Clinical Policy Title:	macitentan
Policy Number:	RxA.433
Drug(s) Applied:	Opsumit®
Original Policy Date:	03/06/2020
Last Review Date:	10/19/2023
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. Prescribed by or in consultation with a cardiologist or a pulmonologist;
4. 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;
5. Dose does not exceed 10 mg per day.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 10 mg per day.

Approval Duration
Commercial: 12 months
Medicaid: 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 April 24, 2023.
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 April 24, 2023.
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 April 24, 2023.

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 rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 3. References were updated.	07/20/2020	09/14/2020
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