Pharmacy Policy Bulletin

Title: Interferon gamma-1b (Actimmune®)

Policy #: Rx.01.230

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **Interferon gamma-1b (Actimmune®)** as provided under the member's prescription drug benefit.

Description:

Chronic Granulomatous Disease (CGD) is a disorder that causes the immune system to malfunction, resulting in immunodeficiency in patients. CGD is a genetically heterogeneous condition characterized by recurrent, life-threatening bacterial and fungal infections and granuloma formation. These defects result in the inability of phagocytes (neutrophils, monocytes, and macrophages) to destroy certain microbes. Patients with CGD are susceptible to infections from foreign invaders such as bacteria and fungi. Severe Malignant osteopetrosis is a disease where osteoclasts do not function the right way, and abnormal bone development occurs. This abnormal bone development can cause anemia, bleeding, and immunodeficiency.

Interferons bind to specific cell surface receptors and initiate a sequence of intracellular events that lead to the transcription of interferon-stimulated genes. The three major groups of interferons (alpha, beta, gamma) have partially overlapping biological activities that include immunoregulation such as increased resistance to microbial pathogens and inhibition of cell proliferation. Type 1 interferons (alpha and beta) bind to the alpha/ beta receptor. Interferon gamma binds to a different cell surface receptor and is classified as Type 2 interferon. Specific effects of interferon gamma include the enhancement of the oxidative metabolism of macrophages, antibody dependent cellular cytotoxicity (ADCC), activation of natural killer (NK) cells, and the expression of Fc receptors and major histocompatibility antigens.

Actimmune® is an interferon gamma indicated for reducing the frequency and severity of infections associated with Chronic Granulomatous Disease (CGD) and delaying the time to disease progression in patients with severe, malignant osteopetrosis.

Policy:

INITIAL CRITERIA: Interferon gamma-1b (Actimmune®) is approved when ONE of the following is met:

1. Diagnosis of chronic granulomatous disease (CGD); or
2. Diagnosis of severe, malignant osteopetrosis (SMO)

Initial authorization duration: 2 years

REAUTHORIZATION CRITERIA: Interferon gamma-1b (Actimmune®) is re-approved when there is documentation of positive clinical response to therapy (i.e. delay of malignant osteopetrosis disease progression; reduction in the frequency and severity of serious infections associated with Chronic Granulomatous Disease)

Reauthorization duration: 2 years

Black Box Warning as shown in the drug Prescribing Information:

N/A

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Actimmune® (interferon gamma) [package insert]. Rosewell, GA; HZNP Inc.: December 2019. Available from: https://www.hzndocs.com/ACTIMMUNE-Prescribing-Information.pdf. Accessed September 29, 2021.

Chronic granulomatous disease. US National Library of Medicine website. Updated August 18, 2020. Accessed September 29, 2021. Medlineplus.gov/genetics/condition/chronic-granulomatous-disease/#:~:text=Chroninc%20granulomatous%20disease%20is%20a,such%20bacteria%20and%20fungi.

What is severe malignant osteopetrosis (SMO)? Actimmune website. Accessed September 29, 2021. Actimmune.com/severe-malignant-osteopetrosis/

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Actimmune®	Interferon gamma-1b

Cross References:

Rx.01.33 Off Label Use

Rx.01.221 Drugs Exceeding Claim Dollar Limit Threshold

Policy Version Number:	2.00
P&T Approval Date:	September 23, 2021
Policy Effective Date:	January 01, 2022
Next Required Review Date:	September 23, 2022

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does

not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.