

Clinical Pharmacy Program Guidelines for Actimmune

Program	Prior Authorization
Medication	Actimmune [®] (interferon gamma-1b)
Issue Date	8/2014
Pharmacy and Therapeutics Approval Date	6/2017
Effective Date	8/2017

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:

<p>A. <u>Chronic Granulomatous Disease (CGD)</u></p> <p>1. Initial Authorization</p> <p>a. Actimmune will be approved based on the following criterion:</p> <p style="padding-left: 40px;">(1) Diagnosis of chronic granulomatous disease</p> <p style="padding-left: 40px;">Authorization will be issued for 12 months.</p> <p>2. Reauthorization</p> <p>a. Actimmune will be approved based on the following criterion:</p> <p style="padding-left: 40px;">(1) Patient does not show evidence of progressive disease while on Actimmune</p> <p style="padding-left: 40px;">Authorization will be issued for 12 months.</p> <p>B. <u>Osteopetrosis</u></p> <p>1. Initial Authorization</p>
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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. Non-Hodgkin's Lymphoma (NHL) (off-label)

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.

3. References:

1. Actimmune [Package Insert]. Roswell, GA: HZNP USA Inc.; July 2016.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed May 2, 2017.

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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.