

PEDS-C Treatment Period Assessment Summary Week 8 Visit

PDC 24
Rev 0
01/14/2005
Page 1 of 3

38352

Please Use Black Pen To Fill Out Form.

Week #	Date of Assessment	Patient ID	Patient Letter Code	Correction
<i>week</i>	<i>assesdt</i> mm / dd / yyyy	<i>idn</i> - - - - -	<i>letcode</i>	<i>corrfix</i> 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

CRA Use Only

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:

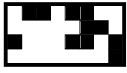
w8medsdt / mm / dd / yyyy

Signature: _____

Certif. #: _____

staffid1 - - - - -

Treatment Period Assessment Summary
Week 8 Visit



1677

Please Use Black Pen To Fill Out Form.

Week # <i>week</i>	Date of Assessment <i>assesdtd</i>	Patient ID <i>idn</i>	Patient Letter Code <i>letcode</i>	<i>corrfix</i> Correction
	mm / dd / yyyy	- - - -		

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 *w8srmpst*

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

C. Date of the test:

w8srmpstdt
mm / dd / yyyy

D. Serum pregnancy test result:

Positive Negative *w8srmpstres*

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:

w8fthrstopdt
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 *w8fprepreg*

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:

w8mthrstopdt
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 *w8mppreg*

Signature: _____

Certif. #: *staffid2* - [] [] [] [] [] []

Treatment Period Assessment Summary
Week 8 Visit

42433

Please Use Black Pen To Fill Out Form.

Week # <i>week</i>	Date of Assessment <i>assessdt</i>	Patient ID <i>idn</i>	Patient Letter Code <i>letcode</i>	<i>corrfix</i> Correction
<input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/>	<input type="text"/> - <input type="text"/> - <input type="text"/>	<input type="text"/>	
	<small>mm / dd / yyyy</small>			

Patient Study Drug Therapy

CRA Use Only

7.A. Has the Patient Medication Diary been reviewed with the parent (patient)?

Yes No *w8meddry*

B. If Yes, Diary start date:

w8meddrydt / /

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 / /

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 / /

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 / /

List of Laboratory Tests Ordered at Week 8

11.A. Hematology:

Done Unable to obtain *w8hmtotst*

B. Chemistry / Pregnancy:

w8chemtst

Liver Biopsy

12. Have slides been sent to the pathology laboratory (Dr. Goodman)?

Yes No *w8lvrbiop*

Signature: _____

Certif. #: _____

staffid3 -