

SPECIALTY GUIDELINE MANAGEMENT

ACTIMMUNE (interferon gamma-1b)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Actimmune is indicated for reducing the frequency and severity of serious infections associated with chronic granulomatous disease (CGD).
2. Actimmune is indicated for delaying time to disease progression in patients with severe, malignant osteopetrosis (SMO).

B. Compendial Uses

Mycosis fungoides/Sezary syndrome

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. **Chronic Granulomatous Disease**

Authorization of 12 months may be granted to reduce the frequency and severity of infections associated with chronic granulomatous disease.

B. **Severe, Malignant Osteopetrosis**

Authorization of 12 months may be granted to delay time to disease progression in patients with severe, malignant osteopetrosis.

C. **Mycosis Fungoides/Sezary Syndrome**

Authorization of 12 months may be granted for treatment of mycosis fungoides or Sezary syndrome.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II who are experiencing benefit from therapy as evidenced by disease stability or disease improvement.

IV. REFERENCES

1. Actimmune [package insert]. Deerfield, IL: Horizon Therapeutics USA, Inc.; May 2021.

| Reference number(s) |
|---------------------|
| 2375-A |

2. The NCCN Drugs & Biologics Compendium 2020 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed July 27, 2021.