

INTERFERON ALFA-2B

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INTERFERON	INTRON A	04528		GPI-10	
ALFA-				(2170006020)	
2B,RECOMB.					

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- 1. Does the patient have **ONE** of the following diagnoses?
 - Hairy cell leukemia
 - Condylomata acuminata
 - AIDS-related Kaposi's sarcoma
 - Chronic hepatitis B
 - Non-Hodgkin's lymphoma
 - Malignant melanoma
 - Chronic phase, Philadelphia chromosome (Ph) positive chronic myelogenous leukemia (CML) patients who are minimally treated (within 1 year of diagnosis)
 - Follicular lymphoma
 - Angioblastoma
 - Carcinoid tumor
 - Chronic myeloid leukemia
 - Laryngeal papillomatosis
 - Multiple myeloma
 - Neoplasm of conjunctiva-neoplasm of cornea
 - Ovarian cancer
 - Polycythemia vera
 - Renal cell carcinoma
 - Skin cancer
 - Thrombocytosis
 - Vulvar vestibulitis

If yes, approve by HICL or GPI-10 for 24 weeks (6 months). If no, continue to #2.

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INTERFERON ALFA-2B

INITIAL CRITERIA (CONTINUED)

- 2. Does the patient have a diagnosis of chronic hepatitis C, genotype 1, 2, 3, 4, 5, or 6 and meet **ALL** of the following criteria?
 - Therapy is prescribed by or in consultation with a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (e.g., hepatologist)
 - The patient has a detectable pretreatment HCV RNA level/viral load of 50 IU/mL or higher
 - The requested medication will be used with ribavirin or the patient has a contraindication to ribavirin
 - The patient had a trial of or contraindication to peginterferon alfa-2a or peginterferon alfa-2b

If yes, approve by HICL or GPI-10 for 24 weeks (6 months). 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 ALFA-2B (Intron A)** requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses:
 - 1. Chronic hepatitis C (type of liver inflammation)
 - 2. Hairy cell leukemia (bone marrow cancer that makes too many white blood cells)
 - 3. Condylomata acuminate (genital warts)
 - 4. AIDS (acquired immunodeficiency syndrome)-related Kaposi's sarcoma (cancer in those with weak immune system that causes tumors of lymph nodes/skin)
 - 5. Chronic hepatitis B (type of liver inflammation)
 - 6. Non-Hodgkin's lymphoma (cancer that starts in your lymphatic system- the disease-fighting network in the body)
 - 7. Malignant melanoma (serious type of skin cancer)
 - 8. Chronic phase, Philadelphia chromosome (type of abnormal gene) positive chronic myelogenous leukemia (type of blood cell cancer that starts in bone marrow) who are minimally treated (within 1 year of diagnosis)
 - 9. Follicular lymphoma (type of lymphatic system cancer)
 - 10. Angioblastoma (certain blood-vessel tumors of the brain)
 - 11. Carcinoid (cancer) tumor
 - 12. Chronic myeloid leukemia (type of cancer that starts in immature white blood cells)
 - 13. Laryngeal papillomatosis (tumors form along the pathways for breathing/digestion)

(Initial denial text continued on next page)

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INTERFERON ALFA-2B

INITIAL CRITERIA (CONTINUED)

- 14. Multiple myeloma (plasma cell cancer)
- 15. Neoplasm of conjunctiva-neoplasm of cornea (eye tumors)
- 16. Ovarian cancer
- 17. Polycythemia vera (cancer where bone marrow makes too many red blood cells)
- 18. Renal cell carcinoma (type of kidney cancer)
- 19. Skin cancer, thrombocytosis (your body makes too many platelets)
- 20. Thrombocytosis (high level of platelets (cells that helps blood clot and stop bleeding) in your blood)
- 21. Vulvar vestibulitis (type of pain around the female sex organ called the vulva)
- B. If you have chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6, approval also requires:
 - 1. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions), infectious disease specialist (a doctor who specializes in the treatment of infections), or a physician specializing in the treatment of hepatitis (such as a hepatologist: a type of liver doctor)
 - 2. You have a detectable pretreatment HCV (hepatitis C virus) RNA level/viral load (amount of virus in your blood) of 50 IU/mL or higher
 - 3. The requested medication will be used with ribavirin or you have a contraindication (harmful for)
 - 4. You had a trial of or contraindication (harmful for) to peginterferon alfa-2a or peginterferon alfa-2b

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 hepatitis C **AND** meet the following criterion? Therapy is prescribed by or in consultation with a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (e.g., hepatologist)

If yes, continue to #2.

If no, approve by HICL or GPI-10 for 24 weeks (6 months).

2. Has the patient already received 24 weeks or more of interferon during this treatment?

If yes, continue to #3.

If no, approve by HICL or GPI-10 for 24 weeks (6 months).

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RENEWAL CRITERIA (CONTINUED)

3. Is the patient's HCV RNA undetectable (less than 50 IU/mL) at 24 weeks?

If yes, approve by HICL or GPI-10 for 24 weeks (6 months). 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 ALFA-2B** (Intron A) requires the following rule(s) be met for renewal:

- A. The request is for continuation of current therapy or renewal with Intron A therapy
- B. If you have chronic hepatitis C (type of liver inflammation), renewal also requires:
 - 1. Therapy is prescribed by or in consultation with a gastroenterologist (a doctor who treats digestive conditions), infectious disease specialist (a doctor who specializes in the treatment of infections), or a physician specializing in the treatment of hepatitis (such as a hepatologist: a type of liver doctor)
 - 2. If you already received 24 weeks or more of interferon treatment, your HCV (hepatitis C virus) RNA level (amount of virus in your blood) is undetectable (less than 50 IU/mL) at 24 weeks

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 Intron A.

REFERENCES

 Intron A [Prescribing Information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp.; November 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A Created: 02/14

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