STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INTERFERON GAMMA-1B, RECOMB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INTERFERON GAMMA-1B, RECOMB.	ACTIMMUNE	06068		GPI-10 (2170006070)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of chronic granulomatous disease (CGD) **AND** meet the following criterion?
   - The medication is prescribed by or given in consultation with a hematologist, infectious disease specialist, or immunologist

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT: Renewal requires the following: 1) patient has demonstrated clinical benefit compared to baseline (e.g. reduction in frequency and severity of serious infections), and 2) patient has not received hematopoietic cell transplantation.

   If no, continue to #2.

2. Does the patient have a diagnosis of severe malignant osteopetrosis (SMO) **AND** meet the following criterion?
   - The medication is prescribed by or given in consultation with an endocrinologist

   If yes, **approve for 6 months by HICL or GPI-10.**
   APPROVAL TEXT: Renewal requires the following: 1) patient has demonstrated clinical benefit compared to baseline (e.g. reduction in frequency and severity of serious infections), and 2) patient has not received hematopoietic cell transplantation.

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON GAMMA-1B, RECOMB (Actimmune)** requires the following rules be met for approval:
   A. You have ONE of the following diagnoses:
      1. Chronic granulomatous disease (CGD: inherited immune system disorder that occurs when a type of white blood cells that usually helps your body fight infections does not work properly)
      2. Severe malignant osteopetrosis (SMO: a bone disease that makes bone abnormally thick and prone to breakage/fracture)

   (Initial denial text continued on the next page)

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INTERFERON GAMMA-1B, RECOMB

INITIAL CRITERIA (CONTINUED)

B. **If you have chronic granulomatous disease, approval also requires:**
   1. The medication is prescribed by or given in consultation with a hematologist (blood doctor), infectious disease specialist (doctor that specializes in treating infections), or immunologist (doctor that specializes in treating and managing allergies, asthma and immunologic disorders)

C. **If you have severe malignant osteopetrosis, approval also requires:**
   1. The medication is prescribed by or given in consultation with an endocrinologist (doctor that specializes in all things relating to our hormones)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of chronic granulomatous disease (CGD) or severe malignant osteopetrosis (SMO) and meet **ALL** of the following criteria?
   - The patient has demonstrated clinical benefit compared to baseline (e.g., reduction in frequency and severity of serious infections)
   - The patient has not received hematopoietic cell transplantation

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INTERFERON GAMMA-1B, RECOMB (Actimmune)** requires the following rules be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Chronic granulomatous disease (CGD: inherited immune system disorder that occurs when a type of white blood cells that usually helps your body fight infections does not work properly)
      2. Severe malignant osteopetrosis (SMO: a bone disease that makes bone abnormally thick and prone to breakage/fracture)
   B. You have shown clinical (medical) benefit compared to baseline (such as reduction in frequency and severity of serious infections)
   C. You have not received hematopoietic cell transplantation (transplant of stem cells from bone marrow, peripheral blood, or umbilical cord blood)

   (Renewal denial text continued on the next page)

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INTERFERON GAMMA-1B, RECOMB

RENEWAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Actimmune.

REFERENCES

- Actimmune [Prescribing Information] Lake Forest, IL: Horizon Therapeutics USA, Inc., January 2020.

Library	Commercial	NSA
No	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20
Created: 09/05
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P&T Approval: 01/20