Clinical Policy: Interferon Gamma-1b (Actimmune)

Reference Number: LA.PHAR.52
Effective Date: 07.23.22
Last Review Date: 02.03.25 ~~04.29.24~~
Line of Business: Medicaid

Coding Implications
Revision Log

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See Important Reminder at the end of this policy for important regulatory and legal information.

****Please note: This policy is for medical benefit****

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
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections 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 CGD;
2. Age ≥ 1 year;
3. Prescribed by or in consultation with a hematologist or infectious disease specialist;
4. Dose does not exceed one of the following (a or b):
   a. Body surface area (BSA) > 0.5 m^2: 50 mcg/m^2 three times weekly;
   b. BSA ≤ 0.5 m^2: 1.5 mcg/kg three times weekly.

Approval duration: 6 months

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

1. Diagnosis of SMO (also known as autosomal recessive osteopetrosis);
2. Prescribed by or in consultation with an endocrinologist or rheumatologist;
3. Age ≥ 1 month;
4. Dose does not exceed one of the following (a or b):
   a. BSA > 0.5 m^2: 50 mcg/m^2 three times weekly;
   b. BSA ≤ 0.5 m^2: 1.5 mcg/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. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration: 6 months

D. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;
   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, request meets 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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – LA.PMN.53 ~~for Medicaid, or evidence of coverage documents~~.

IV. Appendices/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

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CGD, SMO	BSA > 0.5 m^2: 50 mcg/m^2 SC TIW BSA ≤ 0.5 m^2: 1.5 mcg/kg/dose SC TIW	See dosing regimen

VI. Product Availability

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

VII. References

1. Actimmune Prescribing Information. Lake Forest, IL: Horizon Pharma USA, Inc.; March 2021. Available at: www.actimmune.com. Accessed October 12, 2023.

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 November 29, 2023.
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 November 28, 2023.
6. National Comprehensive Cancer Network. Primary Cutaneous Lymphomas Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf. Accessed November 28, 2023.

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	LDH Approval Date
Converted corporate to local policy.	04.22	07.23.22

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CLINICAL POLICY
Interferon Gamma-1b

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Template changes applied to other diagnoses/indications and continued therapy section. References reviewed and updated. Added blurb this policy is for medical benefit only.	06.27.23	10.24.23
Annual review; no significant changes; references reviewed and updated.	04.29.24	07.29.24
Annual review: no significant changes; references reviewed and updated.	02.03.25	

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

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