

ALT Flare Resolution (Adult)

Patient ID ____ - ___ - ___ - ___ - ___ -

This information is to be completed by the physician investigator immediately following resolution of an ALT flare. The information is to reflect the opinion of the physician investigator based on information available at the time of resolution.

SECTION I: ETIOLOGY OF FLARE

- 1. Estimate date of onset (mm/dd/yy): ____ / ____ / ____
- 2. Date of diagnosis (mm/dd/yy): ____ / ____ / ____ /
- 3. Date of resolution (mm/dd/yy): ____ / ___ / ____ /
- Did patient develop symptoms of hepatitis B (fatigue, nausea, anorexia, etc.) during the flare ?
 □ Yes □ No □ Unknown
- 5. Did patient become jaundiced (total bilirubin ≥ 2.5 mg/dL or visible jaundice) during the flare ?
 - □ Yes □ No □ Unknown
- 6. Did patient develop any evidence of hepatic decompensation (ascites, encephalopathy, variceal bleeding, INR > 1.5, albumin < 3.0 g/dL, etc.) during the flare ? □ Yes □ No □ Unknown
- 7. Probable etiology of the ALT flare: _____ if specify required: _____

Probable etiology of flare

Reactivation of hepatitis B

- 1. Spontaneous
- 2. Upon withdrawal of antiviral therapy
- 3. Associated with immunosuppressive therapy (including DAAs)
- 4. Progression of immunodeficiency
- 5. Transition from IT to IA phase

Immune clearance of hepatitis B

- 9. Unsuccessful attempt at immune clearance
- 10. Spontaneous
- 11. Antiviral therapy induced
- 12. Immune reconstitution
- 13. Withdrawal of antiviral therapy with flare and seroconversion
- ALT Flare with no change in HBV DNA
 - 16. No change in HBV DNA

Drug-induced liver disease

- 20. Idiosyncratic reaction, **specify** drug
- 21. Direct toxic reaction, specify drug
- 22. Alcohol
- 23. Acetaminophen

Superimposed liver disease or infection:

- 30. Hepatitis A
- 31. Hepatitis D
- 32. Hepatitis C
- 33. Hepatitis E
- 34. Autoimmune hepatitis
- 35. Other, specify

SECTION II: CLINICAL DECISIONS

- 1. Clinical decisions made in response to the flare (check all that apply):
 - □ Continue to follow, without starting on antiviral therapy
 - □ Continue to follow, already on antiviral therapy
 - □ Hospitalization
 - □ Start on antiviral therapy
 - □ List for liver transplant
 - □ Other, specify _

Physician investigator initials: ______ Date form completed *(mm/dd/yyyy)*: ____/ ___/

- 40.Other, specify
- 41.Unknown
- 42. Acute HBV
- 43. HBV related but inadequate information to determine a specific etiology