

Applicable Drugs: Besremi (ropeginterferon alfa-2b-njft)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 5/23/2022

Date Last Reviewed / Revised: 5/11/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

- I. Documentation of one of the following diagnoses A through B AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication

A. Polycythemia vera

- i. Documentation of a JAK2 V617F mutation.
- ii. Meets criteria a) or b) based on risk stratification:
 - a) Low risk (age < 60 years and no prior history of thrombosis)
 - (1) Documented treatment failure, intolerance, or contraindication to phlebotomy.
 - (2) Documented treatment failure, intolerance, or contraindication to hydroxyurea.
 - b) High risk (age ≥ 60 years and/or prior history of thrombosis)
 - (1) Documented treatment failure, intolerance, or contraindication to hydroxyurea.

Other Uses With Supportive Evidence

B. Essential Thrombocythemia

- i. Documented treatment failure, intolerance, or contraindication to hydroxyurea, peginterferon alfa-2a, or anagrelide.

- II. Minimum age requirement: 18 years old.
- III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.
- IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.
- V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

MEDICATION POLICY:

Besremi (ropeginterferon alfa-2b-njft)



EXCLUSION CRITERIA

- History or presence of active, serious, or untreated autoimmune disease.
- Immunosuppressed transplant recipients.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Besremi (Rpeginterferon alfa-2b-njft) 500 mcg/ml
 - 2 prefilled syringes per 28 days

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

N/A

REFERENCES

1. Besremi. Prescribing information. PharmaEssentia Corporation; 2024. Accessed May 1, 2026. https://us.pharmaessentia.com/downloads/Besremi_USPI_ENG.pdf
2. Gisslinger H, Zagrijtschuk O, Buxhofer-Ausch V, et al. Rpeginterferon alfa-2b, a novel IFNa-2b, induces high response rates with low toxicity in patients with polycythemia vera. *Blood*. 2015;126(15):1762-1769. doi:10.1182/blood-2015-04-637280
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Myeloproliferative Neoplasms Version 1.2026. Updated January 22, 2026. Accessed May 1, 2026. https://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.