HALT-C Trial Q x Q

Peginterferon alfa-2a Dose Adjustments

Form # 28 Version B: 10/01/2001

Purpose of Form #28: The Peginterferon alfa-2a Dose Adjustments form records changes in the dose of Peginterferon alfa-2a.

When to complete Form #28: Form #28 should be used for recording missed doses or adjustments in the dose of Peginterferon alfa-2a if held doses or dose adjustments were due to the protocol or HALT-C physician's discretion.

Section D of Study Visit Form #10 should be used to document missed doses of Peginterferon alfa-2a if initiated by the patient and/or non-HALT-C personnel (such as the patient's primary care physician).

Any Peginterferon alfa-2a dose adjustment made before 10/01/2001 needs to be recorded on Version A of this form. Any Peginterferon alfa-2a dose adjustment made on or after 10/01/2001 needs to be recorded on Version B. Call the DCC to add a second version to a patient's forms in the DMS.

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 DOSE ADJUSTMENTS

General Instructions for Section B:

For each Peginterferon alfa-2a dose adjustment, complete one row of Section B.

Record both increases and decreases in the dose of Peginterferon alfa-2a.

When Peginterferon alfa-2a is permanently or temporarily stopped, record the dose as 0 μg.

Record all Peginterferon alfa-2a dose changes, including:
- Decrease from 180 μg to 90 μg when a patient is randomized to the treatment group at the end of the Lead-In Phase.
- Discontinuation from 180 μg to 0 μg when a patient is randomized to the control group at the end of the Lead-In Phase.
- Discontinuation from 180 μg to 0 μg for Responder Phase patients at W48.
- Discontinuation from previous dose to 0 μg for patients with a completed Form #64 (Death) or Form #25 (Early Termination From Trial).

B1a. Date of dose change
- Record the date the Peginterferon alfa-2a dose was changed using MM/DD/YYYY format.

B1b. Previous dose
- Record the previously prescribed dose of Peginterferon alfa-2a in μg/week.

B1c. Dose changed to

- Record the newly prescribed dose of Peginterferon alfa-2a in μg/week.

B1d. Reason dose was changed

- Record the code number of the primary reason for adjustment Peginterferon alfa-2a dose. Choose one Code from the list below.
- If Reason Code is 55, 6, 7 and 99, it is important to record a succinct explanation why Peginterferon alfa-2a dose was changed. Sixty characters, including spaces and punctuation, are provided. Examples: "Low ANC", "Neutropenia resolved", "Hct dropped", "Infection", "Depressed".

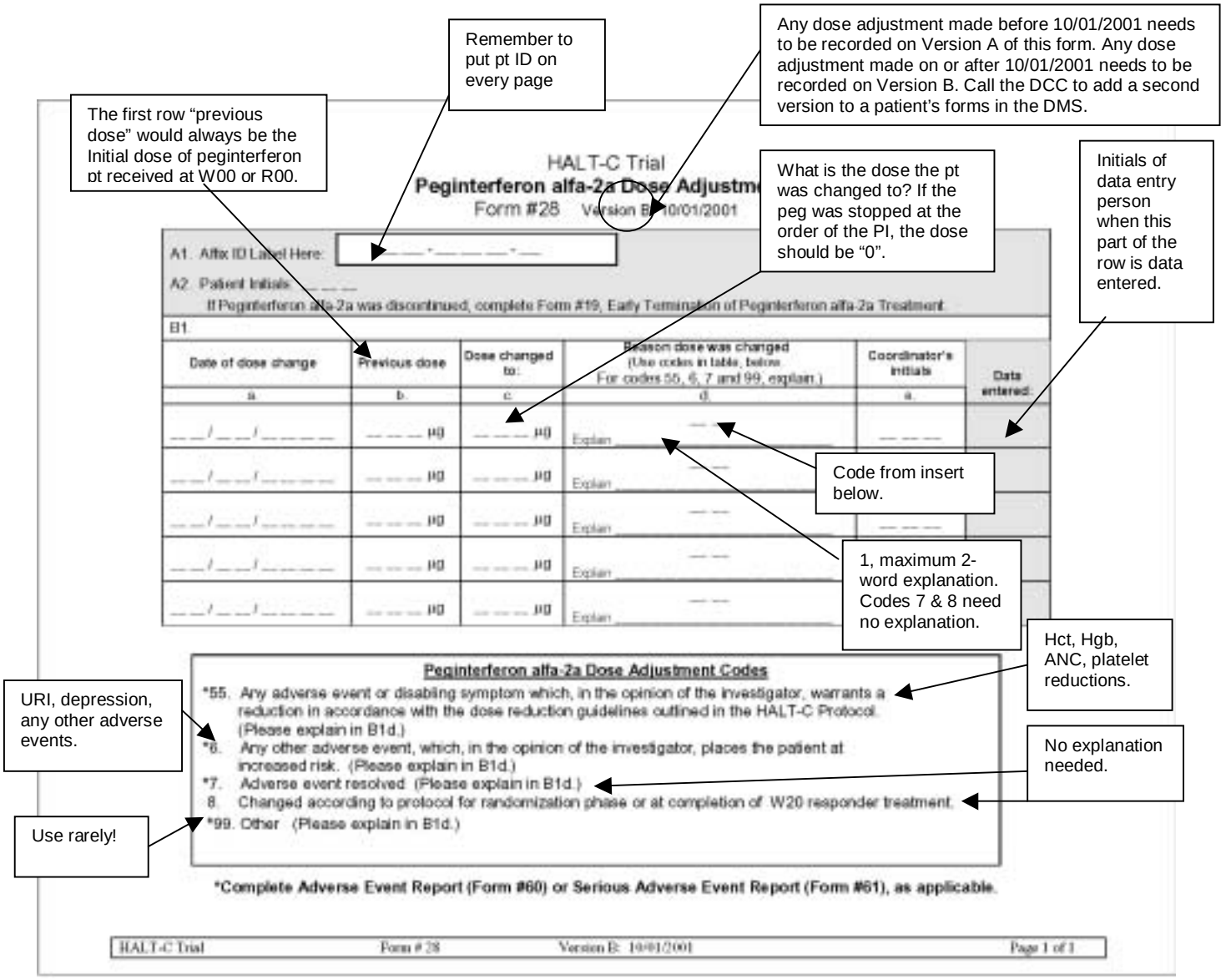
B1e. Enter the initials of the person completing this row of Section B.

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

Peginterferon alfa-2a Dose Adjustment Codes

55. Any adverse event or disabling symptom which, in the opinion of the investigator, warrants a reduction in accordance with the dose reduction guidelines outlined in the HALT-C Protocol.
6. Any other adverse event, which, in the opinion of the investigator, places the patient at increased risk.
7. Adverse event resolved.
8. Changed according to protocol for randomization phase, or at completion of W20 responder treatment, or Breakthrough/Relapser patients entering Randomized Phase.
99. Other.

Dose Adjustment for Peginterferon



The "dose changed to" on one row will always be the same as the next row's "previous dose".

The explanation of why the dose was adjusted is important. Be succinct: neutropenia, Hct dropped, infection, depressed. PI discretion means the PI made a clinical judgment about why the dose should be adjusted. Ask PI why and record. So, in other words, code 99, PI discretion is NOT a possible answer!

When the patient permanently stops peginterferon before W24 if in Lead-in, before W48 if a W20 Responder, or before M48 if Randomized to Treatment, adjust the dose down to "0". Also complete a Form # 19, Early Termination of Peginterferon.

To visualize what has been data entered, print out a report for this patient:
Main Menu/Reports/Clinical/Peg doses.