

Specialty Guideline Management

Actimmune

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
|------------|---------------------|
| Actimmune | interferon gamma-1b |

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications¹

- 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).

Compendial Uses²

Mycosis fungoides/Sezary syndrome

All other indications are considered experimental/investigational and not medically necessary.

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

| |
|---------------------|
| Reference number(s) |
| 2375-A |

- Chronic Granulomatous Disease (CGD): immunologist or prescriber who specializes in the management of CGD
- Severe, malignant osteopetrosis (SMO): endocrinologist
- Mycosis fungoides/Sezary syndrome: hematologist or oncologist

Coverage Criteria

Chronic Granulomatous Disease¹

Authorization of 12 months may be granted to reduce the frequency and severity of infections associated with chronic granulomatous disease (CGD).

Severe, Malignant Osteopetrosis^{1,3}

Authorization of 12 months may be granted to delay time to disease progression in patients with severe, malignant osteopetrosis (SMO).

Mycosis Fungoides/Sezary Syndrome²

Authorization of 12 months may be granted for treatment of mycosis fungoides or Sezary syndrome.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

References

1. Actimmune [package insert]. Deerfield, IL: Horizon Therapeutics USA, Inc.; March 2021.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed August 9, 2025.
3. Orphanet. Autosomal recessive malignant osteopetrosis. Rare disease and orphan drug database. Last updated July 2023. Accessed August 18, 2025. <https://www.orpha.net/>