PEDS-C
Treatment Period Assessment Summary
Week 8 Visit

38352

Please Use Black Pen To Fill Out Form.

Week # week: 0 0 8

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 8 Visit.

1.A. Is the patient willing and able to continue in the study? ○ Yes ○ No w8patcont

B. If **No**, date of the Withdrawal/Close-out Form: w8wddt mm / dd / yyyy

If **No**, skip to item 12.

Vital Signs and Symptom Directed Physical

2.A. Has a Vital Signs and Symptom Directed Physical Exam form been completed? ○ Yes ○ No w8physexm

B. If **Yes**, date of the form: w8physexmdt 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 w8patprob

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

B. Was a Concurrent Medical Condition Form completed? ○ Yes ○ No w8medcon

C. If **Yes**, date of the form: w8medcondt mm / dd / yyyy

D. Was a Serious Adverse Event Form completed? ○ Yes ○ No w8sae

E. If **Yes**, date of the SAE form: w8saedt mm / dd / yyyy

F. Was an Adverse Event Form completed? ○ Yes ○ No w8ae

G. If **Yes**, date of the AE form: w8aedt 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 w8newmed

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

B. Has the Concurrent Medications Form been completed? ○ Yes ○ No w8meds

C. If **Yes**, date of the form: w8medsdt mm / dd / yyyy

CRA Use Only

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

PEDS-C
Treatment Period Assessment Summary
Week 8 Visit

1677

Please Use Black Pen To Fill Out Form.

Week # week 0 0 8 | Date of Assessment assessdt mm / dd / yyyy | Patient ID idn - - | Patient Letter Code letcode | corrfix ◯ Correction

Concurrent Medications and Conditions (Continued)

CRA Use Only

5.A. Is the patient a female at least 10 years of age? ◯ Yes ◯ No w8fem

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

B. Was a serum pregnancy test done? ◯ Yes ◯ No w8srmptst

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

C. Date of the test: w8srmptstdt mm / dd / yyyy

D. Serum pregnancy test result: ◯ Positive ◯ Negative w8srmptstres

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

E. If **Positive**, Date of the Therapy Stop/Restart Form: w8fthrstpdt mm / dd / yyyy

F. 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 w8fpregrep

6.A. Is the patient a sexually active male? ◯ Yes ◯ No w8sexactm

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

B. Is his sexual partner pregnant? ◯ Yes ◯ No w8mppreg

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: w8mthrstpdt 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 w8mppregrep

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

PEDS-C
Treatment Period Assessment Summary
Week 8 Visit

42433

Please Use Black Pen To Fill Out Form.

Week # week: 0 0 8

Date of Assessment assessdt: mm / dd / yyyy

Patient ID idn: - -

Patient Letter Code letcode:

corrfix: ○ Correction

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Patient Study Drug Therapy

7.A. Has the Patient Medication Diary been reviewed with the parent (patient)? ○ Yes ○ No w8meddry

B. If **Yes**, Diary start date: w8meddrydt mm / dd / yyyy

8.A. Have there been any changes in the patient's doses? ○ Yes ○ No w8tda

B. If **Yes**, date of the Therapy Dose Adjustment Report: w8tdadt mm / dd / yyyy

9.A. Has the patient's therapy been stopped for any reason? ○ Yes ○ No w8thrstp

B. If **Yes**, date of the Therapy Stop/Restart Form: w8thrstpdt mm / dd / yyyy

10.A. Has the patient missed any doses since the last visit? ○ Yes ○ No w8misdos

B. If **Yes**, date of the Therapy Missed Dose Form: w8misdosdt mm / dd / yyyy

List of Laboratory Tests Ordered at Week 8

	Done	Unable to obtain	
11.A. Hematology:	○	○	w8hmtotst
B. Chemistry / Pregnancy:	○	○	w8chemtst

Liver Biopsy

	Yes	No	
12. Have slides been sent to the pathology laboratory (Dr. Goodman)?	○	○	w8lvrbiop

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