

HALT-C Trial  
**Beck Depression Inventory-II**  
 Form # 44 Q x Q BDI-II © 1996

**Purpose of Form #44:** To detect depression in study participants using a brief, self-administered instrument.

**When to complete Form #44:** The Beck Depression Inventory-II can be administered in either English or Spanish. The BDI-II should be completed by all patients at the following visits:

- **Screening Phase patients:** Screening Visit 2 (S02).
- **Lead-In Phase patients:** Week 12 (W12), and Week 20 (W20).
- **Responder Phase patients:** Week 36 (W36), Week 48 (W48), Week 60 (W60) and Week 72 (W72).
- **Breakthrough/Relapse patients:** Randomization visit (R00).
- **Randomization Phase patients:** Every visit through Month 54 (M54).

Lead-In patients participating in the Cognitive Effects Ancillary Study at Site 17 (University of Southern California) and Site 18 (University of Michigan) will complete the BDI-II at additional visits as listed below.

- **Cognitive Effects AS patients:** In addition to all administrations listed above, the Beck Depression Inventory II should also be collected at Baseline (W00), Week 4 (W04), Week 20 (W20), and Week 24 (W24).

**SECTION A: GENERAL INFORMATION**

The Beck Depression Inventory-II is a copyrighted form, and therefore, does not have the same format as the other HALT-C forms. It is important that before you give the patient this form to fill out, that you write in the information needed below (Patient ID, Patient's initials, Date form was completed, Visit Number, Initials of the person completing the form) in place of what is printed on the form (Name, Occupation, Marital Status, Age, Sex, Education). Remind the patient not to fill any of the demographic data out on the form.

- A1. Affix the patient ID label over the pre-printed demographics on the form.
  - If the label is not available, write down the words "Patient ID" and record the ID number legibly.
- A2. Write down the words "Patient's initials" and enter the patient's initials exactly as recorded on the Trial ID Assignment form.
- A3. Write down the word "Visit" and enter the three-digit code corresponding to this visit.
- A4. In the Date space in the blue strip at the top of the form, record the date when the BDI-II was administered.
  - When entering this date, use the MM/DD/YYYY format.
- A5. Write down the words: "Person Completing Section A" and enter the initials of the person completing the patient ID, initials, visit number and date fields.

## **COMPLETING THE BDI-II**

The patient should read the instructions provided on the form and then complete the form by circling the number beside the statement that best describes the way s/he has been feeling during the past two weeks including today.

1. The BDI-II requires 5 to 10 minutes to complete. Individuals with moderate to severe depression may require longer to complete the survey.
2. Note that **Item 16** (Changes in Sleeping Pattern) and **Item 18** (Changes in Appetite) have 7 options rated in order as 0, 1a, 1b, 2a, 2b, 3a, and 3b to differentiate between increases and decreases in behavior or motivation. **Only one option** should be selected. This item should be scored by the number of the statement selected.
3. If a subject selects **option 2 or 3** for **Item 2** or **Item 9**, the physician investigator should be contacted for further intervention after the potential for suicide has been further assessed by the collaborating psychiatrist/psychologist. (see **Total Score & Critical Items**, below).
4. It is important that patients complete all of the items on the form.
  - Review the form for any missing items.
  - Make sure that each item has a single statement marked.
  - Ask the patient to correct any missing or doubly marked items.

If the patient is not able to complete this form by her/himself, please note so in the margins of the form and enter the initials of the person completing the form. In this situation, the form should be administered using standard interview technique.

## **SCORING THE BDI-II**

1. The BDI-II is scored by summing the values of the 21 items. Each item is rated on a 4-point scale ranging from **0 to 3**.
2. If an examinee has circled multiple choices for an item (and the interviewer did not notice this at the time), the choice with the highest rating is used as the item score.
3. If a statement was not chosen for a given item, (and the interviewer did not notice this at the time), then the item is scored as a 0.
4. Total up the score of page one and record it in the gray box marked "Subtotal Page 1", at the bottom of the first page.
5. Turn the page over and total up the score for page two and record in the gray box marked "Subtotal Page 2", at the bottom of page two.
6. Rerecord the "Subtotal Page 1" below the "Subtotal Page 2" and add these two scores to obtain the "Total Score". Record the "Total Score" in the blue box provided at the bottom of page two.
7. The minimum total score is **0** and the maximum total score is **63**.

**DATA ENTERING THE BDI-II**

For Data Entry in the HALT-C Data Management System (DMS), enter the score for each of the 21 items. At the end of the DMS form entry, only the Total Score on Page 2, which is marked in a blue box, is data entered. Do not data enter the Subtotal Score on Page 1 or Page 2.

**BDI-II SCORE INTERPRETATION**

Practitioners should keep in mind that all self-report inventories are subject to response bias. That is, some individuals may endorse more symptoms than they actually have and thus produce spuriously high scores, while others might deny symptoms and receive spuriously low scores. In addition, the practitioner is cautioned that the BDI-II may simply reflect the degree of depression, not the diagnosis of depression. Determination of the severity of depression, and the establishment of a diagnosis of depression, require examination by a clinician (physician or psychologist/psychiatrist).

**Total Score & Critical Items**

It is essential that the interviewer be attentive to the Total Beck Depression Inventory Score and to the specific items related to suicidality: Item 2 (pessimism) and Item 9 (suicidality) before the patient finishes with her/his appointment. Patients admitting to suicide ideation (**Item 9**) and pessimism (**Item 2**) with a rating of 2 or 3 should be closely scrutinized for suicide potential. In addition to notifying the Principal Investigator, consultation with the local psychiatry collaborator is indicated.

When the interviewer totals a score that is 15 or greater and/or the items specific to suicidality are scored as a 2 or 3 (see above paragraph), tell the patient that her/his scores indicate that s/he may be having some depressive symptoms and you want to talk to the physician for further assessment. Some patients may feel uncomfortable admitting to having depressive feelings. Reassure them that these symptoms are important to talk about and can be managed with treatment.

It is recommended that BDI-II scores be assessed and managed as follows at the clinical center:

<b><u>BDI-II Score</u></b>	<b><u>Depression severity</u></b>
0 – 10	None to minimal
11 – 14	Mild
15 – 19	Moderate
20 – 28	Severe
≥ 29	Critical

Anti-depressants should be considered for patients with moderate to severe depression (BDI-II > 15) before considering IFN dose reduction, at the discretion of the principal investigator. Additional follow-up for patients is recommended in the Guideline for Management of Depression (See MOO - Management Guidelines).