RAdvance

Clinical Policy Title:	pirtobrutinib
Policy Number:	RxA.794
Drug(s) Applied:	Jaypirca™
Original Policy Date:	04/13/2023
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Mantle cell lymphoma (MCL) (must meet all):

- 1. Diagnosis of relapsed or refractory mantle cell lymphoma (MCL);
- 2. Age \geq 18 years;
- 3. Member must have histologically confirmed MCL;
- 4. Trial and failure of at least two prior therapies, one of which was with a BTKi;
- 5. Member must have an Eastern Cooperative Oncology Group (ECOG) performance status score of 0 to 2;
- 6. Request meets one of the following (a or b):*
 - a. Dose does not exceed 200 mg orally once daily;
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration

Commercial: 2 months **Medicaid:** 2 months

II. Continued Therapy Approval

- A. Mantle cell lymphoma (MCL) (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;
 - 2. Member is responding positively to therapy;
 - 3. If request is for a dose increase, request meets one of the following (a or b):*
 - a. New dose does not exceed 200 mg orally once daily;
 - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN

Approval Duration

Commercial: 6 months

Medicaid: 6 months

References

1. National Comprehensive Cancer Network Guidelines. B-Cell Lymphomas. Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed March 20, 2023.

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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Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	03/20/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023