I. Medication Description

Actimmune (interferon gamma 1b) is a recombinant form of endogenous gamma interferon. Gamma interferon is necessary to activate several immune cells, especially phagocytes. In disorders with abnormal immune functioning, administration of Actimmune leads to activation of phagocytes and prevention of serious infections.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage for Actimmune is provided for treatment of the following:
- Chronic granulomatous disease with recurrent serious infections
  - Initial treatment is prescribed by a hematologist, immunologist or infectious disease specialist
    - AND
  - Member has tried and failed treatment with antibiotics
- Osteopetrosis
  - Initial treatment is prescribed by an endocrinologist
    - AND
  - Disease is severe and malignant

IV. Quantity Limitations

Coverage is available as follows:
- 1 vial (100 mcg or 2 million IU) per dose
- 12 vials (1200mcg or 24 million IU) per 28 days
- Increased quantities can be considered for members with a body surface area greater than 2 m²

V. Coverage Duration

Coverage will be provided for 6 months and may be renewed.

VI. Coverage Renewal Criteria
Coverage can be renewed in 6 month intervals based upon the following criteria:

- Member continues to derive clinical benefit from the drug as shown in a reduction of disease signs and symptoms and improvement in disease state AND
- Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

- Available as 100 mcg (2 million units)/0.5 ml solution for injection
- J9216: 1 billable unit = 3 million units
- Pertinent indications
  - Functional disorders of polymorphonuclear neutrophils- D71
  - Osteopetrosis- Q78.2

VIII. Summary of Policy Changes

- 1/1/12: Specialist criteria added to policy.
- 12/15/12: No changes
- 12/15/13: Added allowed coverage for increased quantities for members with BSA greater than 2 m²
- 1/1/15: no policy changes
- 7/1/15: formulary distinctions made
- 9/15/15: no policy changes
- 7/19/16: no policy changes
- 6/21/17: no policy changes
- 6/15/18: no policy changes

IX. References


*These guidelines are not applicable to benefits covered under Medicare Advantage. Medicare Advantage benefit coverage requests are reviewed in accordance with the guidance set forth in Chapter 15 Section 50 of the Centers for Medicare & Medicaid Services Medicare Benefit Policy Manual.

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.
The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.