Clinical Policy Title:	interferon gamma- 1b
Policy Number:	RxA.022
Drug(s) Applied:	Actimmune®
Original Policy Date:	02/07/2020
Last Review Date:	8/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Chronic Granulomatous Disease (must meet all)**:**

1. Diagnosis of Chronic Granulomatous Disease.

Approval Duration

All Lines of Business (except Medicare): 6 months

B. Severe Malignant Osteopetrosis (must meet all)**:**

1. Diagnosis of Severe Malignant Osteopetrosis (also known as marble bone disease or malignant infantile osteopetrosis (MIOP).

Approval Duration

All Lines of Business (except Medicare): 6 months

C. Mycosis Fungoides (MF) and Sezary Syndrome (SS) (off-label) (must meet all)**:**

1. Diagnosis of Mycosis Fungoides or Sezary Syndrome;
2. If request is for MF, patient is not stage IA-IIA MF with B1 blood involvement;
3. If request is for Sezary syndrome, patient is stage IVA1 or IVA2.

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Interferon Gamma-1b. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at nccn.org. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020

Policy reviewed & updated.	04/29/2020	05/20/2020
Policy was reviewed: 1. Policy title table was updated: Clinical Policy Title was updated to 'interferon gamma- 1b', Drug(s) Applied was updated to 'Actimmune®', Line of business policy applies was updated to All lines of business. 2. Initial approval criteria I.B.2 was updated as Prescribed by or in consultation with an endocrinologist or rheumatologist. 3. Continued therapy approval criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 4. Commercial approval durations were updated to 6 months from 6 months or to the member's renewal date, whichever is longer. Approval duration for HIM was removed. 5. References were updated.	01/25/2021	03/09/2021
Policy was reviewed: 1. Initial Approval Criteria, I.C.3 and I.C.4: updated to include diagnostic criteria IA-IIA, IVA1, and IVA2. 2. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 3. References were reviewed and updated.	11/18/2021	01/17/2022
Policy was reviewed: 1. Initial Approval Criteria I.C.6 and Continued Therapy Criteria II.A.3: Updated to add verbiage Prescribed regimen must be FDA approved or recommended by NCCN. 2. References were reviewed and updated.	07/06/2022	10/19/2022
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days.	8/28/2024	9/13/2024

5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.		