



Actimmune® (interferon gamma-1b)

When requesting Actimmune® (interferon gamma-1b), the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indications

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.

Coverage Guidelines

Chronic granulomatous disease

The individual must meet **all** of the following criteria for authorization:

- Diagnosis has been established by a molecular genetic test identifying a gene-related mutation linked to chronic granulomatous disease; AND
- Actimmune is prescribed by, or in consultation with, an immunologist.

Severe, malignant osteopetrosis

The individual must meet **all** of the following criteria for authorization:

- Diagnosis has been established by one of the following:
 - Radiographic (X-ray) imaging demonstrating skeletal features related to osteopetrosis; OR
 - Molecular genetic test identifying a gene-related mutation linked to malignant osteopetrosis; AND
- Actimmune is prescribed by, or in consultation with, an endocrinologist.

Approval duration: 12 months

Dosing Recommendations

Actimmune is administered subcutaneously.

Body Surface Area (m ²)	Dose (mcg/m ²)	Frequency
Greater than 0.5 m ²	50 mcg/m ²	Three times weekly
Equal to or less than 0.5 m ²	1.5 mcg/kg/dose	Three times weekly

References

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5. Bonilla F, Khan D, Ballas Z, et al. Practice parameter for the diagnosis and management of primary immunodeficiency. *The Journal of Allergy and Clinical Immunology*. 2015;136:5:1186-1205.e78.
6. Yu J, Azar A, Chong H, et al. Considerations in the diagnosis of chronic granulomatous disease. *Journal of the Pediatric Infectious Disease Society*. 2018;7:S6-S11.
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8. Genetics Home Reference. National Institutes of Health, U.S. National Library of Medicine. Available at <https://ghr.nlm.nih.gov/>. Accessed on March 23, 2022. Search terms: osteopetrosis
9. Wu C, Econs M, DiMeglio L, et al. Diagnosis and management of osteopetrosis: consensus guidelines from the osteopetrosis working group. *The Journal of Clinical Endocrinology & Metabolism*. 2017;102:9:3111-3123.