Discontinuation of Study Drug at Week 192

Patient ID __ __ - __ **ID** __ - __ __ __

Instruction: *Begin to complete this form at the Week 180 visit to document that the investigator reviewed information with the participant and begin determination of whether or not the participant meets the criteria to discontinue study medication at the Week 192 visit.*

The form should be entered in the HBRN database within 24 hours following the Week 192 visit.

SECTION I: PI REVIEW OF STUDY DRUG DISCONTINUATION INFORMATION AT WEEK 180 VISIT

Indicate whether or not the study investigator performed the following:	Yes	No
a. Reviewed rationale for antiviral withdrawal with participant **RATWD**	☐	☐
b. Reviewed criteria for treatment discontinuation with participant **CTXDC**	☐	☐
c. Reviewed potential benefits and risks of treatment discontinuation with participant **BENRISK**	☐	☐
d. Reviewed criteria for resuming antiviral treatment with participant **RESUM**	☐	☐
e. Reviewed post treatment follow-up schedule with participant **FUPSCH**	☐	☐
f. Participant given fact sheet reviewed by study investigator **FACTS**	☐	☐
g. Participant signed fact sheet placed in study chart **SIGNFS**	☐	☐
h. Participant reminded that last dose of tenofovir will be on day of week 192 visit, and to bring all remaining study drug to that visit **REMDOSE**	☐	☐
i. Investigator documented discussion with participant in participant record **DOCDISC** Date of discussion *(mm/dd/yy):* **DOCDISCM/D/Y**	☐	☐

SECTION II: CRITERIA FOR DISCONTINUING STUDY DRUG AT WEEK 192 VISIT (Use lab results from Week 180 visit or most recent prior to Week 192 visit. Do not use lab results from the Week 192 visit.)

Indicate whether or not the participant meets each criterion:	Yes	No
a. No cirrhosis on baseline biopsy **NOCIRR**; Ishak score (central read): **ISHAK** (1-4 = no cirrhosis 5-6 = cirrhosis)	☐	☐
b. HBV DNA <1000 IU/mL for the previous 24 weeks (week 156 through 180) **BDNA24W** result: **BDNA1** date: **BDNA1M/D/Y** result: **BDNA2** date: **BDNA2M/D/Y** result: **BDNA3** date: **BDNA3M/D/Y**	☐	☐
c. Albumin ≥ 3.8 g/dL **ALBUMIN** result: **ALB** date: **ALBM/D/Y**	☐	☐
d. INR ≤ 1.3 **INRCR** result: **INR** date: **INRM/D/Y**	☐	☐
e. Direct bilirubin ≤ 0.5 mg/dL **DIRBILI** result: **DBILI** date: **DBILIM/D/Y**	☐	☐
f. Platelet count ≥ 120,000/mm^3 **PLATCT** result: **PLAT** x10^3 date: **PLATM/D/Y**	☐	☐
g. No evidence of clinical decompensation (ascites, hepatic hydrothorax, variceal bleeding, portal hypertensive bleeding, hepatic encephalopathy, CTP score ≥ 7) **NODECOMP**	☐	☐
h. No clinical evidence of portal hypertension **CLINPHTN**	☐	☐
i. No radiologic evidence of portal hypertension **RADPHTN** date of imaging: **MGM/D/Y** (or imaging not clinically indicated, not performed)	☐	☐

j. HBeAg-negative at baseline visit and confirmed at week 180, or HBeAg-positive at baseline visit with HBeAg loss at or before week 144 and confirmed at week 180. In either situation, there can be no HBeAg positive result at or after week 144. **HBEAGNEG** **HBEAGBL** Baseline result: ☐ Pos ☐ Neg ☐ Equiv date: **HBEAGBLM/D/Y** **HBEAG144** Week 144 result: ☐ Pos ☐ Neg ☐ Equiv date: **HBEAG144M/D/Y** **HBEAG180** Week 180 result: ☐ Pos ☐ Neg ☐ Equiv date: **HBEAG180M/D/Y**	☐	☐
k. HBsAg-negative (regardless of anti-HBe status), or if HBsAg-positive, HBeAg-negative and anti-HBe-positive at week 180 **HBSAGNEG** HBsAg result: **HBSAG** ☐ Pos ☐ Neg ☐ Equiv date: **HBSAGM/D/Y** Anti-HBe result: **HBE** ☐ Pos ☐ Neg ☐ Equiv date: **HBEM/D/Y**	☐	☐

SECTION III: DETERMINATION OF STUDY DRUG DISCONTINUATION

1. Is participant eligible per protocol to discontinue study drug at week 192: ☐ Yes ☐ No **ELIGDC**
   a. Date eligibility to discontinue determined *(mm/dd/yy)*: **ELIGDCM** / **ELIGDCD** / **ELIGDCY**
2. Was study drug discontinued at Week 192: ☐ Yes ☐ No **DRUGDC**
   a. If No, reason **NODCRN**
      - ☐ Participant not eligible per one or more of the protocol criteria (as listed in Section II)
      - ☐ Participant preference
      - ☐ Study investigator preference
      - ☐ Other, specify _____ **NODCRNOS** _____

Investigator signature: _____

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