

# PEDS-C Eligibility Summary Form

PDC 04  
Rev 0  
11/17/2004  
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54757

Please Use Black Pen To Fill Out Form.

Week #	Date of Assessment	Patient ID	Patient Letter Code	
<i>week</i>	<i>assessd</i>	<i>idn</i>	<i>letcode</i>	<i>corrfix</i> Correction
mm	dd	yyyy		

### Inclusion Criteria

1. Patient's age at last birthday between 5 and 18 years at enrollment (not yet reached 18th birthday at screening)?
2. Is the patient able to swallow a RV / placebo tablet?
3. Is there at least one positive HCV test done at least 6 months prior to screening?
4. Chronic liver disease, without evidence of cirrhosis, consistent with chronic hepatitis C infection on a liver biopsy obtained within the past 24 months, as assessed by a qualified pathologist?
5. Compensated liver disease (Child-Pugh Grade A clinical classification)?
6. Hemoglobin values  $\geq 11$  g/dL for females;  $\geq 12$  g/dL for males?
7. Normal Thyroid Stimulating Hormone (TSH)?
8. Signed informed consent from parent / legal guardian and assent from the patient and willingness of parent / legal guardian and patient to abide by the requirements of the study?
9. Check if any inclusion criteria answered **No**:

Yes	No	CRA Use Only
<input type="radio"/>	<input type="radio"/>	<i>age5_18</i>
<input type="radio"/>	<input type="radio"/>	<i>swaltab</i>
<input type="radio"/>	<input type="radio"/>	<i>hcv</i>
<input type="radio"/>	<input type="radio"/>	<i>crnliver</i>
<input type="radio"/>	<input type="radio"/>	<i>comliver</i>
<input type="radio"/>	<input type="radio"/>	<i>hgbge11</i>
<input type="radio"/>	<input type="radio"/>	<i>normtsh</i>
<input type="radio"/>	<input type="radio"/>	<i>consent</i>
<input type="checkbox"/>	<input type="checkbox"/>	<i>incno</i>

### Exclusion Criteria

Has the patient had:

10. Any prior treatment with Interferon or RV?
11. Received any investigational drug < 6 weeks prior to the first dose of the study drug?
12. Any systemic antiviral therapy < 6 weeks prior to the first dose of the study drug?  
(Exception: patients who have taken or are expected to require acyclovir for herpetic lesions)?
13. Positive test at screening for:
  - A. Anti-HAV IgM Antibody:
  - B. Hepatitis B Surface Antigen?
  - C. Anti-HBc IgM Antibody?
  - D. Anti-HIV Antibody?
14. History or other evidence of a medical condition associated with chronic liver disease other than HCV:
  - A. Abnormal ceruloplasmin?
  - B. Abnormal alpha-1-antitrypsin?
  - C. Anti-Nuclear Antibody (ANA) > 1:160?
  - D. Anti-Smooth Muscle Antibody (SMA) > 1:80?
15. History or other evidence of bleeding from esophageal varices?

Yes	No	
<input type="radio"/>	<input type="radio"/>	<i>prrv</i>
<input type="radio"/>	<input type="radio"/>	<i>prdrug</i>
<input type="radio"/>	<input type="radio"/>	<i>prthrp</i>
<input type="radio"/>	<input type="radio"/>	<i>poshav</i>
<input type="radio"/>	<input type="radio"/>	<i>poshepb</i>
<input type="radio"/>	<input type="radio"/>	<i>poshbc</i>
<input type="radio"/>	<input type="radio"/>	<i>poshiv</i>
<input type="radio"/>	<input type="radio"/>	<i>hxcr1p</i>
<input type="radio"/>	<input type="radio"/>	<i>hxalph1</i>
<input type="radio"/>	<input type="radio"/>	<i>hxana</i>
<input type="radio"/>	<input type="radio"/>	<i>hx sma</i>
<input type="radio"/>	<input type="radio"/>	<i>hx es bld</i>

Signature: \_\_\_\_\_

Certif. #: \_\_\_\_\_

<i>staffid1</i>	-				
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22487

Week # <i>week</i>	Date of Assessment <i>assessdf</i>	Patient ID <i>idn</i>	Patient Letter Code <i>letcode</i>	<i>corrfix</i> Correction
[ ][ ]	[ ][ ] / [ ][ ] / [ ][ ][ ][ ] <small>mm dd yyyy</small>	[ ][ ] - [ ][ ][ ][ ] - [ ][ ]	[ ][ ][ ][ ]	

### Exclusion Criteria (Continued)

Has the patient had:

	Yes	No		CRA Use Only
16. Decompensated liver disease:				
A. Conjugated bilirubin > 1.5 mg/dL?	<input type="radio"/>	<input type="radio"/>	<i>hxbili15</i>	
B. Ascites?	<input type="radio"/>	<input type="radio"/>	<i>hxasc</i>	
C. Varices?	<input type="radio"/>	<input type="radio"/>	<i>hxvarc</i>	
D. Child-Pugh Grade B or C clinical classification?	<input type="radio"/>	<input type="radio"/>	<i>hxcpcb</i>	
17. History of autoimmune or immunologically mediated disease (e.g. inflammatory bowel disease, idiopathic thrombocytopenic purpura, lupus erythematosus, autoimmune hemolytic anemia, scleroderma, severe psoriasis, or clinical evidence of rheumatoid arthritis)?	<input type="radio"/>	<input type="radio"/>	<i>hximmun</i>	
18.A. Absolute neutrophil count < 1500 cells/mm <sup>3</sup> ?	<input type="radio"/>	<input type="radio"/>	<i>hxntro</i>	
B. Hemoglobin (Hgb) < 11 g/dL for females and < 12 g/dL for males?	<input type="radio"/>	<input type="radio"/>	<i>hxhgb11</i>	
C. WBC > 17.5 x 10 <sup>9</sup> /L ?	<input type="radio"/>	<input type="radio"/>	<i>hxwbc175</i>	
D. Platelet count < 90,000/mm <sup>3</sup> ?	<input type="radio"/>	<input type="radio"/>	<i>hxplat90</i>	
19. Serum creatinine level > 1.5 times the upper limit of normal for age?	<input type="radio"/>	<input type="radio"/>	<i>scgt15</i>	
20. Major depression according to study criteria for a major depressive episode, or a history of severe psychiatric disorder, such as major psychoses, suicidal ideation and/or suicide attempt?	<input type="radio"/>	<input type="radio"/>	<i>depress</i>	
21. History or other evidence of chronic pulmonary or cardiac disease associated with functional limitation?	<input type="radio"/>	<input type="radio"/>	<i>hxcard</i>	
22. History of thyroid disease poorly controlled on prescribed medications? (Patients with elevated thyroid stimulating hormone (TSH) concentrations with elevations of antibodies to thyroid peroxidase and any clinical manifestations of thyroid disease are excluded.)	<input type="radio"/>	<input type="radio"/>	<i>hxthyrd</i>	
23. Poorly controlled diabetes as defined by hemoglobin A1C of > 8% ?	<input type="radio"/>	<input type="radio"/>	<i>hxdiab</i>	
24. Severe retinopathy?	<input type="radio"/>	<input type="radio"/>	<i>retino</i>	
25. History of solid organ or bone marrow transplantation?	<input type="radio"/>	<input type="radio"/>	<i>hxtrans</i>	
26. Coagulopathy (INR > 1.5) ?	<input type="radio"/>	<input type="radio"/>	<i>coagulo</i>	
27. Evidence of an active or suspected cancer or history of malignancy where risk of recurrence is ≥ 20 % within 2 years?	<input type="radio"/>	<input type="radio"/>	<i>cancer</i>	
28. Hemoglobinopathy?	<input type="radio"/>	<input type="radio"/>	<i>hgbpath</i>	
29. Hemophilia?	<input type="radio"/>	<input type="radio"/>	<i>hemophil</i>	
30. History of other evidence of severe illness or any other conditions which would make the patient, in the opinion of the investigator, unsuitable for the study?	<input type="radio"/>	<input type="radio"/>	<i>hxsvrill</i>	
31. Active substance abuse?	<input type="radio"/>	<input type="radio"/>	<i>subabuse</i>	

Signature: \_\_\_\_\_

Certif. #: *staffid2* - [ ][ ][ ]

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24334

Week #	Date of Assessment	Patient ID	Patient Letter Code	
<i>week</i>	<i>assesst</i>	<i>idn</i>	<i>letcode</i>	<i>corrfix</i> Correction
mm	dd / yyyy	- - - -		

### Exclusion Criteria (Continued)

Is the patient:	Yes	No	CRA Use Only
32. A sexually active female of child-bearing potential (defined as age 10 years or older) or a sexually active male who is not practicing two forms of effective contraception?	<input type="radio"/>	<input type="radio"/>	<i>sexactf</i>
33. A female who has had a positive serum pregnancy test within 7 days of initiation of treatment or who is breast-feeding?	<input type="radio"/>	<input type="radio"/>	<i>preg</i>
34. A male whose female partner is pregnant?	<input type="radio"/>	<input type="radio"/>	<i>mfpreg</i>
35. Check if any exclusion criteria answered <b>YES</b> :	<input type="checkbox"/>		<i>excyes</i>

### Concomitant Medication and Treatment

Is the patient taking:	Yes	No	CRA Use Only
36. Anti-neoplastic and/or immunomodulatory treatments (including steroids and radiation)? <small>(Steroids given as physiologic replacement are permitted or as a short course (&lt;7 days) for asthma management)</small>	<input type="radio"/>	<input type="radio"/>	<i>antivir</i>
37. Any investigational drugs, herbals and/or remedies being taken by the patient for possible or perceived effects against HCV?	<input type="radio"/>	<input type="radio"/>	<i>hcvdrg</i>
38. Total dose of acetaminophen that exceeds 1 gram per day?	<input type="radio"/>	<input type="radio"/>	<i>actmgt1</i>
39. Check if any concomitant medication or treatment is answered <b>YES</b> :	<input type="checkbox"/>		<i>medyes</i>

### Eligibility Summary

Question	Yes	No	CRA Use Only
40. Have one or more boxes from questions 9, 35, or 39 been checked?	<input type="radio"/>	<input type="radio"/>	<i>chk93539</i>
If <b>NO</b> , call the ATRS number at the DCC to randomize the patient and to get the medication package numbers.			
If <b>YES</b> , the patient is ineligible. Do not call the ATRS number at the DCC to randomize the patient.			

Signature: \_\_\_\_\_

Certif. #: \_\_\_\_\_

<i>staffid3</i>	-	
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