# PEDS-C
# Treatment Period Assessment Summary
# Week 40 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 |

**Instructions**

Use this form for patients in the Mono/Combo therapy group who had no viral disappearance at Week 24.

**CRA Use Only**

1.A. Is the patient willing and able to continue in the study? ○ Yes ○ No w40ptcnt

B. If **No**, date of the Withdrawal/Close-out Form: w40wddt / / (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 w40phexm

B. If **Yes**, date of the form: w40phxdt / / (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 w40ptprb

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

B. Was a Serious Adverse Event Form completed? ○ Yes ○ No w40sae

C. If **Yes**, date of the SAE form: w40saedt / / (mm dd yyyy)

D. Was a Non-Serious Adverse Event Form completed? ○ Yes ○ No w40ae

E. If **Yes**, date of the AE form: w40aedt / / (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 w40nwmed

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

B. Has the Concurrent Medications Form been completed? ○ Yes ○ No w40meds

C. If **Yes**, date of the form: w40mdsdt / / (mm dd yyyy)

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

# PEDS-C
## Treatment Period Assessment Summary
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**Week #** week | **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** w40fem

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

B. Was a serum pregnancy test done? ○ **Yes** ○ **No** w40spgst

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

C. Date of the test: w40spgdt ___ / ___ / ___ (mm dd yyyy)

D. Serum pregnancy test result: ○ **Positive** ○ **Negative** w40spgrs

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: w40ftrdt ___ / ___ / ___ (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** w40fpgrep

6.A. Is the patient a sexually active male? ○ **Yes** ○ **No** w40xactm

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

B. Is his sexual partner pregnant? ○ **Yes** ○ **No** w40mpreg

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: w40mtrdt ___ / ___ / ___ (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** w40mprep

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

# PEDS-C

# Treatment Period Assessment Summary

# Week 40 Visit



49607

**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 w40mddry

B. If **Yes**, Diary start date: w40mdrdt ___ / ___ / ______ (mm dd yyyy)

8.A. Have there been any changes in the patient's doses? ○ Yes ○ No w40tda

B. If **Yes**, date of the Therapy Dose Adjustment Report: w40tdadt ___ / ___ / ______ (mm dd yyyy)

9.A. Has the patient's therapy been stopped for any reason? ○ Yes ○ No w40thrsp

B. If **Yes**, date of the Therapy Stop/Restart Form: w40thtdt ___ / ___ / ______ (mm dd yyyy)

10.A. Has the patient missed any doses since the last visit? ○ Yes ○ No w40msdos

B. If **Yes**, date of the Therapy Missed Dose Form: w40msddt ___ / ___ / ______ (mm dd yyyy)

### List of Laboratory Tests Ordered at Week 40

| | Done | Unable to obtain | |
|---|---|---|---|
| 11.A. Hematology: | ○ | ○ | w40hmtst |
| B. Chemistry / Pregnancy: | ○ | ○ | w40chmst |
| C. HCV-RNA (Clinical): | ○ | ○ | w40vlcst |
| D. Serum bank: | ○ | ○ | w40serbk |
| E. Urinalysis: | ○ | ○ | w40urnst |

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