Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Actimmune® (interferon gamma-1b)

Effective: May 12, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Actimmune (interferon gamma-1b) is an interferon gamma indicated for reducing the frequency and severity of serious infections associated with Chronic Granulomatous Disease (CGD) and delaying time to disease progression in patients with severe, malignant osteopetrosis (SMO).

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Actimmune for Members when **ALL** of the following criteria are met:

Chronic Granulomatous Disease

Initial Authorization Criteria

1. Documented diagnosis of Chronic Granulomatous Disease

AND

2. Prescribed by or in consultation with an immunologist

Reauthorization Criteria

1. Documented diagnosis of Chronic Granulomatous Disease

AND

2. Prescribed by or in consultation with an immunologist

AND

3. Documentation the patient has experienced a therapeutic response defined by a reduction in the frequency and severity of serious infections associated with Chronic Granulomatous Disease

Severe, Malignant Osteoporosis

Initial Authorization Criteria

1. Documented diagnosis of Severe, Malignant Osteoporosis

AND

2. Prescribed by or in consultation with an endocrinologist

Reauthorization Criteria

1. Documented diagnosis of Severe, Malignant Osteoporosis

AND

2. Prescribed by or in consultation with an endocrinologist

AND

3. Documentation the patient has experienced a therapeutic response defined by an absence of disease progression (e.g., significant reduction in hemoglobin or platelet counts, serious bacterial infection requiring antibiotics, 50 decibel decrease in hearing, progressive optic atrophy)

Limitations

1. Authorizations will be provided for 12 months.
2. Members new to the plan stable on Actimmune should be reviewed against the Reauthorization Criteria.

Codes

None

References

1. Actimmune (interferon gamma-1b) [prescribing information]. Dublin, Ireland: Horizon Pharma Ireland Ltd; August 2015.
2. Key LL Jr, Rodriguiz RM, Willi SM, et al. Long-term treatment of osteopetrosis with recombinant human interferon gamma. N Engl J Med.1995;332(24):1594-99.
3. Zerbe CS, Marciano BE, Holland SM. Chronic granulomatous disease: pathogenesis, clinical manifestations, and diagnosis. In: UpToDate, Waltham, MA: Walters Kluwer Health;2016. Available at UpToDate.com. Accessed July 7, 2021.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

- May 9, 2023: No changes
- February 13, 2024: No changes
- January 14, 2025: No changes (eff 1/14/25)
- May 12, 2026: No changes, Template updated to remove CareLink from the Medical Necessity Guideline template.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.