



Prior Authorization Approval Criteria

Actimmune (gamma interferon)

Generic name:	Gamma interferon
Brand name:	Actimmune
Medication class:	Immunomodulator (interferon)
FDA-approved uses:	Chronic granulomatous disease\ Malignant osteopetrosis
Usual dose range:	CGD: BSA > 0.5 m = 50 mcg/m ² 3 times per week BSA < 0.5 m = 1.5 mcg/kg/dose 3 times per week
Duration of therapy:	Commonly 6 to 9 months in studies
Cost (based on AWP 2006):	\$1,578

Criteria for use (*bullet points below are all inclusive unless otherwise noted*):

Chronic granulomatous disease:

- Failed/intolerant to antibiotics for infection (trimethoprim/sulfamethoxazole and itraconazole)
- Maximum of 3 months for initial approval

OR

Malignant osteopetrosis:

- Diagnosis by X-ray and/or increased LFTs, growth retardation, decreased RBC and WBC counts, deafness/sensorineural hearing loss
- Differential diagnosis to exclude other causes for these clinical presentations

Criteria for continuation of therapy (*bullet points below are all inclusive unless otherwise noted*):

- Decrease in number of infections (CGD)
- Ability to tolerate Actimmune with few or no SEs
- May be used with or without calcitriol in osteopetrosis
- Maximum of 3 months for initial approval
- Maximum of 6 months after initial 3 months

Caution:

- Patients with pre-existing cardiac disease: failure, ischemia or arrhythmias
- Patients with central nervous system diseases; seizures
- Patients with myelosuppression

Monitoring

- Baseline monitoring
- CBC, differential, platelets
- LFTs, RFTs
- Urinalysis

Contraindications:

- Patients who develop or have known hypersensitivity to interferon-gamma, E. coli derived products, or any component of the product.

Not approved if:

- Patient has idiopathic pulmonary fibrosis.
- Patient does not meet the above-stated criteria
- Patient has any contraindications to the use of Actimmune

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 01/2005

First revision: 12/12/07

Second revision: 03/12/08