



Dose Change (Pediatric)

General Instructions

Complete one line for each prescribed dose change (reduction or increase) in one or both study medications. **The Date of Change is the date that the first “changed” dose is taken.** Record the newly prescribed dose for one or both study medications. If only one study medication has been changed, record the current dose of the other study medication. If a Dose Reduction, record the reason for the dose reduction, otherwise leave that column blank.

This form should be used to capture dose reductions or temporary discontinuation of study medication, as prescribed by a medical health care provider. This form should not be used to capture skipped/missed doses of study medication or the permanent discontinuation of both study medications, as when a patient discontinues treatment or study.

Specific Instructions

- Patient ID: Record the Patient ID in the top right hand corner.
- Date of Change: Record the date that the “changed” dose of study drug is taken for the first time. This date may or may not coincide with the date that the change of dose was prescribed.
- Entecavir: 1) Record the most recent prescribed dose of entecavir. If the dose of peg-interferon was adjusted but the dose of entecavir remained the same, record the dose of entecavir.
2) Record the patient’s weight used to determine the prescribed dose. Check “lbs” (pounds) or “kg” (kilograms) to indicate which unit of measure was used.
- Peg-interferon: Record the most recent prescribed dose of peg-interferon. If the dose of entecavir was adjusted but the dose of peg-interferon remained the same, record the dose of peg-interferon.
- Reason for dose reduction: If the dose of either the entecavir or peg-interferon was reduced, record the reason(s) for the reduced dose.
- System ID: Record the system generated ID for the record.