

Clinical Policy: Interferon Gamma- 1b (Actimmune)

Reference Number: CP.PHAR.52

Effective Date: 06.01.10

Last Review Date: 02.25

Line of Business: Commercial, HIM, Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

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 health plans affiliated with Centene Corporation[®] 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 \geq 1 year;
3. Prescribed by or in consultation with an immunologist, hematologist, or infectious disease specialist;
4. Dose does not exceed one of the following (a or b):
 - a. Body surface area (BSA) $>$ 0.5 m²: 50 mcg/m² three times weekly;
 - b. BSA \leq 0.5 m²: 1.5 mcg/kg three times weekly.

Approval duration:

Medicaid/HIM – 6 months

Commercial – 6 months or member's renewal period, whichever is longer

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 \geq 1 month;
4. Dose does not exceed one of the following (a or b):
 - a. BSA $>$ 0.5 m²: 50 mcg/m² three times weekly;
 - b. BSA \leq 0.5 m²: 1.5 mcg/kg three times weekly.

Approval duration:

Medicaid/HIM – 6 months

Commercial – 6 months or member’s renewal period, whichever is longer

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 or hematologist;
3. Age \geq 18 years;
4. Request meets one of the following (a, b, or c):*
 - a. BSA $>$ 0.5 m²: Dose does not exceed 50 mcg/m² three times weekly;
 - b. BSA \leq 0.5 m²: 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:

Medicaid/HIM – 6 months

Commercial – 6 months or member’s renewal period, whichever is longer

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 one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
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 for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 Centene 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 m²: New dose does not exceed 50 mcg/m² three times weekly;

- b. BSA $\leq 0.5 \text{ m}^2$: 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:

Medicaid/HIM – 6 months

Commercial – 6 months or member’s renewal period, whichever is longer

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 one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
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 for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.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	See dosing regimen
	BSA ≤ 0.5 m ² : 1.5 mcg/kg/dose SC TIW	

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 25, 2024.

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 October 31, 2024.
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 October 31, 2024.

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	P&T Approval Date
1Q 2021 annual review: no significant changes; references to HIM.PHAR.21 to HIM.PA.154; references reviewed and updated.	12.02.20	02.21
1Q 2022 annual review: no significant changes; references reviewed and updated.	09.13.21	02.22

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Template changes applied to other diagnoses/indications and continued therapy section.	10.18.22	
1Q 2023 annual review: no significant changes; references reviewed and updated.	11.22.22	02.23
1Q 2024 annual review: no significant changes; references reviewed and updated.	10.12.23	02.24
1Q 2025 annual review: for CGD, added immunologist as an additional prescriber specialist option; for mycosis fungoides and Sezary syndrome, added hematologist as an additional prescriber specialist option; references reviewed and updated.	10.31.24	02.25

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. The Health Plan 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. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible

for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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