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DRUG POLICY

Besremi (ropeginterferon alfa-2b-njft)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Besremi (ropeginterferon alfa-2b-njft) drug policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Besremi is indicated for the treatment of adults with polycythemia vera.

Compendial Uses

1. Myeloproliferative neoplasms
 - A. Essential thrombocythemia
 - B. Myelofibrosis
 - C. Polycythemia vera
2. Chronic myeloid leukemia
3. Systemic mastocytosis
4. Mycosis fungoides/Sézary syndrome
5. Primary cutaneous CD30+ T-cell lymphoproliferative disorders
6. Adult T-cell leukemia/lymphoma

POLICY

Criteria for Initial Approval

Myeloproliferative Neoplasms

Authorization of 12 months may be granted for treatment of essential thrombocythemia when either of the following criteria is met:

1. Member has had an inadequate response or loss of response to prior cytoreductive therapy [e.g., anagrelide, hydroxyurea, or peginterferon alfa-2a (Pegasys)]
2. Peginterferon alfa-2a (Pegasys) is unavailable

Authorization of 12 months may be granted for treatment of myelofibrosis, if peginterferon alfa-2a (Pegasys) is unavailable.

Authorization of 12 months may be granted for treatment of polycythemia vera

Chronic Myeloid Leukemia

Authorization of 12 months may be granted for initial treatment of chronic myeloid leukemia in pregnancy

Systemic Mastocytosis

Authorization of 12 months may be granted for treatment of systemic mastocytosis, if peginterferon alfa-2a (Pegasys) is unavailable

Mycosis Fungoides/Sézary Syndrome

Authorization of 12 months may be granted for treatment of mycosis fungoides/Sézary syndrome, if peginterferon alfa-2a (Pegasys) is unavailable

Primary Cutaneous CD30+ T-Cell Lymphoproliferative Disorders

Authorization of 12 months may be granted for treatment of primary cutaneous CD30+ T-cell lymphoproliferative disorders, if peginterferon alfa-2a (Pegasys) is unavailable

Adult T-Cell Leukemia/Lymphoma

Authorization of 12 months may be granted for treatment of adult T-cell leukemia/lymphoma, if peginterferon alfa-2a (Pegasys) is unavailable

Continuation of Therapy

Myeloproliferative Neoplasms

Authorization of 12 months may be granted if the member is experiencing benefit from therapy as evidenced by improvement in symptoms and/or disease markers (e.g., morphological response, reduction or stabilization in spleen size, improvement of thrombocytosis/leukocytosis)

All Other Indications

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for all other indications in the coverage criteria section, not previously listed, when there is no evidence of unacceptable toxicity or disease progression while on the current regimen

Other

Besremi (ropeginterferon alfa-2b-njft) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limit

Besremi 500 mcg/mL prefilled syringe – 2 prefilled syringes per 28 days

Besremi 500 mcg/0.5 mL pen – 2 pens per 28 days

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

- Besremi [package insert]. Burlington, MA: PharmaEssentia USA Corporation; April 2024.
- The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed May 5, 2026.

POLICY HISTORY

Policy #: 05.04.50

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