



PEDS-C

Treatment Period Assessment Summary  
Week 48 Visit (3)

PDC 75  
Rev 0  
05/23/2005  
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Please Use Black Pen To Fill Out Form.

Week # <i>week</i>	Date of Assessment <i>assessdt</i> mm / dd / yyyy	Patient ID <i>idn</i>	Patient Letter Code <i>letcode</i>	<i>corrfix</i> Correction
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Physical Exam (Continued)

6. Indicate if each organ system is within normal limits. If **No**, specify or comment.

1. Yes No NA 2. Specify

- A. Neurologic:    *a48neur*
- B. Psychologic:    *a48psyc*
- C. Genitourinary:    *a48gnto*
- D. Hematologic / Lymphatic:    *a48hmto*
- E. Allergies / Immunologic:    *a48allr*
- F. Musculoskeletal:    *a48musc*
- G. Other:    *a48othog*

CRA Use Only

7.A. Was the patient referred to another health professional?  Yes  No *a48refr*

If **No**, skip to item 8.

B. Reason for referral: \_\_\_\_\_

C. Date of referral:  /  /  *a48refdt*

D. Name of health professional: \_\_\_\_\_

8. Is the patient a sexually active female at least 10 years old or a sexually active male?  Yes  No *a48sexat*

If **No**, skip to item 10.

9. Indicate all types of contraception used (Answer each item):

- |   | Yes                   | No                    |                 |
|---|-----------------------|-----------------------|-----------------|
| A. Oral contraceptive                           | <input type="radio"/> | <input type="radio"/> | <i>a48cnora</i> |
| B. Intrauterine contraceptive device            | <input type="radio"/> | <input type="radio"/> | <i>a48cniud</i> |
| C. Depot contraceptives (implants, injectables) | <input type="radio"/> | <input type="radio"/> | <i>a48cndep</i> |
| D. Physical barrier (condom, diaphragm)         | <input type="radio"/> | <input type="radio"/> | <i>a48cnphy</i> |
| E. Abstinence                                   | <input type="radio"/> | <input type="radio"/> | <i>a48cnabs</i> |
| F. None   | <input type="radio"/> | <input type="radio"/> | <i>a48cnonn</i> |
| G. Other  | <input type="radio"/> | <input type="radio"/> | <i>a48cnoth</i> |

Specify *a48cnosp*

Signature: \_\_\_\_\_

Certif. #: *staffid2* -

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

### Anthropometry

	A. First measurement	B. Second measurement	C. Unable to measure	CRA Use Only
10. Height:	<i>a48ht1</i> [ ] [ ] . [ ] cm	<i>a48ht2</i> [ ] [ ] . [ ] cm	<input type="radio"/> <i>a48htna</i>	
11. Weight:	<i>a48wt1</i> [ ] [ ] . [ ] kg	<i>a48wt2</i> [ ] [ ] . [ ] kg	<input type="radio"/> <i>a48wtna</i>	
12. Mid-arm circumference (right):	<i>a48arm1</i> [ ] [ ] . [ ] cm	<i>a48arm2</i> [ ] [ ] . [ ] cm	<input type="radio"/> <i>a48armna</i>	
13. Biceps skinfold: (right):	<i>a48bskn1</i> [ ] [ ] . [ ] mm	<i>a48bskn2</i> [ ] [ ] . [ ] mm	<input type="radio"/> <i>a48bskna</i>	
14. Triceps skinfold: (right):	<i>a48tskn1</i> [ ] [ ] . [ ] mm	<i>a48tskn2</i> [ ] [ ] . [ ] mm	<input type="radio"/> <i>a48tskna</i>	
15. Subscapular skinfold: (right):	<i>a48sskn1</i> [ ] [ ] . [ ] mm	<i>a48sskn2</i> [ ] [ ] . [ ] mm	<input type="radio"/> <i>a48sskna</i>	
16. Iliac skinfold: (right):	<i>a48iskn1</i> [ ] [ ] . [ ] mm	<i>a48iskn2</i> [ ] [ ] . [ ] mm	<input type="radio"/> <i>a48iskna</i>	
17.A. Has a DXA scan been performed?	<input type="radio"/> Yes <input type="radio"/> No <i>a48dxa</i>			
B. If Yes, date of scan:	<i>a48dxadt</i> [ ] [ ] / [ ] [ ] / [ ] [ ] [ ] [ ]			
18.A. Has a Bio-electrical Impedance Analysis been performed?	<input type="radio"/> Yes <input type="radio"/> No <i>a48bia</i>			
B. If Yes, date of BIA:	<i>a48biadt</i> [ ] [ ] / [ ] [ ] / [ ] [ ] [ ] [ ]			
19.A. Has the parent / patient been given the 3-day food diary?	<input type="radio"/> Yes <input type="radio"/> No <i>a48fdry</i>			
B. If Yes, date of first diary day:	<i>a48fdrdt</i> [ ] [ ] / [ ] [ ] / [ ] [ ] [ ] [ ]			
20.A. Has the Physical Activity Assessment been completed?	<input type="radio"/> Yes <input type="radio"/> No <i>a48pact</i>			
B. If Yes, date completed:	<i>a48pacdt</i> [ ] [ ] / [ ] [ ] / [ ] [ ] [ ] [ ]			

Signature: \_\_\_\_\_

Certif. #: *staffid3* [ ] [ ] - [ ] [ ] [ ] [ ]

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Week # <i>week</i>	Date of Assessment <i>assesdtdt</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"/>	<input type="text"/>
	mm / dd / yyyy			

Concurrent Medications and Conditions

CRA Use Only

21.A. Ask the parent (or patient) the following question:

Has your child (have you) had any other problems since your last visit?

Yes  No *a48ptprb*

If No, skip to item 22.

B. Was a Serious Adverse Event Form completed?

Yes  No *a48sae*

C. If Yes, date of the SAE form:

*a48saedt*  /  /   
mm / dd / yyyy

D. Was a Non-Serious Adverse Event Form completed?

Yes  No *a48ae*

E. If Yes, date of the AE form:

*a48aedt*  /  /   
mm / dd / yyyy

22.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 *a48nwmed*

If No, skip to item 23.

B. Has the Concurrent Medications Form been completed?

Yes  No *a48meds*

C. If Yes, date of the form:

*a48mdsdt*  /  /   
mm / dd / yyyy

23.A. Is the patient a female at least 10 years of age?

Yes  No *a48fem*

If No, skip to item 24.

B. Has a serum pregnancy test been done?

Yes  No *a48spgst*

C. If Yes, date of the serum test:

*a48spgdt*  /  /   
mm / dd / yyyy

D. If Yes, serum pregnancy test result:

Positive  Negative *a48spgrs*

If the serum test was **Negative**, skip to item 25.

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

E. If **Positive**, Date of the Therapy Stop/Restart Form:

*a48ftrdt*  /  /   
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 *a48pgrep*

Skip to item 25.

Signature: \_\_\_\_\_

Certif. #: \_\_\_\_\_

*staffid4*  -

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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"/>	<input type="text"/>
	mm / dd / yyyy			

Concurrent Medications and Conditions (Continued)

CRA Use Only

24.A. Is the patient a sexually active male?  Yes  No *a48xactm*

If No, skip to item 25.

B. If Yes, is his sexual partner pregnant?  Yes  No *a48mpreg*

If No, skip to item 25. If Yes, stop therapy and begin untreated follow-up at the next visit.

C. If Yes, Date of the Therapy Stop/Restart Form: *a48mtrdt*  /  /

<input type="text"/>	/	<input type="text"/>	/	<input type="text"/>
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 *a48mprep*

Ophthalmology Exam

25.A. Has the patient had an ophthalmology exam?  Yes  No *a48opexm*

If No, skip to item 26.

B. Date of Ophthalmology Summary: *a48opxdt*  /  /

<input type="text"/>	/	<input type="text"/>	/	<input type="text"/>
mm		dd		yyyy

C. Did the patient have new or worsening ocular symptoms?  Yes  No *a48opsym*

If No, skip to item 26.

D. Was the patient referred to another ophthalmologist?  Yes  No *a48opref*

E. If Yes, date of referral: *a48oprdt*  /  /

<input type="text"/>	/	<input type="text"/>	/	<input type="text"/>
mm		dd		yyyy

F. If Yes, name of the ophthalmologist: \_\_\_\_\_

Patient Study Drug Therapy

26.A. Has the Patient Medication Diary been reviewed with the parent (patient)?  Yes  No *a48mddry*

B. If Yes, Diary start date: *a48mrdrt*  /  /

<input type="text"/>	/	<input type="text"/>	/	<input type="text"/>
mm		dd		yyyy

27.A. Have there been any changes in the patient's doses?  Yes  No *a48tda*

B. If Yes, date of the Therapy Dose Adjustment Report: *a48tdadt*  /  /

<input type="text"/>	/	<input type="text"/>	/	<input type="text"/>
mm		dd		yyyy

Signature: \_\_\_\_\_ Certif. #: *staffid5*  -

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

Patient Study Drug Therapy (Continued)

28.A. Has the patient's therapy been stopped for any reason?

Yes  No *a48thrsp*

B. If Yes, date of the Therapy Stop/Restart Form:

*a48thtdt* / /

29.A. Has the patient missed any doses since the last visit?

Yes  No *a48msdos*

B. If Yes, date of the Therapy Missed Dose Form:

*a48msdtt* / /

CRA Use Only

Depression Screen

30.A. Was the patient's raw score greater than 19 on the CDI or greater than 15 on the CES-D?

Yes  No *a48cdi19*

If No, skip to item 31.

B. If Yes, was the patient referred for depression management according to Protocol requirements?

Yes  No *a48refdp*

If No, skip to item 31.

If Yes, continue drug therapy and begin a Depression Management Tracking Form.

List of Laboratory Tests Ordered at Week 48

31.A. Hematology:

Done  Unable to obtain  *a48hmtst*

B. PT / PTT:

*a48ptst*

C. Chemistry / Pregnancy:

*a48chmst*

D. HCV-RNA (Clinical):

*a48vlcst*

E. HCV-RNA (Research):

*a48vlrst*

F. Thyroid function:

*a48thyst*

G. Serum bank:

*a48serbk*

H. Urinalysis:

*a48urnst*

Signature: \_\_\_\_\_

Certif. #: \_\_\_\_\_

*staffid6* -

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mm	dd / yyyy	- - -		

### Quality of Life Tests Administered at Week 48

Test Name	1. Completed		2. Form date			3. Completed by		CRA Use Only
	Yes	No	mm	dd	yyyy	Patient	Parent	
32.A. CHQ (Patient)	<i>a48cht</i>	<input type="radio"/>	<i>a48chtdt</i>	/	/	<i>a48chtby</i>	<input type="radio"/>	
B. CHQ (Parent)	<i>a48chr</i>	<input type="radio"/>	<i>a48chrdt</i>	/	/	<i>a48chrby</i>	<input type="radio"/>	
C. BRIEF (Parent)	<i>a48brf</i>	<input type="radio"/>	<i>a48brfdt</i>	/	/	<i>a48brfby</i>	<input type="radio"/>	
D. CBCL (Parent)	<i>a48cbc</i>	<input type="radio"/>	<i>a48cbcdt</i>	/	/	<i>a48cbcby</i>	<input type="radio"/>	
E. ABCL (Parent)	<i>a48abc</i>	<input type="radio"/>	<i>a48abcdt</i>	/	/	<i>a48abcby</i>	<input type="radio"/>	
F. LEC (Parent)	<i>a48lec</i>	<input type="radio"/>	<i>a48lecdt</i>	/	/	<i>a48lecby</i>	<input type="radio"/>	
G. SF-36 (Parent)	<i>a48s36</i>	<input type="radio"/>	<i>a48s36dt</i>	/	/	<i>a48s36by</i>	<input type="radio"/>	

Signature: \_\_\_\_\_

Certif. #: *staffid7* - [ ] [ ] [ ] [ ] [ ] [ ]