

PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Besremi Prior Authorization Policy

- Besremi® (ropeginterferon alfa-2b-njft subcutaneous injection – PharmaEssentia)

REVIEW DATE: 11/15/2023

OVERVIEW

Besremi, an interferon alfa-2b, is indicated for treatment of adults with **polycythemia vera**.¹

Guidelines

The National Comprehensive Cancer Network guidelines for myeloproliferative neoplasms (version 3.2023 – October 25, 2023) discuss therapies for polycythemia vera.² 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, hydroxyurea, and Pegasys® (peginterferon alfa-2a subcutaneous injection) are listed as a “preferred” regimens for symptomatic low-risk polycythemia vera (category 2A). In high-risk patients, “preferred” regimens for cytoreductive therapy include hydroxyurea, Pegasys, and Besremi [category 2A for all]. Besremi can also be used if the patient has an inadequate response or loss of response to hydroxyurea or interferons, if not previously used. A footnote states that Pegasys is an option for younger patients or in pregnant patients in need of cytoreductive therapy for both low-risk and high-risk disease.

POLICY STATEMENT

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 patients 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Besremi is recommended in those who meet the following criteria:

FDA-Approved Indication

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

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Besremi is not recommended in the following situations:

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.

11/15/2023

© 2023. All Rights Reserved.

This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

Note: An example of an interferon product is Pegasys® (peginterferon alfa-2a subcutaneous injection).

2. **Hepatitis B Virus.** Besremi is not indicated for hepatitis B.¹ Pegylated interferons are recommended in American Association for the Study of Liver Diseases (AASLD) guidelines for chronic hepatitis B (updated 2018).³ Phase I/II data suggest similar efficacy between Besremi and Pegasys for chronic hepatitis B; however, further data are needed.⁴
3. **Hepatitis C Virus.** Besremi is not indicated for hepatitis C.¹ 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).⁵
4. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Besremi® subcutaneous injection [prescribing information]. Burlington, MA: PharmaEssentia; November 2021.
2. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines in Oncology (version 3.2023 – October 25, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on November 14, 2023.
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. Roppeginterferon 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 9, 2023.