

PEDS-C Eligibility Summary Form

PDC 04
Rev 0
11/17/2004
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Please Use Black Pen To Fill Out Form.

54757

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

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 ≥ 11 g/dL for females; ≥ 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"/>	age5_18
<input type="radio"/>	<input type="radio"/>	swaltab
<input type="radio"/>	<input type="radio"/>	hcv
<input type="radio"/>	<input type="radio"/>	crnliver
<input type="radio"/>	<input type="radio"/>	comliver
<input type="radio"/>	<input type="radio"/>	hgbge11
<input type="radio"/>	<input type="radio"/>	normtsh
<input type="radio"/>	<input type="radio"/>	consent
<input type="checkbox"/>	<input type="checkbox"/>	incno

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"/>	prrv
<input type="radio"/>	<input type="radio"/>	prdrdg
<input type="radio"/>	<input type="radio"/>	prthrp
<input type="radio"/>	<input type="radio"/>	poshav
<input type="radio"/>	<input type="radio"/>	poshepb
<input type="radio"/>	<input type="radio"/>	poshbc
<input type="radio"/>	<input type="radio"/>	poshiv
<input type="radio"/>	<input type="radio"/>	hxcr1p
<input type="radio"/>	<input type="radio"/>	hxalph1
<input type="radio"/>	<input type="radio"/>	hxana
<input type="radio"/>	<input type="radio"/>	hxsgma
<input type="radio"/>	<input type="radio"/>	hxesbld

Signature: _____

Certif. #:

staffid	[][] - [][][][]
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22487

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week	assessdte	idn	letcode	corrfix
mm dd yyyy				Correction

Exclusion Criteria (Continued)

Has the patient had:

16. Decompensated liver disease:

A. Conjugated bilirubin > 1.5 mg/dL?

B. Ascites?

C. Varices?

D. Child-Pugh Grade B or C clinical classification?

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)?

18.A. Absolute neutrophil count < 1500 cells/mm³ ?

B. Hemoglobin (Hgb) < 11 g/dL for females and < 12 g/dL for males?

C. WBC > 17.5 x 10⁹ /L ?

D. Platelet count < 90,000/mm³ ?

19. Serum creatinine level > 1.5 times the upper limit of normal for age?

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?

21. History or other evidence of chronic pulmonary or cardiac disease associated with functional limitation?

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.)

23. Poorly controlled diabetes as defined by hemoglobin A1C of > 8% ?

24. Severe retinopathy?

25. History of solid organ or bone marrow transplantation?

26. Coagulopathy (INR > 1.5) ?

27. Evidence of an active or suspected cancer or history of malignancy where risk of recurrence is ≥ 20 % within 2 years?

28. Hemoglobinopathy?

29. Hemophilia?

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?

31. Active substance abuse?

Yes No

CRA Use Only

<input type="radio"/>	<input type="radio"/>	hxbili15
<input type="radio"/>	<input type="radio"/>	hxasc
<input type="radio"/>	<input type="radio"/>	hxvarc
<input type="radio"/>	<input type="radio"/>	hxcpcb
<input type="radio"/>	<input type="radio"/>	hximmun
<input type="radio"/>	<input type="radio"/>	hxntro
<input type="radio"/>	<input type="radio"/>	hxhgb11
<input type="radio"/>	<input type="radio"/>	hxwbc175
<input type="radio"/>	<input type="radio"/>	hxplat90
<input type="radio"/>	<input type="radio"/>	scgt15
<input type="radio"/>	<input type="radio"/>	depress
<input type="radio"/>	<input type="radio"/>	hxcad
<input type="radio"/>	<input type="radio"/>	hxthyrd
<input type="radio"/>	<input type="radio"/>	hxdiab
<input type="radio"/>	<input type="radio"/>	retino
<input type="radio"/>	<input type="radio"/>	hxtrans
<input type="radio"/>	<input type="radio"/>	coagulo
<input type="radio"/>	<input type="radio"/>	cancer
<input type="radio"/>	<input type="radio"/>	hgbpath
<input type="radio"/>	<input type="radio"/>	hemophil
<input type="radio"/>	<input type="radio"/>	hxsvrill
<input type="radio"/>	<input type="radio"/>	subabuse

Signature: _____

Certif. #: _____

staffid2	-				
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week	assesst	idn	letcode	corrfix Correction
<div style="border: 1px solid black; width: 40px; height: 20px;"></div>	<div style="border: 1px solid black; width: 120px; height: 20px; display: flex; align-items: center;"> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="margin: 0 5px;">/</div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div> <div style="display: flex; justify-content: space-around; font-size: 8px;"> mmddyyyy </div>	<div style="border: 1px solid black; width: 60px; height: 20px; display: flex; align-items: center;"> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="margin: 0 5px;">-</div> <div style="border: 1px solid black; width: 20px; height: 20px; margin-right: 5px;"></div> <div style="margin: 0 5px;">-</div> <div style="border: 1px solid black; width: 20px; height: 20px;"></div> </div>	<div style="border: 1px solid black; width: 40px; height: 20px;"></div>	

Exclusion Criteria (Continued)

Is the patient:

- | | | |
|--|---|----------------|
| 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? | Yes No | |
| | <input type="radio"/> <input type="radio"/> | sexactf |
| 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"/> | preg |
| 34. A male whose female partner is pregnant? | <input type="radio"/> <input type="radio"/> | mfpreg |
| 35. Check if any exclusion criteria answered YES : | <input type="checkbox"/> | excyes |

Concomitant Medication and Treatment

Is the patient taking:

- | | | |
|--|---|----------------|
| 36. Anti-neoplastic and/or immunomodulatory treatments (including steroids and radiation)?
(Steroids given as physiologic replacement are permitted or as a short course (<7 days) for asthma management) | Yes No | |
| | <input type="radio"/> <input type="radio"/> | antivir |
| 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"/> | hcvdrg |
| 38. Total dose of acetaminophen that exceeds 1 gram per day? | <input type="radio"/> <input type="radio"/> | actmgt1 |
| 39. Check if any concomitant medication or treatment is answered YES : | <input type="checkbox"/> | medyes |

Eligibility Summary

- | | | |
|--|---|-----------------|
| 40. Have one or more boxes from questions 9, 35, or 39 been checked? | Yes No | |
| | <input type="radio"/> <input type="radio"/> | chk93539 |

If **NO**, call the ATRS number at the DCC to randomize the patient and to get the medication package numbers.

If **YES**, the patient is ineligible. Do not call the ATRS number at the DCC to randomize the patient.

Signature: _____

Certif. #:

staffid3

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