Visit Evaluation (Pediatric)

Patient ID __ __ - __ **ID** __ - __ __ __
Date of Evaluation: **DOEDATE**
Protocol timepoint *(see codes)*: **TMPT**

Last protocol visit *(mm/dd/yy)*: **LVM** / **LVD** / **LVY**

SECTION I: ADVERSE EFFECTS

1. Has the patient had any of the following signs, symptoms, or side effects since the last protocol visit:

	Yes	No		Yes	No
a. Fatigue **FATIG**	☐	☐	k. Joint aches **JOINT**	☐	☐
b. Trouble sleeping **TSLP**	☐	☐	l. Diarrhea **DIARR**	☐	☐
c. Headache **HEADACH**	☐	☐	m. Vomiting **VOMIT**	☐	☐
d. Dizziness **DIZZ**	☐	☐	n. Upset stomach **USTOM**	☐	☐
e. Depression **DEPRESS**	☐	☐	o. Muscle pain **MUSPN**	☐	☐
f. Weight loss (unintentional) **WGTLOSS**	☐	☐	p. Rash **RASH**	☐	☐
g. Decreased appetite **DAPP**	☐	☐	p. Skin irritation **SKIN**	☐	☐
h. Vision problems **VISION**	☐	☐	q. Cold/Flu-like symptoms **FLU**	☐	☐
i. Nausea **NAUS**	☐	☐	q. Hair loss **HAIR**	☐	☐
j. Upper abdominal pain **ADPAIN**	☐	☐	r. Other **SYMOTH**	☐	☐
k. Breathing problems **BREATH**	☐	☐	If yes, specify: **SYMOTHS**		

2. Has the patient experienced any adverse events or side effects of study drug (reportable at the level of detail of an adverse event), since the last protocol visit? **AE**
   ☐ Yes *(Complete an Adverse Events form, if SAE complete the MedWatch form too)*
   ☐ No

SECTION II: CONCOMITANT MEDICATIONS

1. Has there been any change (start or stop) in prescription medications since the last protocol visit? **CONMED**
   ☐ Yes ☐ No If Yes, update the Concomitant Medication Log
2. Is the patient currently taking any herbs, "natural" or herbal medications? **MEDHERB** ☐ Yes ☐ No ☐ Unknown
3. Is the patient currently taking vitamins or minerals? **MEDVIT** ☐ Yes ☐ No ☐ Unknown
   If Yes, *(check all that apply)*
   ☐ Multi-vitamin **VITMULT** ☐ Vitamin D **VITD** ☐ Vitamin E **VITE** ☐ Folate **VITFOL** ☐ Iron **VITFE** ☐ Calcium **VITCA** ☐ Other **VITOTH**
4. Is the patient currently taking any antiviral therapy for hepatitis B (other than study drug)? **TXHBV** ☐ Yes ☐ No
   If Yes, record all treatments

Antiviral Therapy (see codes)	Data Started* *(mm/dd/yy)*	Date Stopped* *(mm/dd/yy)*	**or** Currently on Therapy
TXB1	**TXB1BM/D/Y**	**TXB1EM/D/Y**	**TXB1CUR**
TXB2	**TXB2BM/D/Y**	**TXB2EM/D/Y**	**TXB2CUR**
TXB3	**TXB3BM/D/Y**	**TXB3EM/D/Y**	**TXB3CUR**
TXB4	**TXB4BM/D/Y**	**TXB4EM/D/Y**	**TXB4CUR**
TXB5	**TXB5BM/D/Y**	**TXB5EM/D/Y**	**TXB5CUR**

1 = IFN
2 = Entecavir
3 = Telbivudine
4 = Lamivudine
5 = Adefovir
6 = Peg-IFN
7 = Tenofovir
8 = Emtricitabine
9 = Truvada
-3 = Unknown

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SECTION III: STUDY MEDICATION *(weeks 4 through 52, do not complete for Control patients)*

1. Did patient return unused bottle of entecavir? **ETVRET** ☐ Yes ☐ No ☐ N/A
2. Did patient return used vials of peginterferon? **PEGRET** ☐ Yes ☐ No ☐ N/A
3. Did the patient return a completed diary? **DIARY** ☐ Yes ☐ No ☐ N/A
4. Ask the patient the following questions:

   "Many people don't take their medications perfectly all of the time."

   a. Over the past 7 days, how many times did you miss taking your entecavir pill/liquid? **ETVMISS** ☐ Unknown
   b. Last dose of entecavir taken prior to visit (*mm/dd/yy*): **ETVM** /**ETVD** /**ETVY** ☐ Unknown
   c. Over the past 4 weeks, how many times did you miss taking your peg-interferon injection? ____ ☐ Unknown **PEGMISS**
   d. Last dose of peginterferon taken prior to visit (mm/dd/yy): **PEGM** / **PEGD** / **PEGY** ☐ Unknown
5. Was there a prescribed change in dose (decrease or increase) since the last protocol visit? ☐ Yes ☐ No **DCFORM**

   If Yes, complete the Dose Change form
6. Was counseling on adherence provided during visit? **MATI** ☐ Yes ☐ No

Complete Study Drug Log weeks 4 through 52

Confirm acceptable method of contraception, when applicable

SECTION IV: PHYSICAL ASSESSMENT (*Complete at weeks 8, 12, 16, 24, 36, 48, 56, 60, 72, 84 and 96)*

1. Height **HGT** 1 ☐ inches 2 ☐ cm **HINCM** ☐ Not done
2. Weight: **WGT** 1 ☐ lbs. 2 ☐ kg **WLBKG** ☐ Not done
3. Blood pressure: **BPS** / **BPD** mmHg ☐ Not done

SECTION V: ABDOMINAL IMAGING

1. Were abdominal imaging tests performed? ☐ Yes ☐ No **IMG**

   If Yes,
   a. Date of test *(mm/dd/yy)*: **IMGM** / **IMGD** / **IMGY**
   b. Tests performed *(check all that apply)*:
      ☐ CT **IMCT** ☐ MRI **IMMRI** ☐ Liver ultrasound **IMULT** ☐ Other **IMO** ____**IMOS**_____
   c. Any evidence of HCC? **IMHCC** ☐ Yes ☐ No If Yes, complete HCC form

SECTION VI: BIOSPECIMENS

1. Were samples obtained at this visit? ☐ Yes ☐ No **BIOSPEC**

   If Yes, *(check all that apply):* ☐ NIDDK repository **NIDDKR** ☐ Central Lab **CLAB** ☐ Genetics **GEN** ☐ Immunology study **IMM**

SECTION VII: TANNER STAGE (*Complete at weeks 48, 72, and 96)*

Instructions: *Transcribe responses from the Tanner Stage questionnaire to the items below. If the patient is not of age to complete the Tanner Stage questionnaire, check "Not done".*

1. Physical growth: 1 ☐ I 2 ☐ II 3 ☐ III 4 ☐ IV 5 ☐ V ☐ Unknown ☐ Prefer not to answer ☐ Not done **TANPHY**
2. Pubic hair growth: 1 ☐ I 2 ☐ II 3 ☐ III 4 ☐ IV 5 ☐ V ☐ Unknown ☐ Prefer not to answer ☐ Not done **TANPUB**

SECTION VIII: ADMINISTRATIVE (*Complete at weeks 4, 10, 14, 20, 28, 32, 40 and 44)*

1. How was the visit completed? 1 ☐ Telephone 2 ☐ Clinic **VTYPE**

Data collector initials: **DCID** Date data collection completed *(mm/dd/yy)*: **DCM** / **DCD** / **DCY**