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| **Clinical Policy Title:** | macitentan |
| **Policy Number:** | RxA.433 |
| **Drug(s) Applied:** | Opsumit® |
| **Original Policy Date:** | 03/06/2020 |
| **Last Review Date:** | 08/28/2024 |
| **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.

**Approval Duration**

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

**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 |
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| Policy established. | 01/2020 | 03/06/2020 |
| Policy was reviewed:<br>1. Policy title table was updated. | 07/20/2020 | 09/14/2020 |

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| 2. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”.<br>3. References were updated. | | |
| Policy was reviewed:<br>1. Initial Approval Criteria I.A.2 was updated to remove “Member has documented proof of negative pregnancy test…”.<br>2. Initial Approval Criteria and Continued Therapy Approval criteria were updated to remove HIM approval duration.<br>3. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...".<br>4. References were reviewed and updated. | 06/25/2021 | 09/14/2021 |
| Policy was reviewed:<br>1. References were reviewed and updated. | 03/28/2022 | 07/18/2022 |
| Policy was reviewed:<br>1. Initial Approval Criteria, I.A.2: Updated to include new criteria pertaining to indication PAH, “PAH is symptomatic”.<br>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):<br>a. Inadequate response or contraindication to acute vasodilator testing;<br>b. Contraindication or clinically significant adverse effects to calcium channel blockers are experienced.”<br>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):<br>a. Diagnosis of PAH was confirmed by right heart catheterization;<br>b. Member is currently on any therapy for the diagnosis of PAH;”<br>4. References were reviewed and updated. | 04/24/2023 | 07/13/2023 |
| Policy was reviewed. | 10/19/2023 | 10/19/2023 |
| Policy was reviewed: | 08/28/2024 | 9/13/2024 |

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| 1. Removed prescriber restrictions.<br>2. Removed dose restrictions.<br>3. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days.<br>4. Removed reauthorization requirement for positive response to therapy.<br>5. Updated approval duration verbiage.<br>6. References were reviewed and updated. | | |