

## HALT-C Trial Q x Q

### Baseline Medications Interview

Form # 7 Version B: 12/03/2001

**Purpose of Form #7:** The Baseline Medications Interview form records all prescription, complementary, herbal, and alternative medications, and all other over the counter medications that the patient is currently taking. This list of baseline medications will be used to generate a list of medications on the patient's Visit Control Sheet for the next study visit. This form also uses patient interview format to record the historic use of complementary, herbal, and alternative medications.

**When to complete Form #7:** This form is completed at the baseline visit (W00) for all Lead-In patients entering the trial. It is also completed at the randomization visit (R00) for Express patients.

#### **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 the visit number.
- A4. Record the date of the baseline visit using the MM/DD/YYYY format.
- A5. Enter the initials of the person completing the form.

#### **SECTION B: CURRENT PRESCRIBED MEDICATIONS**

##### General Instructions for Section B:

- Record the currently used prescription medication names in the spaces provided, one medication per line. Prescription medications are those medications that require a prescription to obtain. Only oral prescription medications should be included, not lotions, ointments, or topical sprays.
  - In the shaded column B2b, record the code for each medication, using the Medication Code List.
  - The Medication Code List is a special list prepared for this trial. It is provided in a separate binder. Prescription medications have codes of the form XXX\_R01. The first three letters are the first three letters of the first ingredient (listed in alphabetic order).
- B1. A doctor or nurse practitioner must have prescribed the medications. If the answer is YES, circle 1 and continue to B2. If the answer is NO, circle 2 and skip to C1.
  - B2a. Record prescription medication names in the spaces provided, one per line.
  - B2b. Record the code for each medication, using the Medication Code List.

## **SECTION C: PAST HERBAL, ALTERNATIVE, DIETARY SUPPLEMENTS AND OTHER BOTANICAL MEDICATIONS**

### General Instructions for Section C:

- For this section only, show the patient card #10, Complementary and Alternative Medications. The interest in section C is primarily with the medications included on card # 10.
- Record all complementary and alternative medication names in the spaces provided, one per line. Only oral medications should be included, not lotions, ointments, or topical sprays. Herbal or alternative dietary supplements should be recorded in section C.
- To record multiple medications or combination medications (such as milk thistle with echinacea), record each 'active' ingredient on a separate line.
- To record vitamins with herbs, record only the herbs or botanical medications, one herb or botanical medication per line in Section C. For example, if the patient says he/she is taking vitamin A, C and E with chamomile, ginkgo, and goldenseal, record chamomile, ginkgo, and goldenseal, list each on a separate line in Section C. Multiple vitamins can be coded as such without listing each vitamin.
- Record the code for each medication, using the Medication Code List. The Medication Code List is a special list prepared for this trial. It is provided in a separate binder. Nonprescription (herbal, alternative, dietary supplements, over the counter) medications have codes of the form XXX\_001. The first three letters are the first three letters of the most frequently used common name of the herb or alternative medicine or the first active ingredient (listed in alphabetical order) of the over the counter medication.
- Repeat questions C2a - C2d for each medication the patient took at least once a week for one month or longer.

C1. If the answer is YES, circle 1 and continue to C2. If the answer is NO, circle 2 and skip to D1. If the answer is DON'T KNOW, circle -8 and skip to D1.

C2a. Record the medication name in the space provided, one per line.

C2b. Record the code for each medication, using the Medication Code List.

C2c. Record the total number of years the patient has taken the medication at least once a week for one month or longer. If the patient states less than a year, record 00. Do not leave C2c blank.

C2d. Record the total number of months the patient has taken the medication at least once a week for one month or longer. If the patient states the answer in years, for example states 'about 2 years' probe to determine if this was exactly 2 years. If the patient states yes, it was 2 years, record 02 in C2c and 00 in C2d.

**SECTION D: CURRENT NON-PRESCRIPTION MEDICATIONS (HERBAL, ALTERNATIVE, OR OTHER OVER THE COUNTER)**

- Record all non-prescription medications or supplements in the spaces provided, one per line. Only oral non-prescription medications or supplements should be included, not lotions, ointments, or topical sprays.
  - Do not repeat items listed in Section C.
  - Record the code for each medication, using the Medication Code List.
- D1. The medications should NOT have been prescribed by a doctor or nurse practitioner. If the answer is YES, circle 1 and continue to D2. If the answer is NO, circle 2 and the form is complete.
- D2a. Record the non-prescription medication name in the spaces provided, one medication per line.
- D2b. Record the code for each medication, using the Medication Code List. Most combination medications are listed as such in the code list. If a combination is not listed, code the separate ingredients. Multiple vitamins may be coded as such rather than listing all of the ingredients.