PEDS-C
Treatment Period Assessment Summary
Week 20 Visit

58795

Please Use Black Pen To Fill Out Form.

Week # week: 0 2 0

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 20 Visit.

CRA Use Only

1.A. Is the patient willing and able to continue in the study? ○ Yes ○ No w20patcont

B. If **No**, date of the Withdrawal/Close-out Form: w20wddt 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 w20physexm

B. If **Yes**, date of the form: w20physexmdt 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 w20patprob

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

B. Was a Concurrent Medical Condition Form completed? ○ Yes ○ No w20medcon

C. If **Yes**, date of the form: w20medcondt mm / dd / yyyy

D. Was a Serious Adverse Event Form completed? ○ Yes ○ No w20sae

E. If **Yes**, date of the SAE form: w20saedt mm / dd / yyyy

F. Was an Adverse Event Form completed? ○ Yes ○ No w20ae

G. If **Yes**, date of the AE form: w20aedt 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 w20newmed

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

B. Has the Concurrent Medications Form been completed? ○ Yes ○ No w20meds

C. If **Yes**, date of the form: w20medsdt mm / dd / yyyy

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

PEDS-C
Treatment Period Assessment Summary
Week 20 Visit

17260

Please Use Black Pen To Fill Out Form.

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

Concurrent Medications and Conditions (Continued)

5.A. Is the patient a female at least 10 years of age? ○ Yes ○ No w20fem

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

B. Was a serum pregnancy test done? ○ Yes ○ No w20srmptst

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

C. Date of the test: w20srmptstdt mm / dd / yyyy

D. Serum pregnancy test result: ○ Positive ○ Negative w20srmptstres

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: w20fthrstpdt 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 w20fpregrep

6.A. Is the patient a sexually active male? ○ Yes ○ No w20sexactm

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

B. Is his sexual partner pregnant? ○ Yes ○ No w20mppreg

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: w20mthrstpdt 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 w20mppregrep

CRA Use Only

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

PEDS-C
Treatment Period Assessment Summary
Week 20 Visit

56927

Please Use Black Pen To Fill Out Form.

Week # week: 0 2 0

Date of Assessment assessdt: mm / dd / yyyy

Patient ID idn: - -

Patient Letter Code 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 w20meddry

B. If **Yes**, Diary start date: w20meddrydt: mm / dd / yyyy

8.A. Have there been any changes in the patient's doses? ○ Yes ○ No w20tda

B. If **Yes**, date of the Therapy Dose Adjustment Report: w20tdadt: mm / dd / yyyy

9.A. Has the patient's therapy been stopped for any reason? ○ Yes ○ No w20thrstp

B. If **Yes**, date of the Therapy Stop/Restart Form: w20thrstpdt: mm / dd / yyyy

10.A. Has the patient missed any doses since the last visit? ○ Yes ○ No w20misdos

B. If **Yes**, date of the Therapy Missed Dose Form: w20misdosdt: mm / dd / yyyy

List of Laboratory Tests Ordered at Week 20

	Done	Unable to obtain	
11.A. Hematology:	○	○	w20hmtotst
B. Chemistry / Pregnancy:	○	○	w20chemtst

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