| Reference number(s) |
| --- |
| 5060-A |

# Specialty Guideline Management
# Besremi

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| Besremi | ropeginterferon alfa-2b-njft |

## Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

### FDA-Approved Indication

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

### Compendial Uses[2]

- Myeloproliferative neoplasms
  - Essential thrombocythemia
  - Myelofibrosis
  - Polycythemia vera
- Chronic myeloid leukemia
- Systemic mastocytosis
- Mycosis fungoides/Sézary syndrome
- Primary cutaneous CD30+ T-cell lymphoproliferative disorders
- Adult T-cell leukemia/lymphoma

All other indications are considered experimental/investigational and not medically necessary.

| Reference number(s) |
| --- |
| 5060-A |

# Coverage Criteria

## Myeloproliferative Neoplasms[1-2]

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

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

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

## Systyemic Mastocytosis[2]

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

## Mycosis Fungoides/Sézary Syndrome[2]

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[2]

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[2]

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.

# References

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