Clinical Policy: Interferon Gamma- 1b (Actimmune)

Reference Number: CP.PHAR.52
Effective Date: 06.01.10
Last Review Date: 02.21
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Interferon gamma-1b (Actimmune®) is a recombinant form of gamma interferon.

FDA Approved Indication(s)
Actimmune is indicated for:
- Reducing the frequency and severity of serious infections associated with chronic granulomatous disease (CGD)
- Delaying time to disease progression in patients with severe, malignant osteopetrosis (SMO)

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Actimmune is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Chronic Granulomatous Disease (must meet all):
      1. Diagnosis of CGD;
      2. Age ≥ 1 year;
      3. Prescribed by or in consultation with a hematologist or infectious disease specialist;
      4. Dose does not exceed one of the following (a or b):
         a. Body surface area (BSA) > 0.5 m²: 50 mcg/m² three times weekly;
         b. BSA ≤ 0.5 m²: 1.5 mcg/kg three times weekly.

   Approval duration:
   Medicaid/HIM – 6 months
   Commercial – 6 months or member’s renewal period, whichever is longer

   B. Severe Malignant Osteopetrosis (must meet all):
      1. Diagnosis of SMO (also known as autosomal recessive osteopetrosis);
      2. Prescribed by or in consultation with an endocrinologist or rheumatologist;
      3. Age ≥ 1 month;
      4. Dose does not exceed one of the following (a or b):
         a. BSA > 0.5 m²: 50 mcg/m² three times weekly;
         b. BSA ≤ 0.5 m²: 1.5 mcg/kg three times weekly.

   Approval duration:
   Medicaid/HIM – 6 months
Commercial – 6 months or member’s renewal period, whichever is longer

C. Mycosis Fungoides, Sezary Syndrome (off-label) (must meet all):
1. Diagnosis of mycosis fungoides or Sezary syndrome;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Request meets one of the following (a, b, or c):*
   a. BSA > 0.5 m²: Dose does not exceed 50 mcg/m² three times weekly;
   b. BSA ≤ 0.5 m²: Dose does not exceed 1.5 mcg/kg three times weekly;
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or member’s renewal period, whichever is longer

D. Other diagnoses/indications
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy
A. All Indications in Section I (must meet all):
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Documentation supports that member is currently receiving Actimmune for mycosis fungoides or Sezary syndrome and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a, b, or c):
   a. BSA > 0.5 m²: New dose does not exceed 50 mcg/m² three times weekly;
   b. BSA ≤ 0.5 m²: New dose does not exceed 1.5 mcg/kg three times weekly;
   c. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or member’s renewal period, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2):
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is
III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
- BSA: body surface area
- CGD: chronic granulomatous disease
- FDA: Food and Drug Administration
- SMO: severe, malignant osteopetrosis

Appendix B: Therapeutic Alternatives
- Not applicable

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): hypersensitivity to interferon gamma, *E. coli* derived products, or any component of the product
- Boxed warning(s): none reported

V. Dosage and Administration

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<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
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<tbody>
<tr>
<td>CGD, SMO</td>
<td>BSA &gt; 0.5 m²: 50 mcg/m² SC TIW</td>
<td>See dosing regimen</td>
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<td></td>
<td>BSA ≤ 0.5 m²: 1.5 mcg/kg/dose SC TIW</td>
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VI. Product Availability

Single-use vial for injection: 100 mcg (2 million IU)/0.5 ml

VII. References


Interferon Gamma-1b

Oncology

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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<td>J9216</td>
<td>Injection, interferon, gamma 1-b, 3 million units</td>
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Reviews, Revisions, and Approvals

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Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health
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The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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