PEDS-C
Treatment Period Assessment Summary
Week 1 Visit

48110

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
Use this form for all therapy groups at Week 1 Visit.

CRA Use Only

1.A. Is the patient willing and able to continue in the study? ○ Yes ○ No w1patcont

B. If **No**, date of the Withdrawal/Close-out Form: w1wddt ___ / ___ / ____ (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 w1physexm

B. If **Yes**, date of the form: w1physexmdt ___ / ___ / ____ (mm dd yyyy)

Concurrent Medications and Conditions

3.A. *Ask the parent (or patient) the following question:*
Has your child (have you) had any other problems since your last visit? ○ Yes ○ No w1patprob

If **No**, skip to item 4.

B. Was a Concurrent Medical Condition Form completed? ○ Yes ○ No w1medcon

C. If **Yes**, date of the form: w1medcondt ___ / ___ / ____ (mm dd yyyy)

D. Was a Serious Adverse Event Form completed? ○ Yes ○ No w1sae

E. If **Yes**, date of the SAE form: w1saedt ___ / ___ / ____ (mm dd yyyy)

F. Was an Adverse Event Form completed? ○ Yes ○ No w1ae

G. If **Yes**, date of the AE form: w1aedt ___ / ___ / ____ (mm dd yyyy)

4.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 w1newmed

If **No**, skip to item 5.

B. Has the Concurrent Medications Form been completed? ○ Yes ○ No w1meds

C. If **Yes**, date of the form: w1medsdt ___ / ___ / ____ (mm dd yyyy)

Signature: ____________________ **Certif. #:** staffid1 ___ - ___

60768

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Concurrent Medications and Conditions (Continued)

CRA Use Only

5.A. Is the patient a female at least 10 years of age? ○ Yes ○ No w1fem

If **No**, skip to item 6.

B. What was the first day of her last menstrual period? w1mensdt mm / dd / yyyy NA ○ w1mensdtna

C. Does she show secondary amenorrhea of 1 week or more? ○ Yes ○ No ○ NA w1amenor

If **No** or **NA**, skip to item 7.

D. Was a serum pregnancy test done? ○ Yes ○ No w1srmptst

If **No**, skip to item 7.

E. Date of the test: w1srmptstdt mm / dd / yyyy

F. Serum pregnancy test result: ○ Positive ○ Negative w1srmptstres

If **Negative**, skip to item 7.
If **Positive**, stop therapy and begin untreated follow-up at the next visit.

G. If **Positive**, Date of the Therapy Stop/Restart Form: w1fthrstpdt mm / dd / yyyy

H. If **Positive**, was the pregnancy reported to your PI, the DCC/CRO, and the Ribavirin Registry (1-800-593-2214) within 24 hours? ○ Yes ○ No w1fpregrep

6.A. Is the patient a sexually active male? ○ Yes ○ No w1sexactm

If **No**, skip to item 7.

B. Is his sexual partner pregnant? ○ Yes ○ No w1mppreg

If **No**, skip to item 7.
If **Yes**, stop therapy and begin untreated follow-up at the next visit.

C. If **Yes**, Date of the Therapy Stop/Restart Form: w1mthrstpdt 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 w1mppregrep

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

17180

PEDS-C
Treatment Period Assessment Summary
Week 1 Visit

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

Patient Study Drug Therapy

7.A. Has the Patient Medication Diary been reviewed with the parent (patient)? ○ Yes ○ No w1meddry

B. If **Yes**, Diary start date: w1meddrydt ___ / ___ / ____ (mm dd yyyy)

8.A. Have there been any changes in the patient's doses? ○ Yes ○ No w1tda

B. If **Yes**, date of the Therapy Dose Adjustment Report: w1tdadt ___ / ___ / ____ (mm dd yyyy)

9.A. Has the patient's therapy been stopped for any reason? ○ Yes ○ No w1thrstp

B. If **Yes**, date of the Therapy Stop/Restart Form: w1thrstpdt ___ / ___ / ____ (mm dd yyyy)

10.A. Has the patient missed any doses since the last visit? ○ Yes ○ No w1misdos

B. If **Yes**, date of the Therapy Missed Dose Form: w1misdosdt ___ / ___ / ____ (mm dd yyyy)

List of Laboratory Tests Ordered at Week 1

	Done	Unable to obtain	
11.A. Hematology:	○	○	w1hmtotst
B. Chemistry:	○	○	w1chemtst
C. HCV-RNA (Research):	○	○	w1hcvrshtst

Signature: ______________________ **Certif. #:** staffid3 ___ - ___