Medical Drug Clinical Criteria

Subject:	Actimmune (interferon gamma-1b)		
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Overview

This document addresses the use of Actimmune (interferon gamma-1b). Actimmune is a biologic response modifier primarily used in the management of chronic granulomatous disease and severe malignant osteopetrosis.

The FDA approved indications for Actimmune include chronic granulomatous disease and severe malignant osteopetrosis. The National Comprehensive Cancer Network® (NCCN) provides additional recommendations with a category 2A level of evidence for the use of Actimmune in mycosis fungoides and Sezary syndrome.

Definitions and Measures

Chronic Granulomatous Disease: A heterogeneous group of primary inherited immunodeficiency disorders which increase the body's susceptibility to recurrent, potentially life-threatening bacterial and fungal infections and abnormal inflammatory responses that result in excessive granuloma formation.

Mycosis Fungoides: A sub-type of cutaneous T-cell lymphoma in which tumor cells invade the skin causing reddening (erythroderma) and/or plaques. There may also be involvement of lymph nodes, blood, and internal organs.

Sézary Syndrome: A sub-type of cutaneous T-cell lymphoma characterized by itching and redness with T cell leukemia whose cells clonally match those invading the skin. Sézary Syndrome has historically been more difficult to treat than mycosis fungoides.

Severe Malignant Osteopetrosis: A rare inherited disorder, sometimes referred to as marble bone disease or malignant infantile osteopetrosis, characterized by defective osteoclast function leading to abnormal bone development resulting in bone fractures, problems with vision and hearing, and abnormal appearance of the face and head.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Actimmune (interferon gamma-1b)

Requests for Actimmune (interferon gamma-1b) may be approved if the following criteria are met:

I. Individual has a diagnosis of one of the following:
   A. Chronic granulomatous disease; **OR**
   B. Severe malignant osteopetrosis; **OR**
   C. Mycosis fungoides, including Sezary syndrome (NCCN 2A).

Requests for Actimmune (interferon gamma-1b) may not be approved for the following:

I. Advanced ovarian or primary peritoneal cancer; **OR**
II. Atopic dermatitis; **OR**
III. Brain tumors; **OR**
IV. Chronic hepatitis C; **OR**
V. Friedreich's ataxia; **OR**

VI. Idiopathic pulmonary fibrosis; **OR**
VII. Invasive fungal infection, post-transplantation (for example, after hematopoietic stem cell or solid organ transplantation); **OR**
VIII. Metastatic renal cell cancer; **OR**
IX. Pulmonary tuberculosis; **OR**
X. When the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J9216	Injection, interferon, gamma-1b, 3 million units [Actimmune]

ICD-10 Diagnosis

C84.00-C84.09	Mycosis fungoides
C84.10-C84.19	Sézary disease
D71	Functional disorders of polymorphonuclear neutrophils (chronic granulomatous disease)
Q78.2	Osteopetrosis

Document History

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- 05/17/2019 – Annual Review: First review of Actimmune clinical criteria. Wording and formatting changes. Add reference for off label criteria. Coding reviewed: No changes

References

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: September 11, 2024.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on September 11, 2024.
    a. Primary Cutaneous Lymphomas. V3.2024. Revised August 22, 2024.