UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Actimmune

Program	Prior Authorization
Medication	Actimmune® (interferon gamma-1b)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	8/2014
Pharmacy and Therapeutics Approval Date	6/2020
Effective Date	8/2020

1. Background:

Actimmune (interferon gamma-1b) is a biologic response modifier indicated for the treatment of chronic granulomatous disease to reduce the frequency and severity of serious infections. It is also indicated in the treatment of severe, malignant osteopetrosis to delay the time to progression.[1] The National Cancer Comprehensive Network (NCCN) recommends use of Actimmune in mycosis fungoides (MF) and Sézary syndrome (SS).[2]

2. Coverage Criteria:

A. Chronic Granulomatous Disease (CGD)

1. Initial Authorization

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

(1) Diagnosis of chronic granulomatous disease

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.

B. 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.

C. Primary Cutaneous Lymphomas

1. **Initial Authorization**

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

      (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.

D. NCCN Recommended Regimens

1. **Initial Authorization**

   a. **Actimmune** will be approved for uses not outlined above if supported by The

National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. **Reauthorization**

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

(1) Documentation of positive clinical response to Actimmune therapy

Authorization will be issued for 12 months.

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]. Roswell, GA: HZNP USA Inc.; May 2017.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed April 29, 2020.

Program	Program type – Prior Authorization
Change Control	
Date	Change
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	Added NCCN recommended regimen criteria. Updated references.
6/2019	Changed Non-Hodgkin's Lymphoma to Primary Cutaneous Lymphomas. Updated references.

6/2020	Annual review. Updated reference. Added Additional Clinical Rules section.