

**Generic Name:** Ropeginterferon alfa-2b-njft

**Therapeutic Class or Brand Name:** Besremi®

**Applicable Drugs (if Therapeutic Class):** N/A

**Preferred:** N/A

**Non-preferred:** N/A

**Date of Origin:** 5/23/2022

**Date Last Reviewed / Revised:** 11/18/2024

## PRIOR AUTHORIZATION CRITERIA

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

- I. Documentation of the following diagnosis AND must meet all criteria listed under the applicable diagnosis:  
FDA-Approved Indication
  - A. Polycythemia vera and BOTH criteria i and ii are met:
    - i. Documentation of a JAK2 V617K mutation.
    - ii. Documented trial and failure of intolerance to or contraindication to hydroxyurea and phlebotomy.
- 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 clinical practice guidelines.
- 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).

## EXCLUSION CRITERIA

- Moderate or severe hepatic impairment (Child-Pugh B or C).
- History or presence of active serious or untreated autoimmune disease.
- Immunosuppressed transplant recipients.
- History of severe psychiatric disorders (particularly severe depression, suicidal ideation, or suicide attempt).

## OTHER CRITERIA

- N/A

## QUANTITY / DAYS SUPPLY RESTRICTIONS

- Besremi (Ropeginterferon alfa-2b-njft) 500 mcg/ml) 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 that the medication is effective.

## APPENDIX

N/A

## REFERENCES

1. Besremi. Prescribing information. PharmaEssentia Corporation; 2024. Accessed October 1, 2024. [https://us.pharmaessentia.com/downloads/Besremi\\_USPI\\_ENG.pdf](https://us.pharmaessentia.com/downloads/Besremi_USPI_ENG.pdf)
2. Gisslinger H, Zagrijtschuk O, Buxhofer-Ausch V, et al. Ropeginterferon 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. NCCN Clinical Practice Guidelines in Oncology. Myeloproliferative Neoplasms V.2.2024. Updated August 8, 2024. Accessed. October 1, 2024. [https://www.nccn.org/professionals/physician\\_gls/pdf/mpn.pdf](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.