

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3164-3
Program	Step Therapy
Medication	Besremi® (ropeginterferon alfa-2b-njft)
P&T Approval Date	6/2022, 6/2023, 6/2024
Effective Date	9/1/2024

1. Background:

Step Therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a patient to try Pegasys® (peginterferon alfa-2a) before providing coverage for Besremi® (ropeginterferon alfa-2b-njft) for the treatment of polycythemia vera (PV). *

Pegasys and Besremi are preferred first-line treatments for polycythemia vera per the National Comprehensive Cancer Network (NCCN).¹ Pegasys is a covalent conjugate of recombinant interferon alfa-2a indicated for the treatment of hepatitis B and C² and is NCCN recommended for PV.¹ Besremi is a covalent conjugate of interferon alfa-2b indicated for the treatment of adults with PV.³

Patients currently on Besremi as documented in claims history will be allowed to continue their current therapy. Patients new to therapy will be required to meet the coverage criteria below.

Coverage Information:

For patients under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria^{a,b}:

<p>A. <u>Patients less than 19 years of age</u></p> <p>1. Besremi will be approved based on the following criterion:</p> <p style="padding-left: 40px;">a. Patient is less than 19 years of age</p> <p style="text-align: center;">Authorization will be issued for 12 months.</p> <p>B. <u>Polycythemia vera</u></p> <p>1. Besremi will be approved based on one of the following criteria:</p> <p style="padding-left: 40px;">a. History of failure, contraindication, or intolerance to Pegasys (peginterferon alfa-2a) (Document date and duration of trial)</p>

-OR-

b. **Both** of the following:

(1) Patient is currently on Besremi therapy

-AND-

(2) Patient has **not** received a manufacturer supplied sample at no cost from a prescriber's office, or any form of assistance from the PharmaEssentia Patient Assistance Program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) or a 30-day free trial from a pharmacy as a means to establish as a current user of Besremi

*Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the PharmaEssentia Patient Assistance Program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

C. Other Indications

1. **Besremi** will be approved

Authorization will be issued for 12 months

^a State mandates may apply. Any federal regulatory requirements and the patient specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

^b Coverage of oncology medications may be approved based on state mandates.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits and/or Notification may be in place.
- Coverage of oncology medications may be approved based on state mandates.

4. References:

1. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed May 3, 2024.
2. Pegasys [package insert]. South San Francisco, CA: Genentech USA, Inc.; March 2021.
3. Besremi [package insert]. Burlington, MA: PharmaEssentia Corporation; November 2021.

Program	Step Therapy - Besremi® (ropeginterferon alfa-2b-njft)
Change Control	
6/2022	New program.
6/2023	Annual review. Updated references.
6/2024	Annual review. Updated references.