HCC Form

General Instructions

The HCC Form is completed at the time a patient is initially diagnosed with hepatocellular carcinoma. The HCC Form captures data to verify the diagnosis of HCC according to current AASLD criteria as well as information about the extent and staging of the tumor(s).

Confirmation of HCC diagnosis must be made by histology provided by one of the following reports:

- Liver biopsy
- Pathology
- Autopsy

OR in the absence of histological evidence, AFP lab result and the results from appropriate imaging test(s) as determined by current AASLD guidelines:

- Nodules < 1 cm found on surveillance will be followed with ultrasound at intervals of 12-24 weeks until a diagnosis of HCC is made or no growth is seen over 2 years.
- Nodules equal to 1 cm or between 1 to ≤ 2 cm will be investigated further with dynamic studies, such as contrast ultrasound, triphasic CT or MRI with contrast. Two studies must agree with the appearance of HCC, such as hypervascularity with washout in the venous phase, before a diagnosis is determined.
- If the nodule is > 2 cm and has the typical features on a dynamic imaging technique or AFP > 200 ng/ml, a diagnosis of HCC may be made.
- If these conditions are not met, a biopsy may be performed. Biopsy slides will be collected at the time of diagnosis or surgery/transplant.

Specific Instructions

Patient ID**:**	Record the Patient ID in the top right hand corner.
Date diagnosed:	Record the date (month/day/year) that patient first met criteria for diagnosis of HCC.
Histologic confirmation:	Check “Yes” or “No” to indicate if histologic confirmation is available. If yes, record the following i. Source of histology result: check “Biopsy”, “Surgically resected liver”, or “Explanted liver”. ii. Date (month/day/year) of biopsy, resection, or explant procedure. iii. Check “Yes” or “No” to indicate if slides were obtained for the HBRN. Every effort should be made to obtain slides for the central reading. If possible, obtain slides that do not have to be returned to the local institution. If this is not possible, slides will be returned to the local institution after being read by the HBRN central pathologists.
First imaging:	Record the date (month/day/year) imaging was performed that first showed a lesion with characteristics of HCC. If imaging results that show characteristics of HCC are not available, check “N/A” (not applicable).

If imaging results are available, record the following for the imaging that first showed a lesion characteristic of HCC:

i. Type of imaging that first showed a lesion characteristic of HCC: "MRI", "CT", "Ultrasound", "PET", or "PET/CT"
ii. Number of tumor nodules present with characteristics of HCC. If the number is not known, check "Unknown".
iii. Location of the tumor nodules with characteristics of HCC: "Right lobe", "Left lobe, or "Bilobar". If the location is not known, check "Unknown".
iv. Maximum diameter of the largest nodule with characteristics of HCC, in centimeters. If a measurement is not available or not known, check "Unknown".
v. Check "Yes, "No" or "Unknown" to indicate if portal vein invasion is present.

Additional imaging: Check "Yes" or "No" to indicate if additional imaging was completed.

If yes, record the following

i. Date (month/day/year) imaging was performed
ii. Type of imaging: "MRI", "CT", "Ultrasound", "PET", or "PET/CT"
iii. Number of tumor nodules present with characteristics of HCC. If the number is not known, check "Unknown"
iv. Location of the tumor nodules with characteristics of HCC: "Right lobe", "Left lobe, or "Bilobar". If the location is not known, check "Unknown".
v. Maximum diameter of the largest nodule with characteristics of HCC, in centimeters. If a measurement is not available or not known, check "Unknown".
    - In reference to this nodule, also check "Yes", "No", or "Unknown" to indicate if this nodule is in the same location as the largest nodule with characteristics of HCC shown on the first imaging.
vi. Check "Yes, "No" or "Unknown" to indicate if portal vein invasion is present.

AFP: Record the AFP result at the time of HCC diagnosis, or closest to the time of diagnosis, and the date (month/day/year) the test was performed. If the test result is not known, check "Unknown".

Hepatic encephalopathy: Check "None", "Mild", or "Moderate-severe" to indicate the stage of hepatic encephalopathy at the time of diagnosis of HCC as determined by the investigator. If the stage of hepatic encephalopathy is not known, check "Unknown".

The West Haven classification is provided as a reference.

None	Grade 0	Lack of detectable changes in personality or behavior. Minimal changes in memory, concentration, intellectual function, and coordination. Asterixis is absent.
Mild	Grade 1	Trivial lack of awareness. Shortened attention span. Impaired addition or subtraction. Hypersomnia, insomnia, or inversion of sleep pattern. Euphoria, depression, or irritability. Mild confusion. Slowing of ability to perform mental tasks. Asterixis can be detected.

Moderate - Severe	Grade 2	Lethargy or apathy. Disorientation. Inappropriate behavior. Slurred speech. Obvious asterixis. Drowsiness, lethargy, gross deficits in ability to perform mental tasks, obvious personality changes, inappropriate behavior, and intermittent disorientation, usually regarding time.
	Grade 3	Somnolent but can be aroused, unable to perform mental tasks, disorientation about time and place, marked confusion, amnesia, occasional fits of rage, present but incomprehensible speech
	Grade 4	Coma with or without response to painful stimuli

Grade of ascites: Check "None", "Mild", or "Moderate-severe" to indicate the grade of ascites at the time of diagnosis of HCC. If the grade of ascites is not known, check "Unknown".

None: not present

Mild: managed without diuretics or controlled with diuretics without the need for paracentesis.

Moderate – severe: requires therapeutic paracentesis regularly.

Barcelona staging: Check the Barcelona staging score that best reflects the status of the patient at the time of diagnosis of HCC:

Stage 0 - Fully active, normal life, no symptoms.
Stage 1 - Minor symptoms, able to do light activity.
Stage 2 - Capable of self-care but unable to carry out work activities. Up for more than 50% waking hours.
Stage 3 - Limited self care capacity. Confined to bed or chair>50% waking hours.
Stage 4 - Completely disabled. Confined to bed or chair.
Unknown – insufficient information to evaluate.

Tumor staging: Record the TNM classification for each individual factor (T-factor, N-factor, M-factor) according to the American Liver Tumor Study Group Modified Tumor-Node-Metastasis (TNM) Classification.

Classification	Definition
TX, NX, MX	Not assessed
T0, N0, M0	Not found
T1	1 nodule ≤ 1.9 cm
T2	One nodule 2.0-5.0 cm; two or three nodules, all < 3.0cm
T3	One nodule > 5.0 cm; two or three nodules, at least one > 3.0 cm
T4a	Four or more nodules, any size
T4b	T2, T3, or T4a plus gross intrahepatic portal hepatic vein involvement as indicated by CT, MRI, or ultrasound
N1	Regional (portal hepatitis) nodes, involved
M1	Metastatic disease, including extrahepatic portal or hepatic vein involvement

If there is insufficient information to evaluate a factor check "Unknown" for that factor.

Previous imaging:	Record the most recent date (month/day/year) of imaging when the results did not show a tumor nodule with characteristics of HCC. If previous imaging was not completed or results are not available prior to the diagnosis of HCC, check "N/A" (not applicable). • Check "MRI", "CT", "Ultrasound", "PET", or "PET/CT" to indicate the type of imaging.
HCC treatment:	Check "Yes", "No" or "Unknown" to indicate if the patient has received treatment for HCC since the initial diagnosis of HCC. If yes, record the date (month/day/year) treatment was first administered.