



BE-DRI

Question by Question Specifications Guide

Form 263: Follow-up Medication Audit Data Entry into DMS

Version 04/14/05 (B)

I. Purpose

This is a question by question guide for Data Managers outlining how to input information collected on the Follow-up Medication Audit Report into the DMS. Before the Interviewer/Data Collector meets with the patient for the Randomization Visit or VS05-VS11, the Data Manager must print out the Medication Audit Report from the DMS. This report reflects the medications the patient reported taking, and is still taking since the last audit. This report can be found by logging into the ADEPT Production Site, clicking on BE-DRI study → BE-DRI reports → BE-DRI part/event reports → BE-DRI Medication Report. Click on BE-DRI Medication Report, enter the patient's ID number, and select the visit for which the patient is scheduled.

II. Section A

- A1. **Study ID Number:** Enter the Study ID Number from the F263 Medication Audit Report form.
- A2. **Visit Code:** Enter the circled visit code provided on the Medication Audit Report.
- A3. **Date Audit Completed:** Enter the date that the Follow-up Medication Audit is completed. All dates must be in the format of mm/dd/yyyy.
- A4. **Interviewer's Initials:** Enter the initials of the BE-DRI Interviewer/Data Collector completing the Audit. Enter the first initial in the first space provided, middle initial in the second space provided and last initial in the third space provided. If there is not a middle initial, strike a mark in the second space. If the last name is hyphenated or if there are 2 last names, enter the initials of the first last name in the third space.
- A5. **Interview Type:** Enter the circled code that describes the interview mode used to complete the Audit.

III. Section B. The Medication Audit

- B1. B1 is asked of the patient by the Data Collector, for purposes of obtaining all new and continuing drug information. B1 is not data entered.

B2. ALL PRESCRIPTION MEDICATIONS WITH THE EXCEPTION OF DIURETICS AND ANTICHOLINERGIC MEDICATIONS:

Are there any prescription discontinuations since the last audit? If the Interviewer/Data collector has circled Discontinuation (2) in field B2aa for any previously reported medications on the Medication Audit Report, then the Data Manager should enter Yes(1) into the DMS. If the Interviewer/Data Collector has not circled Discontinuation (2) in field B2aa for any previously reported medications on the Medication Audit Report, the Data Manager should enter No (2).

B2ab. Med ID Number (from Medication Audit Report): Enter the pre-printed Med ID number from the Medication Audit Report for the first discontinued prescription medication.

B2a. Medication Name: After entering the medication ID number, the corresponding medication name will automatically appear in this field.

B2d. Medication Stop Date: Enter the medication stop date as written on the Medication Audit Report. This date should be in month/year or month/day/year format. If this date is missing, code 09/09/0909 and ask the INDC to confirm the correct date with the patient.

This is a repeating segment. The DMS will prompt you with an option to enter another discontinued medication. If the patient has discontinued more than one medication, continue until each discontinuation has been entered. Once you have entered all discontinuations, choose “no” from the pop-up screen.

ARE THERE ANY PRESCRIPTION ADDITIONS SINCE THE LAST AUDIT?

If the Interviewer/Data collector has circled Addition (1) in field B2aa for any previously reported medications on the Medication Audit Report, then the Data Manager should enter Yes (1) into the DMS. If the Interviewer/Data Collector has not circled Addition (1) in field B2aa for any previously reported medications on the Medication Audit Report, then the Data Manager should enter No (2).

B2a. Medication Name: Enter the name of the prescription medication that the patient has reported.

B2b. Frequency: Enter the frequency code recorded on the Medication Audit Report.

B2c. Start date: Enter the date on which the patient began taking this medication. The date should be in month/year or month/day/year format. If this date is missing, code 09/09/0909 and ask the INDC to confirm the correct date with the patient.

B2d. Stop date: Enter the medication stop date as written on the Medication Audit Report. This date should be in month/year or month/day/year format. If this date is missing, code 09/09/0909 and ask the INDC to confirm the correct date with the patient. If the patient reported that she is still taking this medication, the Data Manager should enter “01/01/0101” in this field.

B2e. Source Code: Enter the source code recorded on the Medication Audit Report.

This is a repeating segment. The DMS will prompt you with an option to enter another addition. If the patient has added more than one medication, continue until each addition has been entered. Once you have entered all additions, choose “no” from the pop-up screen.

B3. ALL DIURETICS AND ANTICHOLINERGIC MEDICATIONS

Are there any prescription (diuretic or anticholinergic) discontinuations since the last audit? If the Interviewer/Data collector has circled Discontinuation (2) in field B3aa for any previously reported medications on the Medication Audit Report, then the Data Manager should enter Yes(1) into the DMS. If the Interviewer/Data Collector has not circled Discontinuation (2) in field B3aa for any previously reported medications on the Medication Audit Report, the Data Manager should enter No (2).

B2ab. Med ID Number (from Medication Audit Report): Enter the pre-printed Med ID number from the Medication Audit Report for the first discontinued prescription medication.

B2a. Medication Name: After entering the medication ID number, the corresponding medication name will automatically appear in this field.

B2d. Medication Stop Date: Enter the medication stop date as written on the Medication Audit Report. This date should be in month/year or month/day/year format. If this date is missing, code 09/09/0909 and ask the INDC to confirm the correct date with the patient.

This is a repeating segment. The DMS will prompt you with an option to enter another discontinued medication. If the patient has discontinued more than one medication, continue until each discontinuation has been entered. Once you have entered all discontinuations, choose “no” from the pop-up screen.

ARE THERE ANY PRESCRIPTION (DIURETICS) ADDITIONS SINCE THE LAST AUDIT?

If the Interviewer/Data collector has circled Addition (1) in field B3aa for any previously reported medications on the Medication Audit Report, then the Data Manager should enter Yes (1) into the DMS. If the Interviewer/Data Collector has not circled Addition (1) in field B3aa for any previously reported medications on the Medication Audit Report, then the Data Manager should enter No (2).

B2a. Medication Name: Enter the name of the prescription medication that the patient has reported.

B2b. Dose: Enter the dosage reported.

B2c. Frequency: Enter the frequency code recorded on the Medication Audit Report.

B2d. Start date: Enter the date on which the patient began taking this medication. The date should be in month/year or month/day/year format. If this date is missing, code 09/09/0909 and ask the INDC to confirm the correct date with the patient.

B2e. Stop date: Enter the medication stop date as written on the Medication Audit Report. This date should be in month/year or month/day/year format. If this date is missing, code 09/09/0909 and ask the INDC to confirm the correct date with the patient. If the patient reported that she is still taking this medication, the Data Manager should enter “01/01/0101” in this field.

B2f. Source Code: Enter the source code recorded on the Medication Audit Report.

The DMS will prompt you with an option to enter another addition. If the patient has added more than one medication, continue until each addition has been entered. Once you have entered all additions, choose “no” from the pop-up screen.

B4. Does patient report use of diuretics? Enter code recorded by INDC.

B4a. Does patient report a change in the dose? Enter code recorded by INDC.

B5. Does patient report use of an anticholinergic medication? Enter code recorded by INDC.

B6. Does patient report use of cholinergic agonist? Enter code recorded by INDC.

B7. Does patient report use of tricyclic antidepressants? Enter code recorded by INDC.

B8. Does patient report use of duloxetine? Enter code recorded by INDC.

B9. B9 is asked of the patient by the Data Collector, for purposes of obtaining all new and continuing drug information. B9 is not data entered.

B10. ALL NON-PRESCRIPTION MEDICATIONS

Are there any non-prescription discontinuations since the last audit? If the Interviewer/Data collector has circled Discontinuation (2) in field B10aa for any previously reported medications on the Medication Audit Report, then the Data Manager should enter Yes(1) into the DMS. If the Interviewer/Data Collector has not circled Discontinuation (2) in field B10aa for any previously reported medications on the Medication Audit Report, the Data Manager should enter No (2).

B10ab. Med ID Number (from Medication Audit Report): Enter the Med ID number from the Medication Audit Report Form for the first discontinued prescription medication.

B10a. Medication Name: After entering the medication ID number, the corresponding medication name will automatically appear in this field.

B10d. Medication Stop Date: Enter the medication stop date as written on the Medication Audit Report. This date should be in month/year or month/day/year format. If this date is missing, code 09/09/0909 and ask the INDC to confirm the correct date with the patient.

This is a repeating segment. The DMS will prompt you with an option to enter another discontinued medication. If the patient has discontinued more than one medication, continue until each discontinuation has been entered. Once you have entered all discontinuations, choose “no” from the pop-up screen.

ARE THERE ANY NON-PRESCRIPTION ADDITIONS SINCE THE LAST AUDIT?

If the Interviewer/Data collector has circled Addition (1) in field B10aa for any previously reported medications on the Medication Audit Report, then the Data Manager should enter Yes (1) into the DMS. If the Interviewer/Data Collector has not circled Addition (1) in field B10aa for any previously reported medications on the Medication Audit Report, then the Data Manager should enter No (2).

B10a. Medication Name: Enter the name of the prescription medication that the patient has reported.

B10b. Frequency: Enter the frequency code recorded on the Medication Audit Report.

B10c. Start date: Enter the date on which the patient began taking this medication. The date should be in month/year or month/day/year format. If this date is missing, code 09/09/0909 and ask the INDC to confirm the correct date with the patient.

B10d. Stop date: Enter the medication stop date as written on the Medication Audit Report. This date should be in month/year or month/day/year format. If this date is missing, code 09/09/0909 and ask the INDC to confirm the correct date with the patient. If the patient reported that she is still taking this medication, the Data Manager should enter “01/01/0101” in this field.

B10e. Source Code: Enter the source code recorded on the Medication Audit Report.

This is a repeating segment. The DMS will prompt you with an option to enter another addition. If the patient has added more than one medication, continue until each addition has been entered. Once you have entered all additions, choose “no” from the pop-up screen.