RAdvance

Clinical Policy Title:	ropeginterferon alfa-2b-njft	
Policy Number:	RxA.719	
Drug(s) Applied:	Besremi®	
Original Policy Date:	01/17/2022	
Last Review Date:	10/19/2023	
Line of Business Policy Applies to:	All lines of business (except Medicare)	

Criteria

I. Initial Approval Criteria

- A. Polycythemia Vera (must meet all):
 - 1. Diagnosis of high risk polycythemia vera (PV);
 - 2. Age \geq 18 years;
 - 3. Prescribed by or in consultation with an oncologist or a hematologist;
 - 4. Trial and failure of hydroxyurea or peginterferon alfa-2a ,unless contraindicated or clinically significant adverse effects are experienced;
 - 5. Documentation of JAK2 V617K mutation;
 - 6. Member meets one of the following:
 - a. For males: Documentation of hemoglobin level of at least 16.5 g/dL or hematocrit level of > 49% or increased red cell mass;
 - b. For females: Documentation hemoglobin level of at least 16 g/dL or a hematocrit level of > 48% or increased red cell mass;
 - 7. Request meets one of the following (a or b): *
 - a. Dose does not exceed 500 mcg subcutaneously every 2 weeks;
 - 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: 6 months

Medicaid: 6 months

II. Continued Therapy Approval

A. Polycythemia Vera (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. Dose does not exceed 500 mcg subcutaneously every 2 weeks;
 - 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.

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.

© 2023 RxAdvance Corporation. All rights reserved. This policy contains the confidential and proprietary information of RxAdvance. Unauthorized reproduction, distribution, modification, display, storage, transmission, or use of this policy or any information contained herein is strictly prohibited.

Revised 10/2023



Approval Duration Commercial: 6 months Medicaid: 6 months

References

- New guidelines from the nccn for polycythemia vera hematology & oncology. Available at: <u>https://www.hematologyandoncology.net/files/2017/11/ho1117ClinUpdate-1.pdf</u>. Accessed October 26, 2022.
- 2. National Comprehensive Cancer Network. Myeloproliferative Neoplasms Version 3.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf. Accessed October 26, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	12/01/2021	01/17/2022
 Policy was reviewed: Initial Approval Criteria, I.A.3: Updated to include new prescriber criteria Prescribed by or in consultation with an oncologist or a hematologist. Initial Approval Criteria, I.A.4: Updated trial and failure criteria from Failure of hydroxyurea at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced defined by one of the following(a-e): Need for phlebotomy to keep hematocrit less than 45% after 3 months on 2 g/day of HU; Platelet count >400 × 109/L and white blood count >10 × 10⁹/L after 3 months on 2 g/day of HU; Reduction of splenomegaly <50% after 2 g/day of HU; Absolute neutrophil count <1.0 × 10⁹/L or hemoglobin <10 g/dL; Presence of hydroxyurea side effects at any dose of hydroxyurea or peginterferon alfa-2a ,unless contraindicated or clinically significant adverse effects are experienced. 	10/26/2022	01/17/2023
Policy was reviewed.	10/19/2023	10/19/2023

© 2023 RxAdvance Corporation. All rights reserved. This policy contains the confidential and proprietary information of RxAdvance. Unauthorized reproduction, distribution, modification, display, storage, transmission, or use of this policy or any information contained herein is strictly prohibited.