PEDS-C
Treatment Period Assessment Summary
Week 24 Visit

56182

Please Use Black Pen To Fill Out Form.

Week # week: 024

Date of Assessment assessdt: mm / dd / yyyy

Patient ID idn: - -

Patient Letter Code letcode

corrfix: ○ Correction

Instructions

Use this form for all therapy groups at the Week 24 visit.

CRA Use Only

1.A. Is the patient willing and able to continue in the study? Yes ○ No ○ w16patcont

If **Yes**, skip to item 2.

B. If **No**, Date of Withdrawal / Close-out w16wddt: mm / dd / yyyy

Vital Signs and Symptom Directed Physical

2.A. Has a Vital Signs and Symptom Directed Physical Exam Form been completed? Yes ○ No ○ w16physexm

B. If **Yes**, date of form: w16physexmdt: mm / dd / yyyy

Anthropometry

	A. First measurement	B. Second measurement	C. Unable to measure
3. Height:	w24ht1 . cm	w24ht2 . cm	○ w24htna
4. Weight:	w24wt1 . kg	w24wt2 . kg	○ w24wtna
5. Mid-arm circumference (right):	w24arm1 . cm	w24arm2 . cm	○ w24armna
6. Biceps skinfold: (right):	w24bskn1 . mm	w24bskn2 . mm	○ w24bsknna
7. Triceps skinfold: (right):	w24tskn1 . mm	w24tskn2 . mm	○ w24tsknna
8. Subscapular skinfold: (right):	w24sskn1 . mm	w24sskn2 . mm	○ w24ssknna
9. Iliac skinfold: (right):	w24iskn1 . mm	w24iskn2 . mm	○ w24isknna

Signature: _____ **Certif. #:** staffid1 -

PEDS-C
Treatment Period Assessment Summary
Week 24 Visit

2082

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Week # week 0 2 4 | Date of Assessment assessdt mm / dd / yyyy | Patient ID idn - - | Patient Letter Code letcode | corrfix Correction

Anthropometry (Continued)

CRA Use Only

10.A. Has a DXA scan been performed? ○ Yes ○ No w24dxa

B. If **Yes**, date of scan: w24dxadt mm / dd / yyyy

11.A. Has a Bio-electrical Impedance Analysis been performed? ○ Yes ○ No w24bia

B. If **Yes**, date of BIA: w24biadt mm / dd / yyyy

12.A. Has the parent / patient been given the 3-day food diary? ○ Yes ○ No w24fdry

B. If **Yes**, date of first diary day: w24fdrydt mm / dd

13.A. Has the Physical Activity Assessment been completed? ○ Yes ○ No w24pact

B. If **Yes**, date completed: w24pactdt mm / dd / yyyy

Concurrent Medication and Conditions

14.A. *Ask the parent (or patient) the following question*:
"Has your child (have you) had any other problems since your last visit?" ○ Yes ○ No w24patprob

If **No**, skip to item 15.

B. Was a Concurrent Medical Conditions form completed? ○ Yes ○ No w24medcon

1. If **Yes**, date of the form: w24medcondt mm / dd / yyyy

C. Was a Serious Adverse Event form completed? ○ Yes ○ No w24sae

1. If **Yes**, date of SAE form: w24saedt mm / dd / yyyy

D. Was an Adverse Event form completed? ○ Yes ○ No w24ae

1. If **Yes**, date of AE form: w24aedt mm / dd / yyyy

Signature: _____ **Certif. #:** staffid2 -

PEDS-C
Treatment Period Assessment Summary
Week 24 Visit

2378

Please Use Black Pen To Fill Out Form.

Week # week: 0 2 4

Date of Assessment assessdt: mm / dd / yyyy

Patient ID idn: - -

Patient Letter Code letcode

corrfix: ○ Correction

Concurrent Medication and Conditions

CRA Use Only

15.A. *Ask the parent (or patient) the following question*:
"Has your child (have you) taken any new medicines, other than those given to you within this study, since the last visit?" ○ Yes ○ No w24newmed

If **No**, skip to item 16.

B. Was a Concurrent Medications form completed? ○ Yes ○ No w24meds

1. If **Yes**, date of the form: w24medsdt: mm / dd / yyyy

16.A. Is the patient a female at least 10 years of age? ○ Yes ○ No w24fem

If **No**, skip to item 17.

B. Has a urine pregnancy test been done? ○ Yes ○ No w24urnptst

If **No**, skip to item 18.

C. Date of the urine test: w24urnptstdt: mm / dd / yyyy

D. Urine pregnancy test result: ○ Positive ○ Negative w24urnptstres

If **Negative**, skip to item 18.

E. If **Positive**, date of serum test: w24srmptstdt: mm / dd / yyyy

F. Serum pregnancy test result: ○ Positive ○ Negative w24srmptstres

If either the urine or serum test was **Positive**, stop therapy and begin untreated follow-up at the next visit.

G. If either **Positive**, Date of the Therapy Stop/Restart Form: w24fthrstpdt: mm / dd / yyyy

H. If either **Positive**, was the pregnancy reported to your PI, the DCC/CRO, and the Ribavirin Registry (1-800-593-2214) within 24 hours? ○ Yes ○ No w24fpregrep

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

PEDS-C
Treatment Period Assessment Summary
Week 24 Visit

38332

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Week # week: 0 2 4

Date of Assessment assessdt: mm / dd / yyyy

Patient ID idn: - -

Patient Letter Code letcode

corrfix: ◯ Correction

Concurrent Medication and Conditions (Continued)

CRA Use Only

17.A. Is the patient a sexually active male? ◯ Yes ◯ No w24sexactm

If **No**, skip to item 18.

B. Is his sexual partner pregnant? ◯ Yes ◯ No w24mppreg

If **No**, skip to item 18.
If **Yes**, stop therapy and begin untreated follow-up at the next visit.

C. If **Yes**, Date of the Therapy Stop/Restart Form: w24mthrstpdt mm / dd / yyyy

D. If **Yes**, was the pregnancy reported to your PI, the DCC/CRO, and the Ribavirin Registry (1-800-593-2214) within 24 hours? ◯ Yes ◯ No w24mppregrep

18.A. Has the patient had an ophthalmologic exam? ◯ Yes ◯ No w24opexm

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

B. If **Yes**, date of the Ophthalmology Summary:: w24opexmdt mm / dd / yyyy

C. Did the patient have new or worsening ocular disorders? ◯ Yes ◯ No w24ocdisordr

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

D. If **Yes**, was the patient referred to an ophthalmologist? ◯ Yes ◯ No w24oprefer

E. If **Yes**, date of the referral: w24opreferdt mm / dd / yyyy

Patient Study Drug Therapy

19.A. Has the Patient Medication Diary been reviewed with the parent (patient)? ◯ Yes ◯ No w24meddry

B. If **Yes**, Diary start date: w24meddrydt mm / dd / yyyy

20.A. Have there been any changes in the patient's doses? ◯ Yes ◯ No w24tda

B. If **Yes**, date of the Therapy Dose Adjustment Report: w24tdadt mm / dd / yyyy

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PEDS-C
Treatment Period Assessment Summary
Week 24 Visit

49046

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Date of Assessment assessdt: mm / dd / yyyy

Patient ID idn: - -

Patient Letter Code letcode

corrfix: ○ Correction

Patient Study Drug Therapy (Continued)

21.A. Has the patient's therapy been stopped for any reason? ○ Yes ○ No w24thrstp

B. If **Yes**, date of the Therapy Stop/Restart Form: w24thrstpdt: mm / dd / yyyy

22.A. Has the patient missed any doses since the last visit? ○ Yes ○ No w24misdos

B. If **Yes**, date of the Therapy Missed Dose Form: w24misdosdt: mm / dd / yyyy

Depression Screen

23.A. Was the patient's raw score greater than 19 on the CDI or greater than 15 on ther CESD? ○ Yes ○ No w24cdigt19

If **No**, skip to item 24.

B. If **Yes**, was the patient referred for depression management according to Protocol requirements? ○ Yes ○ No w24refdep

If **No**, skip to item 24.
If **Yes**, continue drug therapy and begin a Depression Management Tracking Form.

List of Laboratory Tests Ordered at Week 24

	Done	Unable to obtain	
24.A. Hematology:	○	○	w24hmtotst
B. PT / PTT:	○	○	w24pttst
C. Chemistry / Pregnancy:	○	○	w24chemtst
D. HCV-RNA (Clinical):	○	○	w24hcvclntst
E. HCV-RNA (Research):	○	○	w24hcvrshtst
F. Thyroid function:	○	○	w24thyrdtst
G. Serum bank:	○	○	w24sermtst
H. Urinalysis:	○	○	w24urintst

CRA Use Only

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PEDS-C
Treatment Period Assessment Summary
Week 24 Visit

35200

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Week # week: 0 2 4

Date of Assessment assessdt: mm / dd / yyyy

Patient ID idn: - -

Patient Letter Code letcode

corrfix ○ Correction

Quality of Life Tests Administered at Week 24

Test Name	1. Completed (Yes / No)	2. Form date (mm / dd / yyyy)	3. Completed by (Patient / Parent)
25.A. CHQ (Patient)	w24chqpt ○ ○	w24chqptdt / /	w24chqptby ○ ○
B. CHQ (Parent)	w24chqpr ○ ○	w24chqprdt / /	w24chqprby ○ ○
C. BRIEF (Parent)	w24brief ○ ○	w24briefdt / /	w24briefby ○ ○
D. CBCL (Parent)	w24cbcl ○ ○	w24cbcldt / /	w24cbclby ○ ○
E. ABCL (Parent)	w24abcl ○ ○	w24abcldt / /	w24abclby ○ ○
F. LEC (Patient)	w24lec ○ ○	w24lecdt / /	w24lecby ○ ○
G. SF-36 (Parent)	w24sf36 ○ ○	w24sf36dt / /	w24sf36by ○ ○

CRA Use Only

Remember to obtain HCV-RNA test results and to use the Treatment Failure / Reassignment Report Week 24 to evaluate responses to therapy.

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