

Besremi (ropeginterferon alfa-2b-njft)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Besremi (ropeginterferon alfa-2b-njft)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Besremi (ropeginterferon alfa-2b-njft) may be approved when the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Individual is using for the treatment of polycythemia vera.

Requests for Besremi (ropeginterferon alfa-2b-njft) may not be approved for any of the following:

- I. Individual has a moderate or severe hepatic impairment (Child-Pugh B or C); **OR**
- II. Individual has a severe or unstable cardiovascular disease (e.g., uncontrolled hypertension, congestive heart failure (\geq NYHA class 2), serious cardiac arrhythmia, significant coronary artery stenosis, unstable angina) or recent stroke or myocardial infarction; **OR**
- III. Individual has an eGFR <30 mL/min; **OR**
- IV. Individual has had a history of active serious or untreated autoimmune disease; **OR**
- V. Individual is an immunosuppressed transplant recipient; **OR**
- VI. Individual has an existence of, or history of severe psychiatric disorders, particularly severe depression, suicidal ideation or suicide attempt; **OR**
- VII. When the above criteria are not met and for all other indications.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: November 18, 2021.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on November 18, 2021.
 - a. Myeloproliferative Neoplasms. V2.2021. Revised August 18, 2021.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.