



**Prior Authorization  
Oncology (Injectable) – Besremi® (ropeginterferon alfa-2b-njft  
subcutaneous injection)**

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**Product Identifier(s)**

79770

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**National Formulary Medical Necessity**

**Cigna covers ropeginterferon alfa-2b-njft (Besremi®) as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:**

Prior Authorization is recommended for prescription benefit coverage of Besremi. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of individuals treated with Besremi as well as the monitoring required for adverse events and long-term efficacy, approval requires Besremi to be prescribed by or in consultation with a physician who specializes in the condition being treated.

FDA Indication(s)

1. **Polycythemia Vera.** Approve for 1 year the individual meets the following criteria (A and B):
  - A) Individual is ≥ 18 years of age; AND
  - B) Besremi is prescribed by or in consultation with an oncologist.

## Conditions Not Covered

Ropeginterferon alfa-2b-njft (Besremi<sup>®</sup>) is considered experimental, investigational or unproven for ANY other use including the following (this list may not be all inclusive):

- 1. Concomitant Use with Other Interferon Products.** Besremi was not studied in combination with other interferon products; concomitant use would be expected to result in increased toxicity.  
Note: An example of an interferon product is Pegasys<sup>®</sup> (peginterferon alfa-2a subcutaneous injection).
- 2. Hepatitis B Virus.** Besremi is not indicated for hepatitis B.<sup>1</sup> Pegylated interferons are recommended in American Association for the Study of Liver Diseases (AASLD) guidelines for chronic hepatitis B (updated 2018).<sup>3</sup> Phase I/II data suggest similar efficacy between Besremi and Pegasys for chronic hepatitis B; however, further data are needed.<sup>4</sup>
- 3. Hepatitis C Virus.** Besremi is not indicated for hepatitis C.<sup>1</sup> Pegasys, another pegylated interferon, is indicated for the treatment of chronic hepatitis C. However, peginterferons are no longer addressed by the AASLD recommendations for testing, managing, and treating HCV (updated October 24, 2022).<sup>5</sup>

## Background

### Overview

Besremi, an interferon alfa, is indicated for treatment of adults with **polycythemia vera**.<sup>1</sup>

### Guidelines

The National Comprehensive Cancer Network guidelines for myeloproliferative neoplasms (version 3.2022 – August 11, 2022) discuss therapies for polycythemia vera.<sup>2</sup> In low-risk patients, management of cardiovascular risk factors, low-dose aspirin (81 to 100 mg/day), and phlebotomy to maintain hematocrit < 45% are recommended (category 2A for all). Besremi is listed as another recommended regimen (category 2B). A footnote comments that cytoreductive therapy is not recommended for initial treatment. In high-risk patients, preferred regimens for cytoreductive therapy include hydroxyurea or Pegasys<sup>®</sup> (peginterferon alfa-2a subcutaneous injection) [category 2A for both]. Besremi is another recommended regimen in this setting (category 2A). A footnote comments that Pegasys can be considered for younger patients, pregnant patients, or patients who defer hydroxyurea or Besremi.

## References

1. Besremi<sup>®</sup> subcutaneous injection [prescribing information]. Burlington, MA: PharmaEssentia; November 2021.
2. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines in Oncology (version 3.2022 – August 11, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on November 14, 2022.
3. Terrault NA, Lok ASF, McMahon BJ, et al. Update on prevention, diagnosis, and treatment of chronic hepatitis B: AASLD 2018 hepatitis B guidance. *Hepatology*. 2018 Apr;67(4):1560-1599.
4. Huang YW, Hsu CW, Lu SN, et al. Ropeginterferon alfa-2b every 2 weeks as a novel pegylated interferon for patients with chronic hepatitis B. *Hepatol Int*. 2020 Dec;14(6):997-1008.
5. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Testing, managing, and treating hepatitis C. Updated October 24, 2022. Available at: <http://www.hcvguidelines.org>. Accessed on: November 14, 2022.

## Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	No criteria changes.	11/16/2022

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