

## 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. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with one of the following:

- A. Chronic Granulomatous Disease (CGD): immunologist or prescriber who specializes in the management of CGD.
- B. Severe, Malignant Osteopetrosis (SMO): endocrinologist.
- C. Mycosis Fungoides/Sezary Syndrome: hematologist or oncologist.

#### III. 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.

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

#### IV. CONTINUATION OF THERAPY

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

#### V. REFERENCES

1. Actimmune [package insert]. Deerfield, IL: Horizon Therapeutics USA, Inc.; March 2021.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed August 8, 2023.