



ALT Flare Resolution Form (Pediatric)

General Instructions

This form captures information regarding the etiology of the ALT flare and the clinical decisions made in response to the ALT flare. The physician investigator is to provide this information immediately following resolution of the ALT flare, according to information available to him/her from the time of onset through resolution of the flare. Some or all of the information may be "in the opinion of the investigator".

ALT flare definition:

- ALT test result ≥ 600 IU/L in males and ≥ 550 IU/L in females 6 months - 18 months of age
- ALT test result ≥ 400 IU/L in males and ≥ 350 IU/L in females >18 months - <18 years of age

Frequency of follow-up visits (guidelines per standard of care):

- ALT ≤ 1000 IU/L: next visit in 4 weeks
- ALT > 1000 IU/L or total bilirubin > 2.5 mg/dl (in the absence of Gilbert's syndrome): next visit in 2 weeks

Resolution:

- ALT <600 IU/L in males and <500 IU/L in females 6 months – 18 months of age
- ALT < 400 IU/L in males and < 350 IU/L in females >18 months - <18 years of age

Specific Instructions

Patient ID: Record the Patient ID in the top right hand corner.

Section I: Etiology of Flare

Estimate date of onset: Estimate the date (month/day/year) of onset of the ALT flare. This may not necessarily correspond to the date the ALT result met the definition of flare.

Date of diagnosis: Record the date (month/day/year) the ALT test result met the definition of ALT flare, ≥ 400 IU/L in males and ≥ 350 IU/L in females.

Date of resolution: Record the date (month/day/year) the ALT test result met the definition of resolution, < 400 IU/L males and < 350 IU/L in females.

Symptoms: Check "Yes", "No", or "Unknown" to indicate if the patient developed symptoms of hepatitis B during the course of the flare, that were not present prior to onset of the flare. Symptoms include fatigue, nausea, poor appetite, or any other symptom considered to be possibly related to the disease flare.

Jaundice: Check "Yes", "No", or "Unknown" to indicate if the patient became jaundiced during the course of the flare. Jaundice is defined as one of the following:
i. Total bilirubin ≥ 2.5 mg/dL
ii. Visible jaundice: yellow discoloring of the skin, mucous membranes, and eyes.

Hepatic decompensation: Check "Yes", "No", or "Unknown" to indicate if the patient developed any evidence of hepatic decompensation during the course of the flare. Evidence of hepatic decompensation includes abnormal laboratory values associated with hepatic decompensation (e.g. INR > 1.5 or albumin < 3.0 g/dL) or any one of the following:



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Ascites: Defined as an excess of fluid in the peritoneal cavity that is mild, moderate or marked on ultrasound (ultrasound report of minimal fluid around the liver does not meet the definition) or is progressive on serial physical examinations or requires diuretic therapy.

Hepatic hydrothorax: ascites associated pleural effusion.

Variceal bleeding: Defined as GI bleeding from varices present in the esophagus and/or stomach.

Portal hypertensive bleeding: gastrointestinal bleeding associated with portal hypertension.

Hepatic encephalopathy: Characterized by recurrent disturbances of consciousness, impaired intellectual function, neuromuscular abnormalities, metabolic slowing on EEG and elevated serum ammonia levels. Symptoms include changes in mental state, consciousness, behavior and personality, decrease in performance of simple self-care tasks, and muscle spasms or rigidity. Also known as portal-systemic encephalopathy.

Etiology: Record the corresponding code for the most probable etiology of the flare, as determined at the time of resolution of the flare. Provide only one etiology. If a specific etiology is not listed, code "Other" and record the etiology in the space provided. If the etiology requires specific information (e.g. idiosyncratic reaction, direct toxic reaction), record the information in the "specify" field. If the most probable etiology cannot be determined, use "Unknown". Refer to the study codebook or the data form for the list of etiologies.

Section II: Clinical Decisions

Clinical decisions: Check each of the actions taken in response to the ALT flare, from the time of onset through resolution. If an action is not listed, check "Other" and specify the action taken in the space provided.