PEDS-C
Screening Visit 1 Form

20482

Please Use Black Pen To Fill Out Form.

Week # week | Date of Assessment assessdt (mm / dd / yyyy) | Patient ID idn | Patient Letter Code letcode | corrfix ○ Correction

Instructions

Before starting this exam, call the DCC to register the patient and to get a patient ID and lettercode. All screening assessments are to be obtained 1 to 35 days before the Baseline visit. The liver biopsy must be performed within 24 months of the screening visit.

Demographics

CRA Use Only

1. Patient's birth date: mm / dd / yyyy pdobsv

2. Patient's gender: ○ Male ○ Female pgender

3.A. Patient's ethnic identification: ○ Hispanic or Latino ○ Not Hispanic or Latino ○ Unknown phisp

B. Patient's racial identification (Answer each item):

	Yes	No		Yes	No
1. American Indian or Alaskan Native	○	○ amerind	4. Native Hawaiian or Pacific Islander	○	○ pacisind
2. Asian	○	○ asian	5. White	○	○ white
3. Black or African American	○	○ black	6. Unknown	○	○ raceunk

Vital Signs and Physical Measurements

4. Weight: wtsv . kg

5. Height: htsv . cm

6.A. Temperature: tmpsv . C

6.B. Site: ○ Oral ○ Axillary ○ Unable to obtain tmpsitsv

7.Blood Pressure: A. Systolic sysbpsv mmHg B. Diastolic diabpsv mmHg ○ Unable to obtain bpnasv

8. Pulse: pulssv bpm ○ Unable to obtain pulsnasv

Informed Consent

9. Has informed consent been obtained from a parent / guardian? ○ Yes ○ No pgcnsnt

10. Has assent been obtained from the patient? ○ Yes ○ No ○ NA ptassnt

Medical History

11. Indicate PAST medical conditions (excluding the illness being treated in the study) by indicating if the appropriate organ system or condition is within normal limits. Complete the rest of the item, if response is **No**.

	1. Yes	No	2. Specify / Comment	3. Still a problem? Yes	No
A. Ear, Nose, throat:	○	○ hxearsv		hxearpb ○	○
B. Eyes:	○	○ hxeyesv		hxeyepb ○	○

Signature: _____ Certif. #: staffid1 -

PEDS-C
Screening Visit 1 Form

12484

Please Use Black Pen To Fill Out Form.

Week # week

Date of Assessment assessdt mm / dd / yyyy

Patient ID idn - - -

Patient Letter Code letcode

corrfix Correction

Medical History (Continued)

11. Indicate PAST medical conditions (excluding the illness being treated in the study) by indicating if the appropriate organ system or condition is within normal limits. Complete the rest of the item, if response is **No**.

	1. Yes	No	2. Specify / Comment	3. Still a problem? Yes	No
C. Respiratory:	○	○ hxrespsv		hxresppb ○	○
D. Cardiovascular:	○	○ hxcardsv		hxcardpb ○	○
E. Gastrointestinal:	○	○ hxgastsv		hxgastpb ○	○
F. Hepatobiliary or Pancreas:	○	○ hxhepasv		hxhepapb ○	○
G. Urinary system:	○	○ hxurinsv		hxurinpb ○	○
H. Reproductive system:	○	○ hxreprsv		hxreprpb ○	○
I. Neurologic:	○	○ hxneursv		hxneurpb ○	○
J. Blood and Lymphatic:	○	○ hxbldsv		hxbldpb ○	○
K. Endocrine and Metabolic:	○	○ hxendosv		hxendopb ○	○
L. Musculoskeletal:	○	○ hxmuscsv		hxmuscpb ○	○
M. Skin:	○	○ hxskinsv		hxskinpb ○	○
N. Psychiatric:	○	○ hxpsycsv		hxpsycpb ○	○
O. Drug allergies:	○	○ hxdrgalsv		hxdrgalpb ○	○
P. Food allergies:	○	○ hxfodalsv		hxfodalpb ○	○
Q. Environmental allergies:	○	○ hxenvalsv		hxenvalpb ○	○
R. Active substance abuse:	○	○ hxsubabsv		hxsubabpb ○	○
S. Other:	○	○ hxothrsv		hxothrpb ○	○

12. Date of initial HCV diagnosis: hcvdtsv mm / dd / yyyy

Date Unknown ○ hcvdtuk

CRA Use Only

Signature: _____

Certif. #: staffid2 -

PEDS-C
Screening Visit 1 Form

5217

Please Use Black Pen To Fill Out Form.

Week # week | Date of Assessment assessdt (mm / dd / yyyy) | Patient ID idn | Patient Letter Code letcode | corrfix Correction

Medical History (Continued)

13. Probable route of HCV transmission (Choose one): hcvroute

- ○ Vertical/Perinatal
- ○ Transfusion recipient
- ○ Sexual contact
- ○ Unknown
- ○ IV Drug use
- ○ Other — Specify: hcvroutesp

14. List the patient's CURRENT medications:

A. Drug 1:
1. Name: drgnam1sv
2. Source: ○ Brand ○ Generic ○ Unknown drgsrc1sv
3. Date started: drgstdt1sv (mm / dd / yyyy) Date Unknown ○ drgstdtuk1sv
4. Route of administration: ○ PO ○ PR ○ SC ○ IM ○ IV ○ Other drgrt1sv
5. Dose: drgdos1sv 6. Dose unit: drgunit1sv
7. Frequency: drgfrq1sv
8. Indication: _____

B. Drug 2:
1. Name: drgnam2sv
2. Source: ○ Brand ○ Generic ○ Unknown drgsrc2sv
3. Date started: drgstdt2sv (mm / dd / yyyy) Date Unknown ○ drgstdtuk2sv
4. Route of administration: ○ PO ○ PR ○ SC ○ IM ○ IV ○ Other drgrt2sv
5. Dose: drgdos2sv 6. Dose unit: drgunit2sv
7. Frequency: drgfrq2sv
8. Indication: _____

CRA Use Only

Signature: _____ **Certif. #:** staffid3 -

PEDS-C
Screening Visit 1 Form

16902

Please Use Black Pen To Fill Out Form.

Week # week | Date of Assessment assessdt (mm / dd / yyyy) | Patient ID idn | Patient Letter Code letcode | corrfix ○ Correction

Medical History (Continued)

CRA Use Only

14. List the patient's CURRENT medications:

C. Drug 3:
1. Name: drgnam3sv
2. Source: ○ Brand ○ Generic ○ Unknown drgsrc3sv
3. Date started: drgstdt3sv (mm / dd / yyyy) ○ Date Unknown drgstdtuk3sv
4. Route of administration: ○ PO ○ PR ○ SC ○ IM ○ IV ○ Other drgrt3sv
5. Dose: drgdos3sv 6. Dose unit: drgunit3sv
7. Frequency: drgfrq3sv
8. Indication: _____

D. Drug 4:
1. Name: drgnam4sv
2. Source: ○ Brand ○ Generic ○ Unknown drgsrc4sv
3. Date started: drgstdt4sv (mm / dd / yyyy) ○ Date Unknown drgstdtuk4sv
4. Route of administration: ○ PO ○ PR ○ SC ○ IM ○ IV ○ Other drgrt4sv
5. Dose: drgdos4sv 6. Dose unit: drgunit4sv
7. Frequency: drgfrq4sv
8. Indication: _____

E. Drug 5:
1. Name: drgnam5sv
2. Source: ○ Brand ○ Generic ○ Unknown drgsrc5sv
3. Date started: drgstdt5sv (mm / dd / yyyy) ○ Date Unknown drgstdtuk5sv
4. Route of administration: ○ PO ○ PR ○ SC ○ IM ○ IV ○ Other drgrt5sv
5. Dose: drgdos5sv 6. Dose unit: drgunit5sv
7. Frequency: drgfrq5sv
8. Indication: _____

Signature: _____ Certif. #: staffid4 -

PEDS-C
Screening Visit 1 Form

42544

Please Use Black Pen To Fill Out Form.

Week #	Date of Assessment	Patient ID	Patient Letter Code	
week	assessdt (mm / dd / yyyy)	idn	letcode	corrfix ○ Correction

Medical History (Continued)

CRA Use Only

14. List the patient's CURRENT medications:

F. Drug 6:
1. Name: drgnam6sv
2. Source: ○ Brand ○ Generic ○ Unknown drgsrc6sv
3. Date started: drgstdt6sv (mm / dd / yyyy) ○ Date Unknown drgstdtuk6sv
4. Route of administration: ○ PO ○ PR ○ SC ○ IM ○ IV ○ Other drgrt6sv
5. Dose: drgdos6sv 6. Dose unit: drgunit6sv
7. Frequency: drgfrq6sv
8. Indication: _____

G. Drug 7:
1. Name: drgnam7sv
2. Source: ○ Brand ○ Generic ○ Unknown drgsrc7sv
3. Date started: drgstdt7sv (mm / dd / yyyy) ○ Date Unknown drgstdtuk7sv
4. Route of administration: ○ PO ○ PR ○ SC ○ IM ○ IV ○ Other drgrt7sv
5. Dose: drgdos7sv 6. Dose unit: drgunit7sv
7. Frequency: drgfrq7sv
8. Indication: _____

	Yes	No
15. Has the patient demonstrated that he/she is able to swallow a RV / placebo tablet?	○	○ swaltabsv
16. Is the patient a sexually active female at least 10 years old or a sexually active male?	○	○ sexactfsv

If **No**, skip to item 19.

17. Indicate all types of contraception used (Answer each item):

	Yes	No
A. Oral contraceptive	○	○ cntrorasv
B. Intrauterine contraceptive device	○	○ cntriudsv
C. Depot contraceptives (implants, injectables)	○	○ cntrdeposv
D. Physical barrier (condom, diaphragm)	○	○ cntrdeposv
E. Abstinence	○	○ cntrabssv

Signature: _____ **Certif. #:** staffid5 -

PEDS-C
Screening Visit 1 Form

4266

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Week # week | Date of Assessment assessdt (mm / dd / yyyy) | Patient ID idn | Patient Letter Code letcode | corrfix Correction

Medical History (Continued)

17. Indicate all types of contraception used (Answer each item):

	Yes	No	
F. None	○	○	swaltabsv
G. Other Specify _____	○	○	sexactfsv

18. If the patient is a sexually active male, is his current partner pregnant?

Yes	No	Unknown	
○	○	○	sexactmfprgsv

Physical Exam

19. Is the indicated body area within normal limits? Specify or comment if the response is **No**.

	1. Yes	No	2. Specify / Comment
A. Head, eyes, ears:	○	○ headnrmsv	
B. Nose, mouth, throat:	○	○ nosenrmsv	
C. Neck:	○	○ necknrmsv	
D. Chest (including breasts, axillae):	○	○ chstnrmsv	
E. Genitalia, groin, buttocks:	○	○ gntlnrmsv	
F. Abdomen:	○	○ abdmnrmsv	
G. Each extremity:	○	○ extmnrmsv	
H. Back, including spine:	○	○ backnrmsv	
I. Skin:	○	○ skinnrmsv	

CRA Use Only

Signature: _____ **Certif. #:** staffid6 -

PEDS-C
Screening Visit 1 Form

58264

Please Use Black Pen To Fill Out Form.

Week #	Date of Assessment	Patient ID	Patient Letter Code	
week	assessdt (mm / dd / yyyy)	idn	letcode	corrfix ○ Correction

CRA Use Only

Physical Exam (Continued)

20. Is the indicated organ system within normal limits? Specify or comment if the response is **No**.

	1. Yes	No	2. Specify
A. Neurologic:	○	○	neurnrmsv
B. Psychologic:	○	○	psycnrmsv
C. Genitourinary:	○	○	gentnrmsv
D. Hematologic / Lymphatic:	○	○	hmtonrmsv
E. Allergies / Immunologic:	○	○	allrnrmsv
F. Musculoskeletal:	○	○	muscnrmsv
G. Other:	○	○	othrnrmsv

21. List of laboratory tests ordered at Screening Visit 1.

	Done	Unable to obtain		Done	Unable to obtain
A. Immunology:	○	○ immmntstsv	F. Thyroid function:	○	○ thyrdtstsv
B. Hematology:	○	○ hmtotstsv	G. HCV genotyping:	○	○ hcvgntstsv
C. PT/PTT:	○	○ pttstsv	H. Serum bank:	○	○ sermtstsv
D. Chemistry / Pregnancy:	○	○ chemtstsv	I. Urinalysis:	○	○ urintstsv
E. HCV - RNA:	○	○ hcvtstsv			

Depression Screen

22. Was the patient's score on the CDI greater than 19?

Yes	No
○	○ cdigt19sv

If **No**, skip to item 25.

23. Indicate depressive symptoms present nearly every day during the same two week period which represent a change from the previous level of functioning (Answer each item below).

	Yes	No
A. Depressed mood most of the day	○	○ depmodsv
B. Markedly diminished interest or pleasure in all or almost all activities.	○	○ dimintsv
C. Clinically significant weight loss in the absence of dieting or weight gain (e.g., a change of more than 5% of body weight in a month) or a decrease in appetite, including failure to make expected growth-related weight gains.	○	○ wtlossv
D. Insomnia or hypersomnia	○	○ insomsv

Signature: _____ **Certif. #:** staffid7 –

PEDS-C
Screening Visit 1 Form

45511

Please Use Black Pen To Fill Out Form.

Week # week

Date of Assessment assessdt (mm / dd / yyyy)

Patient ID idn

Patient Letter Code letcode

corrfix Correction

CRA Use Only

Depression Screen (Continued)

	Yes	No	
23.E. Observable psychomotor agitation or retardation	○	○	motagitsv
F. Fatigue or loss of energy	○	○	fatgsv
G. Feelings of worthlessness or excessive or inappropriate guilt	○	○	wrthlssv
H. Diminished ability to think or concentrate or indecisiveness	○	○	dimthnksv
I. Recurrent thoughts of death, recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide	○	○	suicidsv
24. Are **five** of the above symptoms of a major depressive episode present?	○	○	dep5symsv

If **Yes**, DO NOT ENROLL THE PATIENT and skip to signature and Certification #.

Ophthalmologic Exam

	Yes	No	
25.A. Has the patient had an ophthalmologic exam?	○	○	opexmsv

If **No**, skip to item 26.

B. Date of Ophthalmology Summary: (mm / dd / yyyy) opexmdtsv

	Yes	No	
C. Did the patient have severe retinopathy?	○	○	opexmretsv

Liver Biopsy

	Yes	No	
26.A. Has the patient had a liver biopsy in the last 24 months?	○	○	lurbiopsv

If **No**, skip to signature and Certification #.

B. Date of liver biopsy: (mm / dd / yyyy) lurbiopdtsv

Signature: _____ **Certif. #:** staffid8 -