

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: 8/20/2023

PRIOR AUTHORIZATION CRITERIA

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

- I. Documented diagnosis of the following condition AND must meet criteria listed under applicable diagnosis:
 - A. Polycythemia vera and BOTH criteria 1 and 2 are met:
 1. Documentation of a JAK2 V617K mutation.
 2. Documented trial and failure of, intolerance to, or contraindication to hydroxyurea and phlebotomy.
- II. Minimum age requirement: 18 years old.
- III. The prescribing physician is an oncologist or a hematologist.

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 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; 2021. Accessed July 15, 2023. <https://us.pharmaessentia.com/wp-content/uploads/2021/11/BESREMi-USPI-November-2021-1.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.1.2023. Updated May 19, 2023. Accessed. July 15, 2023. 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.