BlueCross BlueShield
Federal Employee Program

BESREMI
(ropeginterferon alfa-2b-njft)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Besremi (ropeginterferon alfa-2b-njft) belongs to the class of type I interferons, which exhibit their cellular effects in polycythemia vera in the bone marrow by binding to a transmembrane receptor termed interferon alfa receptor (IFNAR). Binding to IFNAR initiates a downstream signaling cascade through the activation of kinases, in particular Janus kinase 1 (JAK1) and tyrosine kinase 2 (TYK2) and activator of transcription (STAT) proteins. Nuclear translocation of STAT proteins controls distinct gene-expression programs and exhibits various cellular effects. The actions involved in the therapeutic effects of interferon alfa in polycythemia vera are not fully elucidated (1).

Regulatory Status

FDA-approved indication: Besremi is an interferon alfa-2b indicated for the treatment of adults with polycythemia vera (1).

Besremi contains a boxed warning regarding the risk of serious disorders. Interferon alfa products may cause or aggravate fatal or life-threatening neuropsychiatric, autoimmune, ischemic, and infectious disorders. Patients should be closely monitored with periodic clinical and laboratory evaluations. Therapy should be withdrawn in patients with persistently severe or worsening signs or symptoms of these conditions. In many, but not all cases, these disorders resolve after stopping therapy (1).

Besremi is contraindicated in patients with: (1)

- Existence of, or history of severe psychiatric disorders, particularly severe depression, suicidal ideation, or suicide attempt
- Moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment
- History or presence of active serious or untreated autoimmune disease
- Immunosuppressed transplant recipients

Besremi also contains warnings regarding the following: depression and suicide, endocrine toxicity, cardiovascular toxicity, decreased peripheral blood counts, hypersensitivity reactions, pancreatitis, colitis, pulmonary toxicity, ophthalmologic toxicity, hyperlipidemia, hepatotoxicity, renal toxicity,

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dental and periodontal toxicity, dermatologic toxicity, and driving and operating machinery (1).

Besremi can cause fetal harm when administered to a pregnant woman. Pregnancy testing is recommended in females of reproductive potential prior to treatment with Besremi. Females of reproductive potential should be advised to use an effective method of contraception during treatment with Besremi and for at least 8 weeks after the final dose (1).

A complete blood count (CBC) should be performed regularly, every 2 weeks during the titration phase and every 3-6 months during the maintenance phase. CBC should be monitored more frequently if clinically indicated. Phlebotomy as rescue treatment to normalize blood hyperviscosity may be necessary during the titration phase (1).

The safety and effectiveness of Besremi in pediatric patients less than 18 years of age have not been established (1).

Summary

Besremi (ropeginterferon alfa-2b-njft) is a type I interferon which binds to a transmembrane receptor, interferon alfa receptor (IFNAR). It is indicated for use in adult patients with polycythemia vera. Besremi has many warnings and precautions including the risk of serious disorders, including psychiatric disorders; embryo-fetal toxicity; and decreased peripheral blood counts. The safety and effectiveness of Besremi in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Besremi while maintaining optimal therapeutic outcomes.

References

1. Besremi [package insert]. Burlington, MA: PharmaEssentia USA Corporation; April 2024.
2. NCCN Drugs & Biologics Compendium® Ropeginterferon alfa-2b-njft 2025. National Comprehensive Cancer Network, Inc. Accessed on January 21, 2025.