Prior Authorization Review Panel

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CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 02/01/2022**
Policy Number: PA.CP.PHAR.52	**Effective Date: 01/01/2018** **Revision Date: 01/2022**
Policy Name: Interferon Gamma- 1b (Actimmune)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ✓ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

1Q 2022 annual review: no significant changes; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Interferon Gamma-1b (Actimmune)

Reference Number: PA.CP.PHAR.52
Effective Date: 01/2018
Last Review Date: 01/2022

Coding Implications
Revision Log

Description
Interferon gamma-1b (Actimmune®) is a recombinant form of gamma interferon.

FDA Approved Indication(s)
Actimmune is indicated for:

- Reducing the frequency and severity of serious infections associated with Chronic Granulomatous Disease (CGD)
- Delaying time to disease progression in patients with severe, malignant osteopetrosis (SMO)

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness® that Actimmune is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Chronic Granulomatous Disease (must meet all):
1. Diagnosis of chronic granulomatous disease (CGD);
2. Age ≥ 1 year;
3. Prescribed by or in consultation with a hematologist or infectious disease specialist;
4. Prescribed dose does not exceed one of the following (a or b):
   a. Body surface area > $0.5m^2$: 50 mcg/m^2 three times weekly;
   b. Body surface area ≤ $0.5m^2$: 1.5mcg/kg three times weekly.

Approval duration: 6 months

B. Severe Malignant Osteopetrosis (must meet all):
1. Diagnosis of severe malignant osteopetrosis (SMO) (also known as autosomal recessive osteopetrosis);
2. Age ≥ 1 month;
3. Prescribed by or in consultation with an endocrinologist or rheumatologist;
4. Prescribed dose does not exceed one of the following (a or b):
   a. Body surface area > $0.5m^2$: 50mcg/m^2 three times weekly;
   b. Body surface area ≤ $0.5m^2$: 1.5mcg/kg three times weekly.

Approval duration: 6 months

C. Mycosis Fungoides, Sezary Syndrome (off-label) (must meet all):
1. Diagnosis of mycosis fungoides or Sezary syndrome;
2. Age ≥ 18 years;
3. Prescribed by or in consultation with an oncologist;
4. Request meets one of the following (a, b, or c):
   a. BSA > 0.5 m^2: Dose does not exceed 50 mcg/m^2 three times weekly;
   b. BSA ≤ 0.5 m^2: Dose does not exceed 1.5 mcg/kg three times weekly;

c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

D. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
   b. Documentation supports that member is currently receiving Actimmune for mycosis fungoides or Sezary syndrome and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, requestmeets one of the following (a, b, or c):
   a. BSA > 0.5 m^2: New dose does not exceed 50 mcg/m^2 three times weekly;
   b. BSA ≤ 0.5 m^2: New dose does not exceed 1.5 mcg/kg three times weekly.
   c. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Other diagnoses/indications (1 or 2):

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or Continuity of Care Policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to PA.CP.PMN.53

III. Appedices/General Information

Appendix A: Abbreviation/Acronym Key

BSA: body surface area
CGD: chronic granulomatous disease
FDA: Food and Drug Administration
SMO: severe, malignant osteopetrosis

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity to interferon gamma, *E. coli* derived products, or any component of the product
- Boxed warning(s): none reported

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CGD, SMO	BSA > 0.5 m^2: 50 mcg/m^2 SC TIW	See dosing regimen

Indication	Dosing Regimen	Maximum Dose
	BSA ≤ 0.5 m^2: 1.5 mcg/kg/dose SC TIW	

V. Product Availability

Single-use vial for injection: 100 mcg (2 million IU)/0.5 mL

VI. References

1. Actimmune Prescribing Information. Lake Forest, IL: Horizon Pharma USA, Inc.; March 2021. Available at: www.actimmune.com. Accessed September 13, 2021.

Primary Immunodeficiency

2. Immune Deficiency Foundation. Diagnostic and clinical care guidelines for primary immunodeficiency diseases. Third edition. Copyrights 2008, 2009, 2015 the Immune Deficiency Foundation. Available at: https://primaryimmune.org/sites/default/files/publications/2015-Diagnostic-and-Clinical-Care-Guidelines-for-PI_1.pdf. Accessed September 13, 2021.
3. Bonilla FA, Khan DA, Ballas ZK, et al. Practice parameter for the diagnosis and management of primary immunodeficiency. J Allergy Clin Immunol. November 2015; 136(5): 1186-1205.

Osteopetrosis

4. Wu CC, Econs MJ, DiMeglio L, et al. Diagnosis and management of osteopetrosis: consensus guidelines from the Osteopetrosis Working Group. J Clin Endocrinol Metab September 2017;102(9):3111–23.

Oncology

5. Interferon Gamma-1b. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed September 13, 2021.
6. National Comprehensive Cancer Network. Primary Cutaneous Lymphomas Version 2.2021. Available at: www.nccn.org. Accessed September 13, 2021.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9216	Injection, interferon, gamma 1-b, 3 million units

Reviews, Revisions, and Approvals	Date	Approval Date
Removed diagnostic confirmatory tests and replaced with specialty prescriber requirement. References reviewed and updated.	02/18	
1Q 2019 annual review: references reviewed and updated.	01/19	

Reviews, Revisions, and Approvals	Date	Approval Date
1Q 2020 annual review: off-label age increased to 18 years; removed requirement for confirmatory diagnostic tests for SMO; rheumatologist added as specialist for SMO; continuity of care added for oncology; references reviewed and updated.	01/20	
1Q 2021 annual review: references reviewed and updated.	01/21	
1Q 2022 annual review: no significant changes; references reviewed and updated.	01/2022	