

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1048-14
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
Effective Date	1/1/2024

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:

<p>A. <u>Polycythemia Vera</u></p> <p>1. Besremi will be approved based upon the following criterion:</p> <p>a. Diagnosis of polycythemia vera</p> <p>Authorization will be issued for 12 months.</p> <p>B. <u>NCCN Recommended Regimens</u></p> <p>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</p> <p>Authorization will be issued for 12 months.</p> <p>^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.</p>

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 August 31, 2023 at <https://www.nccn.org/compendia-templates/compendia/nccn-compendia>
2. Besremi [package insert]. Burlington, MA: PharmaEssentia; November 2021.

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.