Clinical Policy: Interferon Gamma-1b (Actimmune)

Reference Number: ERX.SPA.69
Effective Date: 04.01.14
Last Review Date: 02.22
Line of Business: Commercial, Medicaid

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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. Prescribed by or in consultation with a hematologist or infectious disease specialist;
3. Age ≥ 1 year;
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

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 a health plan affiliated with Envolve Pharmacy Solutions 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. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 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 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 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.

Oncology

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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q18 annual review: Removed diagnostic confirmatory tests and replaced with specialty prescriber requirement. Added NCCN compendium supported uses for mycosis fungoides and Sezary syndrome.	11.10.17	02.18
1Q 2019 annual review: no significant changes; references reviewed and updated.	10.25.18	02.19
1Q 2020 annual review: off-label age increased to 18 years; rheumatologist added as specialist for SMO; continuity of care added for oncology; references reviewed and updated.	11.19.19	02.20
1Q 2021 annual review: no significant changes; 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

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

be bound by the foregoing terms and conditions, in addition to the Site Use Agreement for Health Plans associated with Envolve Pharmacy Solutions.