Interferon gamma-1b (Actimmune®)

Place of Service
Home Infusion
Self-Administration

HCPCS: **J9216** per 3 million units

Conditions listed in policy (*see criteria for details*)

- Chronic granulomatous disease (CGD)
- Mycosis fungoides or Sezary syndrome
- Osteopetrosis

AHFS therapeutic class: biologic response modifier

Mechanism of action: biosynthetic (recombinant DNA origin) form of endogenous human interferon gamma

(1) Special Instructions and pertinent Information

This drug is managed under the outpatient Pharmacy Benefit for self-administration. Please contact the member's Pharmacy Benefit for information on how to obtain this drug.

To submit a request to the Medical Benefit, please submit clinical information for prior authorization review and include medical rationale why the patient cannot self-administer this drug in the home.

For plans with self-injectables only covered under the Medical Benefit, please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Actimmune® for conditions NOT listed in section 3 must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Actimmune® for conditions NOT listed in section 3 must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Chronic granulomatous disease (CGD)

1. For reducing the frequency and severity of serious infections associated with CGD

Covered Doses
Body surface area > 0.5 m^2: up to 50 mcg/m^2 (1million IU/m^2) SC 3 times per week.
Body surface area ≤ 0.5 m^2: 1.5 mcg/kg/dose SC 3 times per week.

ICD-10: D71

Mycosis fungoides or Sezary syndrome

Covered Doses
Up to 50 mcg/m^2 SC 3 times per week.

ICD-10:
C84.00-C84.09, C84.10-C84.19

Osteopetrosis

1. For delaying time to disease progression in patients with severe, malignant osteopetrosis

Covered Doses
Body surface area > 0.5 m^2: up to 50 mcg/m^2 (1million IU/m^2) SC 3 times per week
Body surface area ≤ 0.5 m^2: 1.5 mcg/kg/dose SC 3 times per week.

ICD-10:
Q78.2

(4) This Medication is NOT medically necessary for the following condition(s)

Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

- Idiopathic Pulmonary Fibrosis

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:
100 mcg (2 million IU in a single-use vial)

(6) References

- Actimmune (interferon gamma-1b). [Prescribing information]. Deerfield, IL: Horizon Therapeutics USA, Inc.; 3/2021.
- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- National Comprehensive Cancer Network. Primary Cutaneous Lymphomas (Version 1.2022). Available by subscription at: www.nccn.org.

(7) Policy Update

Date of last review: 3Q2022
Date of next review: 3Q2023
Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee