Reinitiation of HBV Treatment in Post-treatment Follow-up Period

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

Instruction: *Complete this form when the information needed to determine whether or not a participant who discontinued study drug (at the Week 192 visit) will be restarted on any HBV therapy during the post-treatment follow-up period.*

SECTION I: CRITERIA FOR RESTARTING HBV TREATMENT

Indicate whether or not the participant meets each criterion:	Yes	No
a. Total bilirubin ≥ 3.0 mg/dL, regardless of HBV DNA or ALT level **CTBILI** Initial result **TBILII** mg/dL Date of sample (*mm/dd/yy*) **TBILIIM/D/Y**	☐	☐
b. Direct bilirubin ≥ 1.0 mg/dL, regardless of HBV DNA or ALT level **CDBILI** Initial result **DBILII** mg/dL Date of sample (*mm/dd/yy*) **DBILIIM/D/Y**	☐	☐
c. INR ≥ 1.3, regardless of HBV DNA or ALT level **CINR** Initial result **INRI** Date of sample (*mm/dd/yy*) **INRIM/D/Y**	☐	☐
d. Evidence of clinical decompensation (ascites, hepatic hydrothorax, variceal bleeding, portal hypertensive bleeding, hepatic encephalopathy, CTP score ≥ 7) **CDECOMP**	☐	☐
e. HBV DNA and ALT values meet one of the below criteria (check the specific criterion below) **CBDNAALT** HBV DNA ≥ 10,000 IU/mL Initial result (UWash central lab) **BDNAI** IU/mL Date (*mm/dd/yy*) **BDNAIM/D/Y** Initial ALT **ALTI** U/L Date (*mm/dd/yy*) **ALTIM/D/Y** Repeat ALT **ALTR1** U/L Date (*mm/dd/yy*) **ALTR1M/D/Y** Repeat ALT **ALTR2** U/L Date (*mm/dd/yy*) **ALTR2M/D/Y** **BDNAALT** ☐ HBV DNA ≥10,000 IU/mL and **ALT >1000 U/L (male or female)** (i.e. only one ALT values >1000 U/L is needed to qualify) **Or** ☐ HBV DNA ≥10,000 IU/mL and **ALT ≥300 U/L for males, ≥200 U/L for females**. A total of one HBV DNA ≥10,000 IU/mL and any 3 ALT values ≥300 (male) or ≥200 U/L (female) over a 4-week (or longer) time frame are needed to qualify. Treatment will be resumed if the third ALT remains ≥300 U/L (male) or ≥200 U/L (female). **or** ☐ HBV DNA ≥10,000 IU/mL and **ALT ≥150 U/L for males or ≥100 U/L for females**. A total of one HBV DNA ≥10,000 IU/mL and any three ALT values ≥150 U/L (male) or ≥100 U/L (female) over the 12 week (or longer) time period are needed to qualify. Treatment will be resumed if the third ALT remains ≥150 U/L (male) or ≥100 U/L (female).	☐	☐
f. At week 192, HBsAg positive and HBeAg positive OR HBsAg positive, HBeAg negative, and anti-HBe negative **CSEROL**	☐	☐
g. Other **COTH**, specify _____ **COTHS** _____	☐	☐

SECTION II: DETERMINATION TO REINITIATE HBV TREATMENT

1. Is participant eligible to restart treatment: ☐ Yes ☐ No **ELIGRS**

   a. Date eligibility to restart determined *(mm/dd/yy)*: **ELIGRSM** / **ELIGRSD** / **ELIGRSY**

2. Was treatment restarted: ☐ Yes ☐ No **TXRS**

   If restarted: Date restarted (*mm/dd/yy*): **TXRSM** / **TXRSD** / **TXRSY**

   Drug restarted: **TXRSDG** ☐ Tenofovir ☐ Other, specify _____ **TXRSDGOS** _____

   If not restarted, reason **NORSRN**

   ☐ Participant not eligible per criteria (listed in Section 1)
   ☐ Participant preference
   ☐ Study investigator preference
   ☐ Other, specify _____ **NORSRNOS** _____

Investigator signature: _____

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