Actimmune

Description

Actimmune (interferon gamma-1B)

Background
Actimmune (interferon gamma-1B) is a bioengineered form of interferon gamma, a protein that acts as a biologic response modifier through stimulation of the human immune system (1).

The interferons are a family of naturally occurring small proteins and glycoproteins produced and secreted by cells in response to viral infections and to synthetic or biological inducers. They exert their cellular activities by binding to specific membrane receptors on the cell surface. Once bound to the cell membrane, interferon's initiate a complex sequence of intracellular events including the following: induction of certain enzymes, suppression of cell proliferation, immunomodulating activities such as enhancement of the phagocytic activity of macrophages and augmentation of the specific cytotoxicity of lymphocytes for target cells, and inhibition of virus replication in virus-infected cells (1).

Regulatory Status
FDA-approved indication: Actimmune is indicated for reducing the frequency and severity of serious infections associated with Chronic Granulomatous Disease. Actimmune is also indicated for delaying time to disease progression in patients with severe, malignant osteopetrosis (1).

Acute and transient “flu-like” symptoms such as fever and chills induced by Actimmune may exacerbate pre-existing cardiac conditions. Actimmune should be used with caution in patients
with pre-existing cardiac conditions, including ischemia, congestive heart failure, or arrhythmia (1).

Reversible neutropenia and thrombocytopenia that can be severe and may be dosed related have been observed during Actimmune therapy. Caution should be exercised when administering Actimmune to patients with myelosuppression. Hematologic tests including complete blood counts, differential and platelet counts should be done prior to initiation and at three month intervals during treatment of Actimmune (1).

Hepatotoxicity has been observed in interferon treated patients. Elevations of AST and/or ALT (up to 25-fold) have occurred and reversible with reduction in dosage or interruption of Actimmune treatment. Renal and liver function tests should be done prior to initiation and at three month intervals during treatment. In patients less than 1 year of age should have liver function tests measured monthly (1).

Related policies
Intron A, Sylatron

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Actimmune may be considered medically necessary in patients for the treatment of chronic granulomatous disease or for the delaying time to disease progression of severe, malignant osteopetrosis and if the conditions indicated below are met.

Actimmune may be considered investigational for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have ONE of the following:

1. Serious infections associated with chronic granulomatous disease (CGD)
2. Severe, malignant osteopetrosis (SMO)
AND ALL of the following:
   a. Complete blood counts, differential and platelet counts completed prior to
      initiation and at three month intervals
   b. Renal and liver function tests completed prior to initiation and at three month
      intervals during treatment. In patients less than 1 year of age, liver function tests
      measured monthly.

Prior – Approval Renewal Requirements

Diagnoses

Patient must have ONE of the following:
   1. Decrease in the number of serious infections associated with chronic
      granulomatous disease
   2. Severe, malignant osteopetrosis

AND ALL of the following:
   a. Complete blood counts, differential and platelet counts completed every three
      months
   b. Renal and liver function tests completed every three months. In patients less than
      1 year of age, liver function tests measured monthly.

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval Renewal Limits

Duration 12 months

Rationale

Summary
Actimmune is indicated for reducing the frequency and severity of serious infections associated with Chronic Granulomatous Disease. Actimmune is also indicated for delaying time to disease progression in patients with severe, malignant osteopetrosis. Hepatotoxicity, reversible neutropenia, and thrombocytopenia have been observed during Actimmune therapy. Caution should be exercised in patients with myelosuppression and pre-existing cardiac conditions, including ischemia, congestive heart failure, or arrhythmia. Hematologic, renal, and liver function tests should be completed prior to initiation of therapy and at three month intervals. Patients less than 1 year of age should have liver functions tests monitored monthly (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Actimmune while maintaining optimal therapeutic outcomes.

References

<table>
<thead>
<tr>
<th>Policy History</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
</tr>
<tr>
<td>August 2011</td>
</tr>
<tr>
<td>November 2011</td>
</tr>
<tr>
<td>December 2012</td>
</tr>
<tr>
<td>March 2014</td>
</tr>
<tr>
<td>March 2015</td>
</tr>
<tr>
<td>March 2016</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Section:</td>
</tr>
<tr>
<td>--------------</td>
</tr>
<tr>
<td>Subsection:</td>
</tr>
<tr>
<td>Subject:</td>
</tr>
</tbody>
</table>

- June 2017    | Annual review and reference update
- June 2018    | Annual editorial review and reference update
- June 2019    | Annual review

**Keywords**

This policy was approved by the FEP® Pharmacy Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.