

Harvard Pilgrim Health Care – Pharmacy Prior Authorization Guideline

Guideline Name	Actimmune (interferon gamma-1b)
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1 . Criteria

Product Name: Actimmune	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 - Both of the following:</p> <p>1.1.1 - Documented diagnosis of Chronic Granulomatous Disease AND</p> <p>1.1.2 - Prescribed by or in consultation with an immunologist</p> <p>OR</p> <p>1.2 - Both of the following:</p> <p>1.2.1 - Documented diagnosis of Severe, Malignant Osteopetrosis AND</p> <p>1.2.2 - Prescribed by or in consultation with an endocrinologist</p>	

Product Name: Actimmune	
Approval Length	12 Month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 - All of the following:</p> <p>1.1.1 - Documented diagnosis of Chronic Granulomatous Disease AND</p> <p>1.1.2 - Prescribed by or in consultation with an immunologist AND</p>	

1.1.3 - Documentation the Member has experienced a therapeutic response defined by a reduction in the frequency and severity of serious infections associated with Chronic Granulomatosis Disease

OR

1.2 - All of the following:

1.2.1 - Documented diagnosis of Severe, Malignant Osteopetrosis

AND

1.2.2 - Prescribed by or in consultation with an endocrinologist

AND

1.2.3 - Documentation the Member has experienced a therapeutic response as defined by an absence of disease progression (e.g., defined as significant reduction in hemoglobin or platelet counts, serious bacterial infection requiring antibiotics, 50 decibel decrease in hearing, progressive optic atrophy)

3 . Background

Benefit/Coverage/Program Information

RATIONALE

To ensure appropriate utilization based on FDA approved indications and treatment guidelines.

FDA APPROVED INDICATIONS

Actimmune (interferon gamma-1b) is an interferon gamma indicated for reducing the frequency and severity of serious infections associated with Chronic Granulomatous Disease (CGD) and delaying time to disease progression in patients with severe, malignant osteopetrosis (SMO).

REFERENCES

- Actimmune (interferon gamma-1b) [prescribing information]. Dublin, Ireland: Horizon Pharma Ireland Ltd; August 2015.
- Key LL Jr, Rodriguiz RM, Willi SM, et al. Long-term treatment of osteopetrosis with recombinant human interferon gamma. N Engl J Med.1995;332(24):1594-99.
- Zerbe CS, Marciano BE, Holland SM. Chronic granulomatous disease: pathogenesis, clinical manifestations, and diagnosis. In: UpToDate, Waltham, MA: Walters Kluwer Health;2016. Available at UpToDate.com. Accessed July 7, 2021.

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