VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Besremi Prior Authorization Policy
- Besremi® (ropeginterferon alfa-2b-njft subcutaneous injection – PharmaEssentia)

REVIEW DATE: 11/17/2021

OVERVIEW
Besremi, an interferon alfa, is indicated for treatment of adults with **polycythemia vera**.[1]

Guidelines
The National Comprehensive Cancer Network guidelines for myeloproliferative neoplasms (version 1.2022 – February 28, 2022) 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 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® (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.

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 criteria (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.
   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 2020).[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 1.2022 – February 28, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 16, 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 August 27, 2020. Available at: http://www.hcvguidelines.org. Accessed on: November 16, 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	11/17/2021
Update	**02/02/2022:** No criteria changes. The policy name was updated to "Oncology (Injectable) – Besremi Prior Authorization Policy"; previously, it was "Oncology – Besremi Prior Authorization Policy".	NA
Update	**03/16/2022:** No criteria changes. The Overview section was updated to include the most recent National Comprehensive Cancer Network myeloproliferative neoplasm guidelines (version 1.2022 – February 28, 2022), which address Besremi.	NA

NA – Not applicable.