## Pegylated Interferon Agents for Hepatitis C

### Override(s) | Approval Duration
---|---
Prior Authorization | **Initial Approval Duration for Monotherapy or Combination with Ribavirin based on Genotype, Treatment Status, or Co-Infection Status: 14 weeks**<br>**Additional Approval Duration Based on documented HCV-RNA results at 12 weeks**:<br>**Approval Duration in Combination with ribavirin and Olysio or Sovaldi: Based on Genotype, Treatment status, Cirrhosis status, Transplant status, Peginterferon Eligibility status, or Q80K polymorphism status**

### Medications | Quantity Limit
---|---
Pegasys (peg-interferon alfa-2a) | 4 vials or 1 kit per 28 days
PEG Intron (peg-interferon alfa-2b) | N/A

<table>
<thead>
<tr>
<th>Genotype (GT) and Treatment Status</th>
<th>Associated Treatment Regimen</th>
<th>HCV RNA Results at treatment week 12*</th>
<th>Additional PEG-IFN Approval Duration</th>
<th>Total PEG-IFN Approval Duration</th>
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</thead>
</table>
| GT 1, 2, 3, 4, 5, 6; treatment-naïve (TN) | PEG-IFN | "Early Virologic Null Responder (EVNR)\(^a\) and "Detectable\(^c\)"<br>"EVNR\(^a\)" and "Undetectable\(^d\)"
"Early Virologic Responder (EVR)\(^b\)" and "Detectable\(^c\)"
"EVR\(^b\)" and "Undetectable\(^d\)"
| N/A | 14 weeks |
| | | | 34-38 weeks | 48-52 weeks |
| GT 1, 4, 5, 6; TN | PEG-IFN + RBV | "Early Virologic Null Responder (EVNR)\(^a\) and "Detectable\(^c\)"<br>"EVNR\(^a\)" and "Undetectable\(^d\)"
"Early Virologic Responder (EVR)\(^b\)" and "Detectable\(^c\)"
"EVR\(^b\)" and "Undetectable\(^d\)"
| N/A | 14 weeks |
| | | | 34 weeks | 48 weeks |
| GT 2, 3; TN | PEG-IFN + RBV | "Early Virologic Null Responder (EVNR)\(^a\) and "Detectable\(^c\)"<br>"EVNR\(^a\)" and "Undetectable\(^d\)"
"Early Virologic Responder (EVR)\(^b\)" and "Detectable\(^c\)"
"EVR\(^b\)" and "Undetectable\(^d\)"
| N/A | 14 weeks |
| | | | 10 weeks | 24 weeks |

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III. Individual does not have a short life expectancy (less than 12 months owing to non-liver related comorbid conditions) that cannot be remediated by treating HCV, by transplantation or other directed therapy (AASLD/IDSA 2016); AND

IV. Individual has compensated liver disease3 (with or without cirrhosis); AND

V. Individual is using with one of the following antiviral treatment regimens:
   A. As monotherapy in treatment-naïve individuals with contraindications or significant intolerance to HCV antiviral agents/regimens and Genotypes 1, 2, 3, 4, 5, or 6; OR
   B. Individual is using in combination with ribavirin and is treatment-naïve or dual (interferon-alfa and ribavirin) treatment-experienced with Genotypes 1, 2, 3, 4, 5, or 6; OR
   C. Individual is using in combination with Olysio (simeprevir) and ribavirin for one of the following:
      1. Individuals with Genotype 1a or 1b with compensated cirrhosis or without cirrhosis; AND
      2. Individual is treatment-naïve or dual (peginterferon and ribavirin) treatment-experienced; AND
      3. Individual has been screened and is negative for the NS3Q80K polymorphism associated with HCV Genotype 1a subtype; AND
      4. Individual is currently on and completing a course of therapy with the requested regimen; OR
      5. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Harvoni OR Zepatier; OR
      6. Individuals with Genotype 4 with compensated cirrhosis or without cirrhosis; AND
      7. Individual is treatment-naïve or dual (peginterferon and ribavirin) treatment-experienced; AND
      8. Individual is currently on and completing a course of therapy with the requested regimen; OR
      9. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Harvoni OR Zepatier; OR
   D. Individual is using in combination with Sovaldi (sofosbuvir) and ribavirin for one of the following:
      1. Individuals with compensated cirrhosis or without cirrhosis, Genotype 1; OR
      2. Individual is treatment-naïve with compensated cirrhosis or without cirrhosis, Genotype 4; AND
      3. Individual is currently on and completing a course of therapy with the requested regimen; OR

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4. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to Harvoni OR Zepatier.

Pegylated interferon agents (Pegasys, PegIntron) for hepatitis C may not be approved for the following:

I. Individual has a diagnosis of autoimmune hepatitis; OR
II. Individual has hepatic decompensation (Child-Pugh Class B or C) prior or during treatment; OR
III. Use of Pegasys (peginterferon alfa-2a) in neonates or infants; OR
IV. Solid organ transplant recipients; OR
V. Individual is using in combination with a regimen containing paritaprevir or Zepatier (elbasvir/grazoprevir); OR
VI. Individual is using in combination with Harvoni (ledipasvir/sofosbuvir) or dasabuvir; OR
VII. Individual is using in combination with a NS5A inhibitor [such as but not limited to, Harvoni (ledipasvir/sofosbuvir), a regimen containing ombitasvir, Daklinza (daclatasvir), Epclusa (sofosbuvir/velpatasvir), or Zepatier (elbasvir/grazoprevir)]; OR
VIII. Individual is requesting for re-treatment as monotherapy or in combination with ribavirin and has received previous treatment for HCV with peginterferon alfa-a or alfa-b and ribavirin; OR
IX. Individual is requesting peginterferon for re-treatment as monotherapy, in combination with ribavirin, in combination with Olysio (simeprevir), or in combination with Sovaldi (sofosbuvir) and has received previous treatment for HCV with one of the following:
   A. A peginterferon-based triple therapy regimen, which includes ribavirin and an oral direct-acting antiviral [Incivek (telaprevir), Victrelis (boceprevir), Olysio (simeprevir), or Sovaldi (sofosbuvir)]; OR
   B. A therapy regimen containing a NS5A inhibitor [such as but not limited to, Harvoni (ledipasvir/sofosbuvir), Daklinza (daclatasvir), ombitasvir, Epclusa (sofosbuvir/velpatasvir), or Zepatier (elbasvir/grazoprevir)]; OR
   C. A therapy regimen containing paritaprevir or dasabuvir.

NOTES:
1. Pegylated interferons (PEG-IFN) have black box warnings for risk of serious disorders and ribavirin-associated effects. PEG-IFN may cause or aggravate fatal or life-threatening neuropsychiatric, autoimmune, ischemic, or infectious disorders. Periodic clinical and laboratory monitoring should occur with discontinuation of therapy for persistently severe or worsening signs or symptoms of a serious disorder. Ribavirin may cause birth defects and/or prenatal death. Pregnancy should be avoided in female individuals or female partners of male individuals receiving treatment with PEG-IFN and ribavirin. Ribavirin can cause hemolytic anemia and result in worsening of cardiac disease.
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## Market Applicability/Effective Date

<table>
<thead>
<tr>
<th>Market</th>
<th>FL &amp; FHK</th>
<th>FL MMA</th>
<th>FL LTC</th>
<th>GA</th>
<th>KS</th>
<th>KY</th>
<th>LA</th>
<th>MD</th>
<th>NJ</th>
<th>NV</th>
<th>NY</th>
<th>TN</th>
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<td>N/A</td>
</tr>
</tbody>
</table>

*FHK- Florida Healthy Kids

**Key References:**


DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2016; Updated periodically.

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