UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 1001-14
Program	Prior Authorization/Notification
Medication	Actimmune® (interferon gamma-1b)
P&T Approval Date	02/2013, 8/2014, 8/2015, 6/2016, 6/2017, 6/2018, 6/2019, 6/2020, 6/2021, 6/2022, 6/2023, 6/2024, 6/2026
Effective Date	9/1/2026

1. Background:

Actimmune (interferon gamma-1b) is indicated for reducing the frequency and severity of serious infections associated with chronic granulomatous disease (CGD). It is also indicated for delaying time to disease progression in patients with severe, malignant osteopetrosis (SMO). The National Cancer Comprehensive Network (NCCN) recommends use of Actimmune in mycosis fungoides (MF) and Sézary syndrome (SS).

Coverage Information:
Members will be required to meet the criteria below for coverage.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

1. **Actimmune** will be approved based on **<u>both</u>** of the following criteria:

   a. Patient has oncology diagnosis

   -AND-

   b. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. <u>Chronic Granulomatous Disease (CGD)</u>

1. **Authorization**

   a. **Actimmune** will be approved based on the following criterion:

      (1) Diagnosis of chronic granulomatous disease

   Authorization will be issued for 12 months.

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2. **Reauthorization**

a. **Actimmune** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Actimmune

Authorization will be issued for 12 months.

C. Osteopetrosis

1. **Initial Authorization**

a. **Actimmune** will be approved based on the following criterion:

(1) Diagnosis of severe, malignant osteopetrosis

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Actimmune** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Actimmune

Authorization will be issued for 12 months.

D. Primary Cutaneous Lymphomas

1. **Initial Authorization**

a. **Actimmune** will be approved based on the following criterion:

(1) Patient has **one** of the following diagnoses:

(a) Mycosis fungoides (MF)
(b) Sézary syndrome (SS)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Actimmune** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Actimmune

Authorization will be issued for 12 months.

E. NCCN Recommended Regimens

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The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limits may apply.

4. References:

1. Actimmune [Package Insert]. Deerfield, IL: Horizon Therapeutics USA Inc.; December 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed April 28, 2026.

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Change Control	
8/2014	Annual review with no changes to Coverage Criteria. Updated formatting and References.
8/2015	Annual review. Added oncology indication requirement to age 19 criteria. Increased authorization and reauthorization from 6 months to 12 months for all indications. Updated references.
6/2016	Annual review. Added reauthorization criteria for CGD. Updated formatting and references.
6/2017	Annual review. Updated references.
6/2018	Annual review. Updated references.
6/2019	Annual review. Updated Non-Hodgkin's Lymphoma to Primary Cutaneous Lymphomas. Updated references.
6/2020	Annual review. Updated references.
6/2021	Annual review. No changes to coverage criteria. Updated background and references.
6/2022	Annual review. No changes to coverage criteria. Updated references.
6/2023	Annual review. No changes to coverage criteria. Added state mandate footnote. Updated reference.
6/2024	Annual review. No changes to coverage criteria.
6/2025	Annual review with no changes to coverage criteria. Updated references.
6/2026	Annual review with no changes to coverage criteria. Updated reference.

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