Clinical Policy Title:	macitentan
Policy Number:	RxA.433
Drug(s) Applied:	Opsumit®, macitentan
Original Policy Date:	03/06/2020
Last Review Date:	07/20/2026
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Pulmonary Arterial Hypertension (must meet all):

1. Diagnosis of PAH;
2. PAH is symptomatic;
3. Member meets one of the following (a or b):
   a. Diagnosis of PAH was confirmed by right heart catheterization;
   b. Member is currently on any therapy for the diagnosis of PAH.

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

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

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

References

1. McLaughlin Vallerie V., Archer Stephen L., Badesch David B., et al. Accf/aha 2009 expert consensus document on pulmonary hypertension. Journal of the American College of Cardiology. 2009;53(17):1573-1619. Available at: https://www.jacc.org/doi/full/10.1016/j.jacc.2009.01.004. Accessed August 28, 2024.
2. Abman SH, Hansmann G, Archer SL, et al. Pediatric pulmonary hypertension: Guidelines from the American Heart Association and American Thoracic Society. Circulation. 2015; 132(21): 2037-99. Available at: https://pubmed.ncbi.nlm.nih.gov/26534956/. Accessed August 28, 2024.
3. Kim NH, Delcroix M, Jenkins DP, et al. Chronic thromboembolic pulmonary hypertension. J Am Coll Cardiol 2013; 62(25 Suppl): D92-99. Available at: https://pubmed.ncbi.nlm.nih.gov/24355646/. Accessed August 28, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated. 2. Continued therapy criteria II.A.1 was	07/20/2020	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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rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 3. References were updated.		
Policy was reviewed: 1. Initial Approval Criteria I.A.2 was updated to remove “Member has documented proof of negative pregnancy test…”. 2. Initial Approval Criteria and Continued Therapy Approval criteria were updated to remove HIM approval duration. 3. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 4. References were reviewed and updated.	06/25/2021	09/14/2021
Policy was reviewed: 1. References were reviewed and updated.	03/28/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.2: Updated to include new criteria pertaining to indication PAH, “PAH is symptomatic”. 2. Initial Approval Criteria, I.A.3: Updated to remove prior trial and failure criteria, “Trial and 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.” 3. Initial Approval Criteria, I.A.4: Updated to include new criteria pertaining to indication PAH, “Member meets one of the following (a or b): a. Diagnosis of PAH was confirmed by right heart catheterization; b. Member is currently on any therapy for the diagnosis of PAH;” 4. References were reviewed and updated.	04/24/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed prescriber restrictions.	08/28/2024	9/13/2024

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2. Removed dose restrictions. 3. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 4. Removed reauthorization requirement for positive response to therapy. 5. Updated approval duration verbiage. 6. References were reviewed and updated.		
Policy was reviewed.	12/05/2024	N/A
Policy was reviewed. 12/11/2025 12/11/2025	12/11/2025	12/11/2025

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