Clinical Policy Title:	bosentan
Policy Number:	RxA.521
Drug(s) Applied:	Bosentan, Tracleer
Original Policy Date:	03/06/2020
Last Review Date:	12/05/2024
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 WHO Group 1 PAH;
2. Enrolled in the bosenten REMS program;
3. Request meets one of the following (a or b):
   a. PAH is symptomatic;
   b. Diagnosis of PAH that is confirmed by right heart catheterization.

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. Galiè N, Humbert M, Vachiery JL, et al. 2015 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension. Kardiol Pol. 2015;73(12):1127-206. doi: 10.5603/KP.2015.0242. Available at: https://www.escardio.org/static-file/Escardio/Guidelines/Publications/PAH/2015%20ESC-ERS%20Gles%20PH-Web%20addenda-ehv317.pdf. Accessed August 28, 2024.
2. Dunlap B, Weyer GW. Pulmonary hypertension: diagnosis and treatment. AFP. 2016;94(6):463-469. Available at: https://www.aafp.org/afp/2016/0915/p463.html . Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical policy title was updated 2. Lines of business policy applies to was updated to all lines of business. 3. Initial criteria updated to include:	09/09/2020	12/07/2020

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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Member must be enrolled in the Bosenten REMS program; 4. Initial and Continued approval duration criteria for Commercial was updated from “Length of benefit” to 6 months and 12 months respectively. 5. Continued therapy approval criteria II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance…”. 6. References were reviewed and updated.		
Policy was reviewed: 1. Reference reviewed and updated.	09/22/2021	12/07/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from diagnosis of PAH to diagnosis of WHO Group 1 PAH. 2. References were reviewed and updated.	09/07/2022	10/19/2022
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed prescriber restrictions. 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.	08/28/2024	09/13/2024
Policy was reviewed.	12/05/2024	N/A

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