JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS151
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	Subject **Besremi**	*Revision Date*	07/20/2022
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Besremi

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I. POLICY

A. **Besremi** (ropeginterferon alfa-2b-njft) will require prior authorization for appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Besremi** may be approved for patients meeting the following:
   1. Patient is 18 years of age or older
   2. Documentation has been submitted showing the following:
      a. Diagnosis of polycythemia vera (PV) with the JAK2V617F mutation
      b. Baseline measurements of the following:
         I. Peripheral blood counts
         II. Serum triglycerides
         III. Liver function tests
         IV. Serum creatinine
      c. Patient has undergone a baseline ophthalmologic exam
      d. Patient has had trial and inadequate response, or contraindication, to hydroxyurea
      e. **Additional requirement for females of reproductive potential:
         I. Patient has had a negative pregnancy test prior to initiation of therapy, and will use an effective method of contraception during treatment
      f. Prescriber is, or has consulted with, an oncologist or hematologist

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 12 months of therapy
B. Approval for continuation of therapy may be extended in 12-month intervals with documentation of the following:

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1. On-treatment laboratory monitoring of peripheral blood counts,serum triglycerides, liver enzymes, and serum creatinine
2. Patient has had eye re-examinations since starting therapy
3. Patient has had a beneficial response to treatment, evidenced by at least one of the following:
    1. Positive morphological response
    2. Reduction or stabilization in spleen size
    3. Improvement of thrombocytosis/leukocytosis

IV. EXCLUSIONS

A. Besremi will not be approved for the following:
1. Pediatric patients
2. Immunosuppressed transplant patients
3. Patients with a history of severe psychiatric disorders, particularly severe depression, suicidal ideation, or suicide attempt
4. Patients with severe or unstable cardiovascular disease, such as uncontrolled hypertension, congestive heart failure (≥NYHA class 2), serious cardiac arrhythmia, significant coronary artery stenosis, or unstable angina
5. Patients with a history of recent stroke or myocardial infarction.
6. Patient with hypersensitivity to interferons
7. Patients with moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment
8. Patients with an eGFR <30 mL/min
9. Patients with a history or presence of active serious or untreated autoimmune disease
10. Any indications or usage that is not FDA-approved, or guideline-supported

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Besremi [prescribing information]. Burlington, MA: PharmaEssentia USA Corp.; November 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: https://www.nccn.org. Accessed June 27 2022.

VI. APPROVALS

Signature on file at JHHC

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7/20/2022	Policy Creation

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