

PHARMACY PRE-AUTHORIZATION CRITERIA



DRUG	Pegasys (peginterferon alfa-2a) Peg-Intron (peginterferon alfa-2b)
POLICY #	23111
INDICATIONS	<p>Pegasys and Peg-Intron, alone or in combination with ribavirin, are indicated for the treatment of adults with chronic hepatitis C virus infection who have compensated liver disease as part of a combination regimen with other hepatitis C virus (HCV) antiviral drugs; treatment of pediatric patients 5 years and older with chronic hepatitis C and compensated liver disease in combination with ribavirin.</p> <p>Monotherapy (for patients with contraindications or who are intolerant to other hepatitis C virus antiviral drugs): Treatment (as a single agent) of chronic hepatitis C in patients with compensated liver disease in patients with contraindications or significant intolerance to other HCV antiviral drugs.</p> <p><u>Note: Current American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) guidelines do not recommend the use of interferon products. Peginterferon and ribavirin, typically in combination with a direct-acting antiviral, remain in use for certain genotypes, particularly in resource-limited settings where newer interferon-free regimens are not accessible.</u></p> <p><u>Pegasys only:</u> Peginterferon alfa-2a, is indicated for the treatment of adult patients with HBeAg positive and HBeAG negative chronic hepatitis B who have compensated liver disease and evidence of viral replication and liver inflammation.</p>
CRITERIA	<p>A. Criteria for use: Peginterferon for chronic Hepatitis C Genotype 3: ConnectiCare considers peginterferon to be medically necessary when all of the following criteria are met:</p> <ul style="list-style-type: none">• Patient must be seen by a gastroenterologist, infectious disease physician, hepatologist, or a transplant physician.• Clinically documented chronic hepatitis C with detectable HCV RNA levels > 50 IU/ml and not previously treated with peginterferon• Viral load and genotype lab report from the previous 3 months must be provided for review• Patient must be treatment naïve• Patient must not have cirrhosis or has compensated cirrhosis

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	<p>B. Criteria for use: Peginterferon for chronic Hepatitis C Genotype 4, 5 or 6: ConnectiCare considers peginterferon to be medically necessary when all of the following criteria are met:</p> <ul style="list-style-type: none"> • Patient must be seen by a gastroenterologist, infectious disease physician, hepatologist, or a transplant physician. • Clinically documented chronic hepatitis C with detectable HCV RNA levels > 50 IU/ml and not previously treated with peginterferon • Viral load and genotype lab report from the previous 3 months must be provided for review • Patient must be treatment naïve <p>C. Criteria for use: Peginterferon alfa 2a (Pegasys) for chronic Hepatitis B: Connecticare considers Pegasys to be medically necessary when all of the following criteria are met:</p> <ul style="list-style-type: none"> • Patient must be seen by a gastroenterologist, infectious disease physician, hepatologist, or a transplant physician • Clinically documented HBeAg positive or HBeAg negative chronic hepatitis B • Compensated liver disease • Evidence of viral replication
<p>LIMITATIONS</p>	<p>The quantity is limited to a maximum of a 30 day supply per fill.</p>
<p>REFERENCES</p>	<ol style="list-style-type: none"> 1. Pegasys® [package insert]. Nutley, NJ: Roche Pharmaceuticals; 2. PEG-Intron® powder for injection [package insert]. Kenilworth, NJ: Schering Corporation. 3. AASLD Guidelines, February 2016
<p>P&T REVIEW HISTORY</p>	<p>09/04, 9/07, 6/08, 9/09, 9/10, 12/11, 10/12, 10/13, 10/14, 11/15, 8/16, 8/17, 7/18</p>

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REVISION RECORD	8/16, 8/17