PEGINTERFERON ALFA 2A OR 2B (PEGASYS OR PEGINTRON)

Generic	Brand	HICL	GCN	Exception/Other
PEGINTERFERON ALFA-2A	PEGASYS, PEGASYS PROCLICK	24035		
PEGINTERFERON ALFA-2B	PEGINTRON	21367		GCN ≠ 29809, 29811, 29812

This drug requires a written request for prior authorization. All requests for hepatitis C medications 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 the past 120 days) or a renewal?

   If yes, continue to #9.
   If no, continue to #2.

2. Is the request for Pegasys vial, kit, or syringes?

   If yes, continue to #3.
   If no, continue to #4.

3. Is the patient being treated for chronic hepatitis B and meet **ALL** of the following criteria?
   - Patient is 3 years of age or older
   - The medication is prescribed by or in consultation with a gastroenterologist, infectious disease specialist, a physician specializing in the treatment of hepatitis (e.g., a hepatologist) or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
   - Patient has no cirrhosis
   - Patient has serum HBeAg positive chronic hepatitis B
   - Patient has evidence of viral replication with elevated serum ALT

   If yes**, approve for 24 weeks (6 months) by HICL with a quantity limit of #4 vials/syringes per 28 days.**
   If no, continue to #5.

4. Is the request for PegIntron **AND** the patient is between 3 and 11 years old?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

5. Is the patient between 3 and 11 years old?

   If yes, continue to #6.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

6. Does the patient meet **ALL** of the following criteria?
   - Patient is being treated for chronic hepatitis C and the medication is prescribed by or in consultation with a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (e.g., a hepatologist)
   - Patient has extrahepatic manifestations of hepatitis C such as cryoglobulinemia, rashes, and glomerulonephritis - as well as advanced fibrosis that requires urgent HCV treatment to minimize future morbidity and mortality
   - Peginterferon is being used with ribavirin or patient has a contraindication to ribavirin
   - Patient has a detectable pretreatment HCV RNA level/viral load (Varies by lab assay but is a level typically greater than or equal to 25 IU/mL)

   If yes, continue to #7.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

7. Is the patient infected with genotype 2 or genotype 3 hepatitis C?

   If yes, **approve by HICL as follows:**
   - **For two-drug regimen with ribavirin (peginterferon plus ribavirin only): approve for up to 24 weeks.**

   If no, continue to #8.

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

   If yes, **approve by HICL as follows:**
   - **For two-drug regimen with ribavirin (peginterferon plus ribavirin only): approve for 48 weeks (12 months).**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

9. Is the request for the treatment of hepatitis B?

   If yes, continue to #10.
   If no, continue to #11.

10. Is the request for Pegasys?

    If yes, **approve for 24 weeks (6 months) by HICL with a quantity limit of #4 vials/syringes per 28 days.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

11. Is the request for the treatment of chronic hepatitis C and meet **ONE** of the following criteria?
    - Requested medication will be used in combination with ribavirin
    - Patient has a contraindication to combination therapy with ribavirin

    If yes, continue to #12.
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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

    If yes, **approve by HICL for up to 32 weeks for a total of 48 weeks of treatment.**
    If no, continue to #13.

13. Does the patient have genotype 2 or 3 hepatitis C?

    If yes, **approve by HICL for a maximum total of 24 weeks of treatment.**
    If no, do not approve.
    DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: The guideline named **PEGINTERFERON ALFA-2A or 2B (Pegasys or PegIntron)** requires a diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6. Requests for Pegasys will also be approved for a diagnosis of chronic hepatitis B. In addition, the following criteria must be met:

For diagnosis of chronic hepatitis B, approval requires:

- Patient is 3 years of age or older
- The medication is prescribed by or in consultation with a gastroenterologist, infectious disease specialist, a physician specializing in the treatment of hepatitis (e.g., a hepatologist) or a specially trained group such as ECHO (Extension for Community Healthcare Outcomes) model
- Patient has no cirrhosis
- Patient has serum HBeAg positive chronic hepatitis B
- Patient has evidence of viral replication with elevated serum ALT

For diagnosis of chronic hepatitis C, approval requires:

- Patient age is between 3 and 11 years old
- The medication is prescribed by or in consultation with a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis (e.g., a hepatologist)
- Patient has extrahepatic manifestations of hepatitis C such as cryoglobulinemia, rashes, and glomerulonephritis - as well as advanced fibrosis that requires urgent HCV treatment to minimize future morbidity and mortality
- Peginterferon is being used with ribavirin or patient has a contraindication to ribavirin
- Patient has a detectable pretreatment HCV RNA level/viral load (Varies by lab assay but is a level typically greater than or equal to 25 IU/mL)

Please discuss the requirements for approval: specific diagnosis, specific lab test (blood test), and the requirement of a physician specialist consult.

RATIONALE

Ensure that ribavirin and interferon are used in combination for treatment of chronic hepatitis C, when indicated. When peginterferon is used as dual therapy in combination with ribavirin, 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:

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RATIONALE (CONTINUED)

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

PEGASYS (peg-interferon alfa-2a) alone or in combination with COPEGUS (ribavirin) is indicated for the treatment of patient's age 5 years and older with chronic hepatitis C virus infection who have compensated liver disease and have not been previously treated with interferon or peginterferon alfa.

PEGASYS is also indicated for treatment of adults with chronic hepatitis C virus infection in patients with HIV/HCV co-infection.

PEGASYS is also indicated for treatment of adults with HBeAg positive and negative chronic hepatitis B who have compensated liver disease and evidence of viral replication and inflammation.

PEGASYS is also indicated for treatment of chronic hepatitis B in children age 3 years and older without cirrhosis, with HBeAg positive chronic hepatitis B and evidence of viral replication with elevated serum ALT.

PEGINTRON (peg-interferon alfa-2B) is indicated for use alone for the treatment of chronic hepatitis C in adults at least 18 years of age with compensated liver disease who have and those who have not been previously treated with interferon alfa.

PEGINTRON (peg-interferon alfa-2B) in combination with REBETOL (ribavirin) is indicated for use in the treatment of chronic hepatitis C in adults and children at least 3 years of age with compensated liver disease.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

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REFERENCES

- Genentech. Pegasys Product Information. South San Francisco, CA. July 2013.
- Guidance from the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) Recommendations for Testing, Managing, and Treating hepatitis C. Available online at http://www.hcvguidelines.org/full-report-view Accessed September 2017.
- Harrington P, Zeng W, and Naeger L. Clinical relevance of detectable but not quantifiable hepatitis C virus RNA during boceprevir or telaprevir treatment. Hepatology 2012; Apr 55 (4): 1048-1057.
- Jacobson I. SVR results of a once-daily regimen of simeprevir (TMC-438) plus sofosbuvir (GS-7977) with or without ribavirin in cirrhotic and non-cirrhotic HCV genotype 1 treatment-naïve and prior null responder patients: the COSMOS study. Program and abstracts of American Association for the Study of Liver Diseases The *Liver Meeting® 2013; November 1-5, 2013. Abstract LB-3.*
- Wantuck J, Ahmed A, and Nguyen M. The epidemiology and therapy of chronic hepatitis C genotypes 4, 5 and 6. Aliment Pharmacol Ther 2014; 39 (2): 137-147.

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