



GENERAL INSTRUCTIONS

This form captures every ALF-related diagnosis from the initial diagnosis at the time of enrollment into the PALF Cohort Study through to the final diagnosis, and any changes in diagnosis during the 12 month follow-up period. The diagnosis recorded is to be the physician's clinical diagnosis.

The initial diagnosis is the physician's clinical diagnosis at the time the patient is first seen for the episode of acute liver failure at the PALF site. If the clinical diagnosis changes during the course of the PALF episode, every change in clinical diagnosis should be added to the log.

Each diagnosis should be classified as a primary or secondary diagnosis.

- There must always be a primary diagnosis. If the primary diagnosis changes over time, report each diagnosis on a separate line and the latest diagnosis date will be considered the primary diagnosis.
- There may not be a secondary diagnosis or there may be more than one secondary diagnosis. Report each diagnosis on a separate line. If a secondary diagnosis is identified and then later ruled out, that line of the log must be updated to indicate that the diagnosis has been "ruled out".
- If a diagnosis rank changes from primary to secondary or vice versa, a new line on the log should be completed for the diagnosis.

This form is in log format and each line should be completed as needed to record new information.

Refer to the Diagnosis Definition Guidelines for testing criteria for each diagnosis. The Diagnosis Definition Guidelines should be used as a reference to guide the tests performed and encourage complete patient evaluations. Ideally, adhering to these guidelines will provide evidence to support the final clinical diagnosis.

SPECIFIC INSTRUCTIONS

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| Patient ID: | Record the Patient ID |
| Diagnosis: | Refer to the study codebook for the list of diagnosis codes, or the dropdown list in the data system. Record the diagnosis. If the child has a diagnosis that is not included in the list, select the 'Other' option and specify the diagnosis in the specify field. Diagnoses that require additional information include: FAO, Mitochondrial, Drug-Induced Hepatitis, and Other. For "Other" indicate the diagnosis, for FAO and Mitochondrial indicate the type, and for Drug-Induced Hepatitis indicate the agent. |
| Date of diagnosis: | Record the date that the diagnosis was determined. If any part of the date is unknown, enter -3 for the unknown part of the date and enter the other parts of the date that are known. If the entire date is unknown, check "Unknown". |
| Rank: | If the patient has more than one diagnosis at any time, enter each diagnosis separately with the same date of diagnosis, and indicate the primary diagnosis and the secondary diagnosis or diagnoses. |
| Secondary diagnosis ruled out: | Record instances when a secondary diagnosis has been ruled out and is no longer believed to be correct by checking "Secondary Diagnosis Ruled Out." Do not rule out a secondary diagnosis that is no longer applicable because it has resolved. Record the date that the diagnosis was ruled out. If any part of the date is unknown, enter -3 for the unknown part of the date and enter the other parts of the date that are known. If the entire date is unknown, check "Unknown". |
| System ID: | Record the system generated ID for the record. |
| Comments: | When applicable, record additional information (e.g. diagnostic test results) to support the diagnoses. Data already captured on other PALF forms should not be recorded here. |