Does documentation support persistent symptoms despite optimized background PAH therapy?
 - a. If yes, go to 18
 - b. If no, deny as not meeting criteria
 18. Has a baseline six-minute walk distance (6MWD) result been submitted?
 - a. If yes, go to 19
 - b. If no, pend for information
 19. Is baseline six-minute walk distance between 150 and 500 meters?
 - a. If yes, go to 20
 - b. If no, deny as not meeting criteria
 20. Has baseline BNP or NT-proBNP been submitted?
 - a. If yes, go to 21
 - b. If no, pend for information
 21. Have baseline hemoglobin and platelet counts been submitted?
 - a. If yes, approve for up to 12 months
 - b. If no, pend for information
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Renewal Criteria

1. Has the member remained compliant with therapy?
 - a. If yes, go to 2
 - b. If no, deny as not meeting criteria
2. Has documentation been submitted supporting continued clinical benefit?
Examples include:
 - Improvement in symptoms Stabilization of symptoms
 - Improvement in WHO Functional Class
 - Stabilization of WHO Functional Class
 - Improvement in exercise tolerance
 - Reduction in PAH-related hospitalization
 - Improvement or stabilization of BNP or NT-proBNP
 - a. If yes, go to 3
 - b. If no, deny as not meeting criteria

3. Does provider follow-up confirm continued use and benefit?
 - a. If yes, go to 4
 - b. If no, deny as not meeting criteria
4. If renewing Winrevair (sotatercept-csrk), has updated six-minute walk distance documentation been submitted?
 - a. If yes, go to 5
 - b. If no, deny as not meeting criteria
5. If renewing Winrevair (sotatercept-csrk), does documentation support at least one of the following?
 - Improvement in six-minute walk distance
 - Improvement in WHO Functional Class
 - Improvement in BNP or NT-proBNP
 - Reduction in PAH-related hospitalization
 - Provider-documented improvement or stabilization in clinical status
 - a. If yes, go to 6
 - b. If no, deny as not meeting criteria
6. If renewing Winrevair (sotatercept-csrk), have updated hemoglobin and platelet counts been submitted and reviewed?
 - a. If yes, approve for up to 12 months
 - b. If no, deny as not meeting criteria

Rationale: These criteria are intended to ensure appropriate use of pulmonary arterial hypertension therapies for members with documented WHO Group 1 PAH or qualifying WHO Group 4 CTEPH. Coverage is limited to FDA-approved or guideline-supported uses and requires specialist involvement, objective confirmation of diagnosis, and progression through least costly clinically appropriate therapies prior to approval of higher-cost agents. Winrevair (sotatercept-csrk) is restricted to members who remain symptomatic despite optimized background therapy and requires objective disease severity and response measures, including six-minute walk testing and laboratory monitoring.

References:

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