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 ≥ 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.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

References

1. New guidelines from the nccn for polycythemia vera – hematology & oncology. Available at: https://www.hematologyandoncology.net/files/2017/11/ho1117ClinUpdate-1.pdf. 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: 1. Initial Approval Criteria, I.A.3: Updated to include new prescriber criteria Prescribed by or in consultation with an oncologist or a hematologist. 2. 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): a. Need for phlebotomy to keep hematocrit less than 45% after 3 months on 2 g/day of HU; b. Platelet count >400 × 109/L and white blood count >10 × 10^9/L after 3 months on 2 g/day of HU; c. Reduction of splenomegaly <50% after 2 g/day of HU; d. Absolute neutrophil count <1.0 × 10^9/L or platelet count <100 × 10^9/L or hemoglobin <10 g/dL; e. Presence of hydroxyurea side effects at any dose of hydroxyurea to Trial and failure of hydroxyurea or peginterferon alfa-2a ,unless contraindicated or clinically significant adverse effects are experienced. 3. References were reviewed and updated.	10/26/2022	01/17/2023
Policy was reviewed.	10/19/2023	10/19/2023