PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 07/16/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

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

Guidelines

The National Comprehensive Cancer Network guidelines for myeloproliferative neoplasms (version 2.2025 – July 8, 2025) 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 or participation in a clinical trial are listed as "preferred" regimens for symptomatic low-risk polycythemia vera (category 2A). In high-risk patients, "preferred" regimens for cytoreductive therapy include hydroxyurea or Besremi (category 2A for both). Besremi is listed as "other recommended regimen"

if the patient has an inadequate response or loss of response to first-line therapy, if not previously used.

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.

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is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

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

CONDITIONS NOT COVERED

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

is(are) considered not medically necessary for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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 October 24, 2022).[5]

REFERENCES

1. Besremi® subcutaneous injection [prescribing information]. Burlington, MA: PharmaEssentia; April 2024.
2. The NCCN Myeloproliferative Neoplasms Clinical Practice Guidelines in Oncology (version 2.2025 – July 8, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 14, 2025.
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: July 5, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	11/15/2023
Annual Revision	No criteria changes.	07/10/2024
Annual Revision	No criteria changes.	07/16/2025