Reference number(s)
2375-A

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 infection associated with chronic granulomatous disease.

B. Severe, Malignant Osteopetrosis
Authorization of 12 months may be granted for 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 will 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]. Lake Forest, IL: Horizon Pharma USA, Inc.; May 2017.

2. The NCCN Drugs & Biologics Compendium 2019 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed October 20, 2019.
3. The NCCN Clinical Practice Guidelines in Oncology Primary Cutaneous Lymphomas (Version 2.2019) 2019 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed October 20, 2019.