

## HALT-C Trial Q x Q

### Peginterferon alfa-2a Accountability Log

Form # 26 Version A: 06/15/2000

**Purpose of Form #26:** The Peginterferon alfa-2a Accountability Log documents the dispensation of Peginterferon alfa-2a to the patient and the return of all vials and remaining trial medication from the patient. The individual documentation of trial medication dispensation and return should be completed in addition to the clinical site's pharmacy records.

**When to complete Form #26:** The form should be updated each time Peginterferon alfa-2a is dispensed to a patient or returned by a patient.

- All patients who entered the Trial as Lead-In patients require a Form #26. Form #26 should be updated when Peginterferon is dispensed or returned during the following study visits:
  - Lead-In Phase Visits.
  - Responder Phase Visits (Peginterferon should not be dispensed at or after the Week 48 visit).
  - Randomization Phase Visits if randomized to the treatment group (Peginterferon should not be dispensed during or after the Month 48 study visit).
- Express patients randomized to the treatment group require a Form #26. Form #26 should be updated when Peginterferon is dispensed or returned during the Randomized Phase (Peginterferon should not be dispensed during or after the Month 48 study visit).
- Express patients randomized to the control group do not require a Form #26.

Only the dispensation or return of Peginterferon alfa-2a is documented on Form #26. Ribavirin dispensation and return is documented on Form #27, Ribavirin Accountability Log.

#### **SECTION A: GENERAL INFORMATION**

- A1. Affix the patient ID label in the space provided.
- If the label is not available, record the ID number legibly.
- A2. Enter the patient's initials exactly as recorded on the Trial ID Assignment form.

#### **SECTION B: PEGINTERFERON ALFA-2a DISPENSED AND RETURNED**

- B1. Initial dose of Peginterferon alfa-2a
- For Lead-In patients, the HALT-C physician determines the initial Peginterferon alfa-2a dosage (not greater than 180 µg/week) at the Baseline (W00) visit, as described in Section H and Appendix D of the HALT-C Protocol. Refer to the Protocol for dosing guidelines for patients with low absolute neutrophil count (ANC).
  - For Express patients randomized to the treatment group, the HALT-C physician determines the initial Peginterferon alfa-2a dosage (not greater than 90 µg/week) at the Randomization (R00) visit, as described in Section J of the HALT-C Protocol.
    - Circle 1 if the initial dose was 180 µg per week.
    - Circle 2 if the initial dose was 90 µg per week.

**General Instructions for Column B2: Peginterferon alfa-2a Dispensed**

For each date that Peginterferon alfa-2a is dispensed, complete one row of Column B2.

If no Peginterferon alfa-2a is dispensed at a visit, do not complete a row of Column B2.

**B2a. Dosage**

- Patients in the Lead-In Phase are dispensed 180 µg vials even if taking a lower weekly dose.
- Circle 1 if the vial was 180 µg.
- Circle 2 if the vial was 90 µg.

**B2b. Date Dispensed**

- Record the date the vials were dispensed to the patient using MM/DD/YYYY format.

**B2c. # Vials Dispensed**

- Record the number of vials dispensed to the patient on this date. Do not record the number of boxes.

**B2d. Batch #**

- Record the batch number on the vials, which begins with "C" followed by 6 digits.
- In the event that two different batch numbers are dispensed on one day, please use two rows.

D/E column. After data entering this row, the data entry person should initial the shaded box.

**General Instructions for Column B3: Peginterferon alfa-2a Returned**

For each date that Peginterferon alfa-2a is returned, complete one row of Column B3.

If no Peginterferon alfa-2a is returned at a visit, do not complete a row of Column B3.

If the patient threw away or lost vials, complete Form #926: Lost Drug Accountability. You do not need to account for vials that were lost or thrown away on Form #26.

**B3a. Date Returned**

- Record the date the vials were returned by the patient using MM/DD/YYYY format.

**B3b. # Vials Returned Used**

- Record the number of used vials returned by the patient on this date.

**B3c. # Vials Returned Unused**

- Record the number of unused vials returned by the patient on this date.

**B2d. Batch #**

- Record the batch number on the vials, which begins with "C" followed by 6 digits.
- If two different batch numbers are returned on one day, please use two rows.

D/E column. After data entering this row, the data entry person should initial the shaded box.