Medical Drug Clinical Criteria

Subject:	BESREMi (ropeginterferon alfa-2b-njft)		
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Overview

This document addresses the use of Besremi (ropeginterferon alfa-2b-njft), for subcutaneous use in the treatment of adults with polycythemia vera. Polycythemia vera causes a thickening of the blood and affects roughly 6,200 people each year in the United States. The disorder causes overproduction of red blood cells, slowing blood flow and increasing the chance for blood clots, stroke, and heart attack. BESREMi is a monopegylated long-acting interferon whose cellular effects occur in the bone marrow by binding to a transmembrane receptor. Binding to this receptor initiates a downstream signaling cascade through the activation of kinases, such as JAK1, TYK2 and activator of transcription (STAT) proteins, which reduce red blood cell production in the bone marrow.

The FDA approval is based on various studies that show after 7.5 years of treatment Besremi majority of individuals with polycythemia vera experienced a complete hematological response. The approval was based on the safety data from PEGINVERA and PROUD/CONTINUATION-PV studies and efficacy data from the PEGINVERA clinical trial.

Individuals take Besremi every 2 weeks, and if successful in lowering the production of red blood cells after a year, individuals can reduce dosing to once per month.

Besremi has a black box warning as interferon alfa may cause or aggravate fatal or life-threatening neuropsychiatric, autoimmune, ischemic, and infectious disorders. Therapy should be withdrawn in patients with persistently severe or worsening signs or symptoms of these conditions. In many, but not all cases, these disorders resolve after stopping therapy.

The National Comprehensive Cancer Network® (NCCN) provides additional recommendations with a category 2A level of evidence for the following uses:

- Myeloproliferative neoplasms-polycythemia vera

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to prior authorization, the review will determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Besremi (ropeginterferon alfa-2b-njft)

Requests for Besremi (ropeginterferon alfa-2b-njft) may be approved when the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Individual is using for the treatment of polycythemia vera (Label, NCCN 2A).

Requests for Besremi (ropeginterferon alfa-2b-njft) may not be approved for any of the following:

I. Individual has a moderate or severe hepatic impairment (Child-Pugh B or C); **OR**
II. Individual has a severe or unstable cardiovascular disease (e.g., uncontrolled hypertension, congestive heart failure (≥ NYHA class 2), serious cardiac arrhythmia, significant coronary artery stenosis, unstable angina) or recent stroke or myocardial infarction; **OR**
III. Individual has an eGFR <30 mL/min; **OR**
IV. Individual has had a history of active serious or untreated autoimmune disease; **OR**
V. Individual is an immunosuppressed transplant recipient; **OR**
VI. Individual has an existence of, or history of severe psychiatric disorders, particularly severe depression, suicidal ideation or suicide attempt; **OR**

VII. When the above criteria are not met and for all other indications.

Quantity Limits

Besremi (ropeginterferon alfa-2b-njft) Quantity Limits

Drug	Limit
Besremi 500 mcg/ml prefilled syringe	2 prefilled syringes per 28 days

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J3490	Unclassified drugs (when specified as [BESREMi] (ropeginterferon alfa-2b-njft))
J3590	Unclassified biological (when specified as [BESREMi] (ropeginterferon alfa-2b-njft))
J9999	Not otherwise classified, antineoplastic drugs (when specified as [BESREMi] (ropeginterferon alfa-2b-njft))
C9399	Unclassified drugs or biologicals (when specified as [BESREMi] (ropeginterferon alfa-2b-njft))

ICD-10 Diagnosis

All diagnoses pend

Document History

Reviewed: 11/15/2024
Document History:

- 11/15/2024 – Annual Review: No changes. Coding Reviewed: No changes.
- 11/19/2023 – Annual Review: No changes. Coding Reviewed: No changes.
- 11/18/2022 – Annual Review: Minor wording and formatting updates. Coding Reviewed: No changes.
- 12/13/2021– New: Add new clinical criteria document with a PA and QL for Besremi. Coding Reviewed: Added HCPCS J3490, J3590 for Besremi. Add diagnoses pend. 9/23/2022 Added HCPCS J9999, C9399.

References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: September 19, 2024.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024 Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on September 19, 2024.
    a. Myeloproliferative Neoplasms. V2.2024. Revised August 8, 2024.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.