

<b>Clinical Policy Title:</b>	ropeginterferon alfa-2b-njft
<b>Policy Number:</b>	RxA.719
<b>Drug(s) Applied:</b>	Besremi®
<b>Original Policy Date:</b>	01/17/2022
<b>Last Review Date:</b>	12/11/2025
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. Polycythemia Vera (must meet all):

1. Diagnosis of high-risk polycythemia vera;
2. Trial and failure of hydroxyurea or peginterferon alfa-2a, unless contraindicated or clinically significant adverse effects are experienced;
3. Documentation of JAK2 V617K mutation;
4. 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.

#### Approval Duration

**All Lines of Business (except Medicare):** 6 months

### II. Continued Therapy Approval

#### A. Polycythemia Vera (must meet all):

1. Member is currently receiving medication in the past 120 days that has been authorized by RxAdvance or the member has met initial approval criteria.

#### Approval Duration

**All Lines of Business (except Medicare):** 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 March 24, 2025.
2. National Comprehensive Cancer Network. Myeloproliferative Neoplasms Version 1.2025. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/mpn.pdf](https://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf). Accessed March 24, 2025.

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	10/26/2022	01/17/2023

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.

<p>include new prescriber criteria Prescribed by or in consultation with an oncologist or a hematologist.</p> <p>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):</p> <ol style="list-style-type: none"> <li>a. Need for phlebotomy to keep hematocrit less than 45% after 3 months on 2 g/day of HU;</li> <li>b. Platelet count <math>&gt;400 \times 10^9/L</math> and white blood count <math>&gt;10 \times 10^9/L</math> after 3 months on 2 g/day of HU;</li> <li>c. Reduction of splenomegaly <math>&lt;50\%</math> after 2 g/day of HU;</li> <li>d. Absolute neutrophil count <math>&lt;1.0 \times 10^9/L</math> or platelet count <math>&lt;100 \times 10^9/L</math> or hemoglobin <math>&lt;10</math> g/dL;</li> <li>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.</li> </ol> <p>3. References were reviewed and updated.</p>		
<p>Policy was reviewed.</p>	<p>10/19/2023</p>	<p>10/19/2023</p>
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Removed prescriber criteria.</li> <li>2. Removed age criteria.</li> <li>3. Removed dosing criteria.</li> <li>4. Updated approval duration verbiage.</li> <li>5. Updated continuation of therapy language.</li> <li>6. Removed reauthorization requirement for positive response to therapy.</li> </ol>	<p>03/24/2025</p>	<p>04/10/2025</p>
<p>Policy reviewed.</p>	<p>12/11/2025</p>	<p>12/11/2025</p>