UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1048-15
Program	Prior Authorization/Notification
Medications	Besremi® (ropeginterferon alfa-2b-njft)
P&T Approval Date	2/2004, 7/2007, 4/2009, 12/2009, 9/2010, 9/2011, 8/2012, 11/2012, 4/2013, 2/2014, 4/2014, 5/2015, 11/2016, 11/2017, 11/2018, 11/2019, 11/2020, 11/2021, 1/2022, 10/2022, 10/2023, 10/2024
Effective Date	1/1/2025

1. Background:

Besremi (ropeginterferon alfa-2b-njft) is an interferon alfa-2b indicated for the treatment of adults with polycythemia vera.[2]

2. Coverage Criteria[a]:

A. Polycythemia Vera

1. **Besremi** will be approved based upon the following criterion:

   a. Diagnosis of polycythemia vera

   Authorization will be issued for 12 months.

B. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

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

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 Step Therapy may be in place.

4. References:

1. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Accessed September 6, 2024 at https://www.nccn.org/compendia-templates/compendia/nccn-compendia
2. Besremi [package insert]. Burlington, MA: PharmaEssentia; April 2024.

Program	Prior Authorization/Notification - Besremi
Change Control	
4/2014	For Pegasys and Peg-Intron, added patients with chronic hepatitis C genotype 3 as a patient population that may receive Sovaldi triple therapy.
2/2014	Removed all age criteria. Added criteria for triple therapy regimen including Olysio. Added criteria for triple therapy regimen including Sovaldi. Added criteria for giant cell tumor of the bone.
5/2015	Revised criteria for treatment of hepatitis C given market removal of Incivek, Infergen and pending removal of Victrelis. Criteria now reflects the shift in treatment of hepatitis C to non-interferon based therapies.
6/2015	Administrative change. Documented approval period for Pegasys "other indications"
11/2016	Annual review. Consolidation of hepatitis B and C criteria. Updated off-label NCCN recommendations for use. Updated references.
11/2017	Annual review. Updated off-label NCCN recommendations for use. Removed CML (Intron A, Pegasys, Pegintron) and systemic light chain amyloidosis (Intron A) indications as no longer rec by NCCN. Updated references.
11/2018	Annual review. Updated background and criteria to include NCCN recommended use for systemic mastocytosis. Updated references.
11/2019	Annual review. Added general NCCN recommendations for use criteria. Updated references.
11/2020	Annual review. Updated background and criteria to include NCCN recommendations. Updated references.
11/2021	Annual review. Removed discontinued products, PegIntron and Sylatron. Updated background and criteria to align with label and NCCN guidelines. Updated references.
1/2022	Added criteria for Besremi. Updated references.
10/2022	Removed Intron A and Pegasys from program, including updates to background, criteria, and references. Added state mandate.
10/2023	Annual review without changes to criteria. Updated references.
10/2024	Annual review without changes to criteria. Updated references.