I. Requirements for Prior Authorization of Hepatitis C Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Pegasys and non-preferred Hepatitis C Agents must be prior authorized: See the most recent version of the Preferred Drug List (PDL), which includes a list of preferred Hepatitis C Agents, at: http://www.dpw.state.pa.us/PartnersProviders/MedicalAssistance/DoingBusiness/MAPharmProg/

B. Review of Documentation for Medical Necessity

In evaluating an initial request for prior authorization of a prescription for Pegasys or a non-preferred Hepatitis C Agent, the determination of whether the requested prescription is medically necessary will take into account the following:

1. For Pegasys - Whether the recipient:
   a. Has a diagnosis of chronic Hepatitis C

   AND

   b. Is 18 years of age or older

   AND

   c. Is being prescribed Pegasys by a specialist (infectious disease, gastroenterology, hepatology, transplant) or in consultation with a specialist

   AND

   d. Has a documented Hepatitis C genotyping

   AND

   e. Has a documented quantitative HCV RNA at baseline that was tested within the past 3 months

   AND

   f. Does not have a contraindication or intolerance of Hepatitis C Agents, such as but not limited to, autoimmune hepatitis or hepatic decompensation

June 1, 2010 (replacing May 1, 2007)
g. Has been evaluated for behavioral health (mental health and/or drug and alcohol) conditions, and will be monitored and referred for behavioral health treatment, if indicated

AND

h. Does not have a history of treatment with pegylated interferon

2. For **Copegus** and **Rebetol** - Whether the recipient:
   a. Has a diagnosis of chronic Hepatitis C

   AND

   b. Has a documented history of contraindication or intolerance of a preferred ribavirin product

3. For **Infergen** – Whether the recipient:
   a. Has a diagnosis of chronic Hepatitis C

   AND

   b. Is 18 years of age or older

   AND

   c. Has a documented history of a contraindication or intolerance of a preferred pegylated interferon

   AND

   d. Is being prescribed Infergen by a specialist (infectious disease, gastroenterology, hepatology, transplant) or in consultation with a specialist

   AND

   e. Has a documented Hepatitis C genotyping

   AND
f. Has a documented quantitative HCV RNA at baseline that was tested within the past 3 months

AND

g. Does not have a contraindication or intolerance of Hepatitis C Agents, such as but not limited to, autoimmune hepatitis or hepatic decompensation

AND

h. Has been evaluated for behavioral health (mental health and/or drug and alcohol) conditions, and will be monitored and referred for behavioral health treatment if indicated

4. For **Peg-Intron** and **Peg-Intron Redipens**, whether the recipient:
   a. Has a diagnosis of chronic Hepatitis C

AND

b. Is;
   i. 3 through 17 years of age and is receiving combination therapy with ribavirin **OR**
   ii. 18 years of age or older and has a documented history of a contraindication or intolerance of a preferred pegylated interferon

AND

c. Is being prescribed Peg-Intron or Peg-Intron Redipens by a specialist (infectious disease, gastroenterology, hepatology, transplant) or in consultation with a specialist

AND

d. Has a documented Hepatitis C genotyping

AND

e. Has a documented quantitative HCV RNA at baseline that was tested within the past 3 months

AND
f. Does not have a contraindication or intolerance of Hepatitis C Agents, such as but not limited to autoimmune hepatitis or hepatic decompensation

AND

g. Has been evaluated for a behavioral health (mental health and/or drug and alcohol) conditions, and will be monitored and referred for behavioral health treatment if indicated.

In evaluating a request for a renewal of prior authorization of a prescription for Pegasys or a non-preferred Hepatitis C Agent, the determination of whether the requested prescription is medically necessary will take into account whether the recipient:

1. Meets the medical necessity guidelines for the specific medication as listed above

AND

2. Has genotype 1 AND

   a. Has a documented quantitative HCV RNA tested at week 12 of therapy AND

      1) Achieved undetectable serum HCV RNA at week 12 compared to baseline

      OR

      2) Achieved at least a 2-log reduction in serum HCV RNA that remains detectable at week 12 compared to baseline

      OR

3. Has genotype 4 AND

   a. Has a documented quantitative HCV RNA tested at week 12 of therapy AND

   b. Has achieved at least a 2-log reduction in serum HCV RNA at week 12 compared to baseline

   OR
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4. Has genotype 2 or 3, in which case the request will be referred to a physician reviewer for a determination of medical necessity

If the recipient does not meet the guidelines listed above, initial requests for prior authorization and requests for renewals of prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient

In evaluating a request for prior authorization of a prescription for Pegasys or a non-preferred Hepatitis C Agent for re-treatment with a Hepatitis C Agent, the determination of whether the requested prescription is medically necessary will take into account whether the recipient:

1. Completed a course of treatment with a non-pegylated interferon and the request is for a pegylated interferon AND

2. Meets the medical necessity guidelines for an initial request for prior authorization

OR

1. Completed a course of treatment with a pegylated interferon, AND

2. Was not a null responder, defined as failing to achieve at least a 2 log drop in HCV RNA from baseline at week 24 AND

3. Has a documented history of abstinence from alcohol or illicit drugs for the previous 3 months AND

4. Does not have a history of non-compliance with Hepatitis C treatment AND

5. Does not have a history of hospitalization due to side effects of the Hepatitis C Agent such as optic nerve changes, a psychiatric incident, or attempted suicide attributable to interferon treatment.

OR

1. Does not meet the guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above, to assess the medical necessity of an initial request and a request for a renewal of prior
authorization of a prescription for Pegasys or a non-preferred Hepatitis C Agent. If the guidelines in Section B are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

All requests for prior authorization of a prescription for Pegasys or a non-preferred Hepatitis C Agent for re-treatment with a Hepatitis C Agent will be automatically forwarded to a physician reviewer for a medical necessity determination.

The physician reviewer will prior authorize the prescription when:

1. The guidelines for re-treatment in Section B. are met, OR
2. In the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

D. Dose and Duration of Therapy

For **initial requests** for prior authorization of Hepatitis C Agents, if the recipient has:

1. Genotype 1 or 4, the approval will be limited to 14 weeks
2. Genotype 2 or 3, the approval will be limited to 24 weeks

For **requests for renewals** of prior authorization of Hepatitis C Agents, if the recipient has:

1. Genotype 1, approval will be limited to:
   a. 48 weeks if the recipient has achieved undetectable serum HCV RNA at week 12 compared to baseline OR
   b. 26 weeks if the recipient has achieved at least a 2-log reduction in serum HCV RNA that remains detectable at week 12 compared to baseline OR
   c. Up to 72 weeks if the recipient has achieved at least a 2-log reduction in serum HCV RNA that is detectable at week 12 that then becomes undetectable at week 24 compared to baseline

2. Genotype 4, approval will be limited to 48 weeks if the recipient has achieved at least a 2-log reduction in serum HCV RNA at week 12 compared to baseline.
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3. Genotype 2 or 3, the request will be referred to a physician reviewer for a determination of medical necessity.

E. Resources


