Visit Evaluation

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**	☐	☐	l. Joint aches **JOINT**	☐	☐
b. Trouble sleeping **TSLP**	☐	☐	m. Diarrhea **DIARR**	☐	☐
c. Headache **HEADACH**	☐	☐	n. Vomiting **VOMIT**	☐	☐
d. Dizziness **DIZZ**	☐	☐	o. Upset stomach **USTOM**	☐	☐
e. Depression **DEPRESS**	☐	☐	p. Muscle pain **MUSPN**	☐	☐
f. Weight loss (unintentional) **WGTLOSS**	☐	☐	q. Rash **RASH**	☐	☐
g. Decreased appetite **DAPP**	☐	☐	r. Skin irritation **SKIN**	☐	☐
h. Vision problems **VISION**	☐	☐	s. Cold/Flu-like symptoms **FLU**	☐	☐
i. Nausea **NAUS**	☐	☐	t. Hair loss **HAIR**	☐	☐
j. Upper abdominal pain **ADPAIN**	☐	☐	u. 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	☐ Vitamin D	☐ Vitamin E	☐ Folate	☐ Iron	☐ Calcium	☐ Other
VITMULT	**VITD**	**VITE**	**VITFOL**	**VITFE**	**VITCA**	**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)	Date 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/TDF
8 = Emtricitabine
9 = Truvada
12 = Tenofovir/TAF
-3 = Unknown

SECTION III: STUDY MEDICATION

SMEDLV 1. Has the patient taken study medication since the last study visit? ☐ Yes ☐ No

If Yes, complete Study Drug Log and complete Section III as appropriate.

   a. Did patient return dispensed bottle of tenofovir? **TENRET** ☐ Yes ☐ No
   b. Did patient return used vials of peginterferon? **PEGRET** ☐ Yes ☐ No ☐ N/A
   c. Did the patient return a completed diary? **DIARY** ☐ Yes ☐ No

d. Ask the patient the following questions:
"Many people don't take their medications perfectly all of the time."

i. Over the past 7 days, how many times did you miss taking your tenofovir pill? TENMISS ☐ Unknown

ii. Last dose of tenofovir taken prior to visit (*mm/dd/yy*): TENM /TEND /TENY ☐ Unknown

PGEMISS iii. Over the past 4 weeks, how many times did you miss taking your peg-interferon injection? ____ ☐ Unknown

iv. Last dose of peg-interferon taken prior to visit (mm/dd/yy): PEGM / PEGD / PEGY ☐ Unknown

e. Was there a prescribed change in dose (decrease or increase) since the last protocol visit? ☐ Yes ☐ No

If Yes, complete the Dose Change form DCFORM

f. Was counseling on adherence provided during visit? MATI ☐ Yes ☐ No

Confirm acceptable method of contraception, when applicable

SECTION IV: PHYSICAL ASSESSMENT

1. Height HGT 1 ☐ inches 2 ☐ cm HINCM ☐ Not done (height required at Weeks 192 and 240)
2. Weight: WGT 1 ☐ lbs 2 ☐ kg WLBKG ☐ Not done
3. Blood pressure: BPS / BPD mmHg ☐ Not done
4. Does the patient currently have any of the following conditions:
   a. Ascites ☐ None ☐ Mild ☐ Moderate ☐ Severe ASC
   b. Hepatic encephalopathy ☐ None ☐ 1 ☐ 2 ☐ 3 ☐ 4 ENC
   c. Hepatic hydrothorax ☐ Yes ☐ No HYD
   d. Variceal bleeding ☐ Yes ☐ No VBLD
   e. Portal hypertensive bleeding ☐ Yes ☐ No PHBLD
   f. Gilbert's syndrome ☐ Yes ☐ No GILSYN
   g. Hemolytic disease ☐ Yes ☐ No HEMLYT
   h. Fanconi syndrome ☐ Yes ☐ No FANC
5. CTP score: _____ ☐ Not calculated CTP

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

NOTE: Patients meeting AASLD criteria for HCC surveillance should have follow-up imaging per standard of care.

SECTION VI: BONE MINERAL DENSITY

1. Was a bone densitometry test performed? ☐ Yes ☐ No BONET

If Yes,

a. Date of test *(mm/dd/yy)*: BONEM / BONED / BONEY

b. Any evidence of osteopenia? ☐ Yes ☐ No OSTPEN

c. Any evidence of osteoporosis? ☐ Yes ☐ No OSTPOR

SECTION VII: 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

Data collector initials: DCID Visit completed: ☐ In-person ☐ Remotely (e.g. phone) VISITC

Date data collection completed *(mm/dd/yy)*: DCM / DCD / DCY