

Drug Policy:

Besremi™ (ropeginterferon alfa-2b-nijft)

POLICY NUMBER UM ONC_1454	SUBJECT Besremi™ (ropeginterferon alfa-2b-nijft)	DEPT/PROGRAM UM Dept	PAGE 1 of 3
DATES COMMITTEE REVIEWED 12/08/21, 05/11/22, 11/09/22, 11/08/23	APPROVAL DATE November 8, 2023	EFFECTIVE DATE November 27, 2023	COMMITTEE APPROVAL DATES 12/08/21, 05/11/22, 11/09/22, 11/08/23
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee	
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS	APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Besremi (ropeginterferon alfa-2b-nijft) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. Continuation requests for a not-approvable medication shall be exempt from this NCH policy provided:

1. The requested medication was used within the last year, AND
2. The member has not experienced disease progression and/or no intolerance to the requested medication, AND
3. Additional medication(s) are not being added to the continuation request.

B. Polycythemia Vera

1. Besremi (ropeginterferon alfa-2b-nijft) may be used as monotherapy in members with confirmed diagnosis of polycythemia vera who have any **ONE** of the following:
 - a. Contraindication to hydroxyurea (e.g., childbearing age)
 - b. Intolerance to hydroxyurea
 - c. A lack of therapeutic response to hydroxyurea.

III. EXCLUSION CRITERIA

- A. Disease progression while taking Besremi (ropeginterferon alfa-2b-nijft).
- B. Concurrent use with other cytoreductive agents (e.g., hydroxyurea), except when transitioning to Besremi (ropeginterferon alfa-2b-nijft).
- C. Dosing exceeds single dose limit of Besremi (ropeginterferon alfa-2b-nijft) 500 mcg.
- D. Investigational use of Besremi (ropeginterferon alfa-2b-nijft) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
 - 1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
 - 2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
 - 3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
 - 4. Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
 - 5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
 - 6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
 - 7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. MEDICATION MANAGEMENT

- A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

- A. Review – Utilization Management Department
- B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

- A. None

VII. REFERENCES

- A. Gisslinger H et al. long term use of ropeginterferon alfa 2-b in polycythemia vera: 5 year results from a randomized controlled study and its extension. 2020;136(Suppl):33. DOI:10.1182/blood-2020-136973.

- B. Gisslinger H, et al. Ropeginterferon alfa-2b, a novel IFN α -2b, induces high response rates with low toxicity in patients with polycythemia vera. *Blood*. 2015;126(15):1762-1769.
- C. Besremi prescribing information. PharmaEssentia USA Corporation Burlington, MA 2021.
- D. Clinical Pharmacology Elsevier Gold Standard 2023.
- E. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2023.
- F. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2023.
- G. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs Bethesda, MD 2023.
- H. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. *J Clin Oncol*. 2014 Apr 20;32(12):1277-80.
- I. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>.
- J. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: <http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>.
- K. NCQA UM 2023 Standards and Elements.