INTERFERON ALFA-2B

Generic	Brand	HICL	GCN	Exception/Other
INTERFERON ALFA-2B	INTRON A	04528		

This drug requires a written request for prior authorization. All requests for medications used to treat hepatitis C require review by a pharmacist prior to final approval.

GUIDELINES FOR USE

1. Is the request for continuation of current therapy (also consider continuation if member has a claim for the currently requested interferon in past 120 days) or a renewal?

   If yes, continue to #8.
   If no, continue to #2.

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

   If yes, **approve by HICL for 24 weeks (6 months).**
   If no, continue to #3.

CONTINUED ON NEXT PAGE

INTERFERON ALFA-2B

GUIDELINES FOR USE (CONTINUED)

3. Is the patient being treated for chronic hepatitis C and currently supervised by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (for example, a hepatologist)?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of chronic hepatitis C and therapy is being supervised by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (for example, a hepatologist) OR interferon use is treatment of one of the following: 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, or vulvar vestibulitis.

4. Is the request for interferon being used with ribavirin or does the patient have a contraindication to ribavirin?

   If yes, continue to #5.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of chronic hepatitis C and therapy is being supervised by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (for example, a hepatologist) ,requires combination therapy with ribavirin, a previous trial of or contraindication to a peginterferon product, and a detectable pretreatment HCV RNA level/viral load of greater than or equal to 50 IU/mL.

5. Does the patient have a detectable pretreatment HCV RNA level/viral load of greater than or equal to 50 IU/mL?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of chronic hepatitis C and therapy is being supervised by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (for example, a hepatologist) ,requires combination therapy with ribavirin, a previous trial of or contraindication to a peginterferon product, and a detectable pretreatment HCV RNA level/viral load of greater than or equal to 50 IU/mL.

CONTINUED ON NEXT PAGE

INTERFERON ALFA-2B

GUIDELINES FOR USE (CONTINUED)

6. Has the patient had a trial of peginterferon alfa-2a or peginterferon alfa-2b, or contraindication to pegylated interferon?

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of chronic hepatitis C and therapy is being supervised by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (for example, a hepatologist) ,requires combination therapy with ribavirin, a previous trial of or contraindication to a peginterferon product, and a detectable pretreatment HCV RNA level/viral load of greater than or equal to 50 IU/mL.

7. Is the patient infected with genotype 1, 2, 3, 4, 5, or 6 hepatitis C?

   If yes, **approve by HICL for 24 weeks (6 months).**
   APPROVAL TEXT: Recommend obtaining HCV RNA level at 12 weeks of treatment to determine if the patient has achieved at least a 2 log reduction (100 fold decrease) in HCV RNA. Renewal requires HCV RNA undetectable (less than 50 IU/mL) at 24 weeks.
   If no, do not approve.
   DENIAL TEXT: Approval requires a diagnosis of chronic hepatitis C and therapy is being supervised by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (for example, a hepatologist) ,requires combination therapy with ribavirin, a previous trial of or contraindication to a peginterferon product, and a detectable pretreatment HCV RNA level/viral load of greater than or equal to 50 IU/mL.

8. Is the patient being treated for chronic hepatitis C and currently supervised by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (for example, a hepatologist)?

   If yes, continue to #9.
   If no, **approve by HICL for 24 weeks (6 months).**

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

   If yes, continue to #10.
   If no, **approve by HICL for 24 weeks (6 months).**

CONTINUED ON NEXT PAGE

INTERFERON ALFA-2B

GUIDELINES FOR USE (CONTINUED)

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

If yes, **approve by HICL for 24 weeks (6 months).**
If no, do not approve.
DENIAL TEXT: Approval requires a diagnosis of chronic hepatitis C and therapy is being supervised by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (for example, a hepatologist) and HCV RNA undetectable (less than 50 IU/mL) at 24 weeks.

RATIONALE

Ensure that ribavirin and interferon are used for combination treatment of chronic hepatitis C. The 16 week initial approval for hepatitis C allow a sufficient length of time for the 12-week HCV RNA result (EVR) to be reported and evaluated by the physician. If the patient did not achieve undetectable viral load at 12 weeks then a total of 72 weeks may be considered if the 24-week HCV RNA is undetectable. Total therapy time for HCV genotypes 1, 4, 5 and 6 is 48 weeks, and for HCV genotypes 2 and 3 is 16 to 24 weeks.

Note on HCV RNA levels defined by lab as undetectable versus detectable but not quantifiable:

Commercially available quantitative HCV RNA assays may have differing limits for quantification and detection. The lower limit of detection is 10 or 50 IU/mL HCV RNA (depends on assay used by lab). The FDA suggests that labs testing HCV RNA levels for patients taking protease inhibitors must use an assay with a lower limit of quantification of 25 IU/mL or less, and a lower limit of detection of 10-15 IU/mL. Generally, patients with detectable but not quantifiable levels of HCV RNA will have lower SVR rates with triple therapy; a detectable but not quantifiable HCV RNA level should not be considered equivalent to an undetectable level. When the product package insert (or Medimpact PA guideline) specifies “undetectable HCV RNA level”, generally an undetectable HCV RNA result is required.

FDA APPROVED INDICATIONS

INTRON A (Inteferon alfa-2b) is indicated for treatment of hairy cell leukemia, condylomata acuminata, AIDS-related Kaposi’s sarcoma, hepatitis C (in combination), malignant melanoma, follicular lymphoma and chronic hepatitis B.

CONTINUED ON NEXT PAGE

INTERFERON ALFA-2B

REFERENCES

- Ghany et al. AASLD Practice Guidelines. Diagnosis, Management, and Treatment of Hepatitis C.Hepatology 2009, 49(4) 1335-74.
- Merck/Schering Corporation. Intron A Product Information. Whitehouse Station, NJ. January 2014.
- Micromedex® Healthcare Series [database online]. Greenwood Village, Colo: Thomson Healthcare. Available at: https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction. [Accessed: January 12, 2013].

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/14

Created: 02/14
Client Approval: 03/14

P&T Approval: 02/14