I. Medication Description

Interferon gamma is a member of the interferon class of drugs. Gamma interferons activate phagocytes, cells capable of ingesting microorganisms. This activation mediates the killing of certain bacteria. Chronic granulomatous disease is an inherited disorder characterized by malfunctioning phagocytes. Interferon gamma is used to reduce the frequency and severity of serious infections in patients with chronic granulomatous disease. Osteopetrosis is a life-threatening, congenital disorder in which an overgrowth of bony structures leads to blindness, deafness and increased susceptibility to infections. Interferon gamma helps to reduce the number of infections, improve bone marrow function and prolong the lives of children with the disease.

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

- 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

- J9216: Injection, interferon, gamma 1-b, 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

IX. References

1. UpToDate Online, retrieved May 2016
3. Facts and Comparisons Online, retrieved April 2011

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.