

## HALT-C Trial Q x Q

### Brief Symptom Inventory (BSI) – Cognitive Effects AS

Form # 154 Version B: 07/16/2001

**Purpose of Form #154:** To record Brief Symptom Inventory (BSI) symptom and summary scale scores in patients participating in the Cognitive Effects Ancillary Study.

**When to complete Form #154:** This form should be completed only at Site 17 (University of Southern California) and Site 18 (University of Michigan) as part of the Cognitive Effects of Long-term Peginterferon alfa-2a Ancillary Study. Express patients are not eligible for the Cognitive Effects Ancillary Study.

Form #154 should be completed at the following study visits:

- **Lead-In Phase patients:** Baseline (W00), Week 4 (W04), and Week 24 (W24).
- **W20 Responder Phase patients:** Week 48 (W48) and Week 72 (W72).
- **Breakthrough/Relapser patients:** Randomization visit (R00) if it is more than one month after the most recent Neuropsychiatric Testing (Form #152).
- **Randomized patients:** Month 12 (M12), Month 18 (M18), Month 24 (M24), Month 30 (M30), Month 36 (M36), Month 42 (M42), Month 48 (M48), and Month 54 (M54).

#### **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.
- A3. Enter the three-digit code corresponding to this visit.
- A4. Record the date the form was completed using MM/DD/YYYY format.
- A5. Enter the initials of the person completing the form.

#### **Brief Symptom Inventory Administration**

The BSI is a brief (approximately 5 - 10 minutes) 53-item self-administered questionnaire with established reliability and validity, designed to assess emotional distress in medical and psychiatric patients. Patients should complete each item using the five-point rating scale of 0 to 4 (0= Not at all, 4 = Extremely).

#### **Brief Symptom Inventory Scoring**

- The raw data from the respondent's answer sheet will be entered into the BSI scoring software (MICROTEST Q Assessment System Software) per manufacturer's instructions.
- The BSI software generates nine symptom scales (e.g. Depression, Anxiety, Somatization) and three summary scales (Global Severity Index (GSI), Positive Symptom Distress Index (PSDI), and Positive Symptom Total (PST)).

- For study purposes, T-scores will be used which have a mean value of 50 with a standard deviation of 10, and a range of 0-100.
- A Profile Report containing a graphic profile of the raw and normalized T-scores for all nine symptom scales and three summary scales will be generated.
- If a patient provides the same response to all 53 items of the BSI, the computer software will not generate a Clinical Profile Report. Under those circumstances, change the response to item #1 by lowering it one value ( i.e. 2 to 1) and then a Clinical Profile Report can be generated. In addition, enter a field level comment indicating that data has been changed in order to generate a report.
- A hard copy of each Profile Report will be kept in the patient's notebook.

## **SECTION B: BRIEF SYMPTOM INVENTORY – PROFILE REPORTS**

- B1. Enter the date the BSI was administered using MM/DD/YYYY format.
- B2. Enter the T-score for each symptom and summary scale from the Profile Report under in rows B2a through B2I using the non-patient norms.
- Three-digit entry is provided for each scale. Record a single zero to the left of a two-digit T score (e.g. 50= 050). Record two zeros to the left of a one-digit T-score when entering the data (e.g. 3 = 003).