

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;
Note: Examples of gene-related mutations linked to chronic granulomatous disease include biallelic pathogenic variants in CYBA, CYBB, NCF1, NCF2, and NCF4.
- 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;
Note: Examples of genes linked to osteoporosis include CA2, CLCN7, IKBLG, ITGB3, LRP5, OSTM1, PLEKHM1, SNX10, TCIRG1, TNFRSF11A, and TNFSF11.
- Actimmune is prescribed by, or in consultation with, an endocrinologist.

Approval duration: 12 months

Dosing Recommendations

Actimmune is administered subcutaneously as follows:

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

1. Actimmune® subcutaneous injection [prescribing information]. Lake Forest, IL: Horizon; May 2021.
2. National Institute of Allergy and Infectious Diseases. Chronic granulomatous disease (CGD). Available at: [https://www.niaid.nih.gov/diseases-conditions/chronic-granulomatous-disease-cgd#:~:text=Chronic%20granulomatous%20disease%20\(CGD\)%20is,threatening%20bacterial%20and%20fungal%20infections](https://www.niaid.nih.gov/diseases-conditions/chronic-granulomatous-disease-cgd#:~:text=Chronic%20granulomatous%20disease%20(CGD)%20is,threatening%20bacterial%20and%20fungal%20infections). Last reviewed May 20, 2022. Accessed on March 29, 2023.
3. Genetics Home Reference. National Institutes of Health, U.S. National Library of Medicine. Available at <https://ghr.nlm.nih.gov/>. Accessed on March 29, 2023. Search terms: chronic granulomatous disease.
4. 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.
5. Charoenngam N, Nasr A, Shirvani A, Holick MF. Hereditary metabolic bone diseases: a review of pathogenesis, diagnosis and management. *Genes*. 2022;13:1880.
6. Genetics Home Reference. National Institutes of Health, U.S. National Library of Medicine. Available at <https://ghr.nlm.nih.gov/>. Accessed on March 29, 2023. Search terms: osteopetrosis.
7. Wu C, Econs M, DiMeglio L, et al. Diagnosis and management of osteopetrosis: consensus guidelines from the osteopetrosis working group. *J Clin Endocrinol Metab*. 2017;102:3111-3123.