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
   1. Mycosis fungoides/Sezary syndrome
   2. Atopic dermatitis

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Chronic Granulomatous Disease
Authorization of 12 months may be granted for the treatment of chronic granulomatous disease.

B. Severe, Malignant Osteopetrosis
Authorization of 12 months may be granted for treatment of severe, malignant osteopetrosis.

C. Mycosis Fungoides/Sezary Syndrome
Authorization of 12 months may be granted for the treatment of mycosis fungoides or Sezary syndrome.

D. Atopic Dermatitis
Authorization of 12 months may be granted for the treatment of atopic dermatitis.

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 May 30, 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 May 30, 2019.
4. IBM Micromedex DRUGDEX (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. (cited: 05/30/2019).