



HBV/HIV Antiviral Therapy Log

General Instructions

The HBV/HIV Antiviral Log captures all HBV or HIV antiviral (antiretroviral) therapy medications that the patient reports taking in the past or during the course of the study. Begin with a history of all HBV and HIV antiviral therapy taken prior to the screening/baseline visit and continue to update the log through the completion of the follow-up period or discontinuation from the study. The list of HBV and HIV antiviral therapy should be reviewed with the patient at every protocol visit and the log updated as necessary.

Do not record a start/stop of medication to reflect a change in dose.

If the patient begins to take a medication that is not already recorded on the log, add the medication to the log, along with the start date.

If the patient stops taking a medication during the course of the study, record the stop date.

Ask the patient to bring either a list of all current medications taken or prescription pill bottles to each visit.

Specific Instructions

Patient ID: Record the Patient ID in the top right hand corner.

Antiviral Therapy: Record the appropriate code for the medication. The name of the medication should be copied as it appears on the label of the pill bottle, if provided. If you know that the patient received interferon or an antiviral but do not know the specific agent, record "Unk" [-3] for the antiviral therapy code. If the antiviral is not listed in the code book then contact the DCC to determine whether the antiviral should be added to the list of coded medications.

Start date: Record the date that the patient took the medication for the first time, regardless of the starting dose or the number of times that the dose has changed since the patient began taking the medication. If any part of the date is unknown, record "Unk" [-3] in that field and complete the remaining fields.

Stop date: Record the date that the patient stopped taking the medication. If any part of the date is unknown, record "Unk" [-3] in that field and complete the remaining fields. If the patient is currently taking the medication, do not complete the date stopped fields and check "Currently on Therapy".

System ID: Record the system generated ID for the record.