



Study Drug Log (Pediatric)

General Instructions

Initiate the Study Drug Log when study drug is dispensed for the first time and update the log every time study drug is dispensed or returned. Use one row per drug, every time either drug is dispensed or returned.

Entecavir:

Instruct the patient to return dispensed bottles of entecavir (with unused tablets/liquid) at every visit.

If the patient does not return unused tablets/liquid of entecavir but reports that they have tablets/liquid remaining, check "No" for "Unused tablets (or liquid)/Used vials returned?" and ask the patient to return all unused tablets/liquid of entecavir at the next visit and then record the total number of unused tablets or mL of entecavir on that date.

When all dispensed bottles of entecavir are returned at a visit and there are no tablets/liquid left or the patient reports that no tablets/liquid are remaining, check "Yes" for "Unused tablets (or liquid)/Used vials returned?" and record zero for "amount/mL returned".

Peg-interferon:

Instruct the patient to return used vials of peg-interferon at every visit.

If the patient does not return used vials of peg-interferon, but reports that they used vials, check "No" for "Unused tablets (or liquid)/Used vials returned?" and ask the patient to return all used vials of peg-interferon at the next visit and then record the total number of used vials of peg-interferon on that date. If the patient reports that they used vials but discarded the used vials, record the number of vials they report as used and check the "patient report only" box under the "amount/mL returned" field.

Specific Instructions

- Patient ID:** Record the Patient ID in the top right hand corner.
- Date:** Record the date that study drug is either returned or dispensed. This date may or may not coincide the date of a protocol visit.
- Study Drug:** Check the box to indicate which medication has been returned or is being dispensed.
- Unused tablets (or liquid)/used vials** Check Yes or No to indicate whether unused tablets or liquid of entecavir or used vials of peg-interferon were returned on this date. If Yes, indicate the number of tablets or used vials that were returned. If entecavir or used vials were returned but unable to be counted, check unknown.
Check the "patient report only" checkbox if the patient did not return the unused tablets or used vials and will not be able to return them at a future visit. Checking this box will indicate that patient report alone will be used to account for use of study drug.
- When dispensing the entecavir or peg-interferon for the first time, check "No" for the "number tablets/used vials returned" and record zero (0) for the "amount returned".
- Amount dispensed:** If study drug was dispensed on this date, indicate the number of tablets or mL of entecavir or the number of vials of peg-interferon that were dispensed.
- The number of tablets/liquid or vials dispensed should equal the number of tablets (or liquid)/vials needed to get the patient through to the next in-person protocol visit, plus few extra tablets or bottle(s) of entecavir and at least one extra vial of peg-interferon. The patient does not have to return the extra vial of peg-interferon at the next visit. The "extra" vials should be continually rotated throughout the course of the treatment period so that the expiration dates of the "extra" vials are not a concern.
- It is acceptable to redispense study medication in an effort to reduce waste.
- System ID:** Record the system generated ID for the record.