Liver Explant Pathology

The Liver Recipient Explant Pathology records are generated and available immediately after a transplant event is reported in WaitlistSM. The liver explant record is completed by the transplant center performing the transplant.

The liver explant record must be completed within 60 days from the record generation date. See OPTN Policies for additional information. Use the search feature to locate specific policy information on Data Submission Requirements.

Provider Information

Recipient Center: The transplant center reported in Waitlist displays. Verify that the center information is the hospital where the transplant operation was performed. The Provider Number is the 6-character Medicare identification number of the hospital. This is followed by the Center Code and Center Name. If the information is incorrect, contact the Help Desk at (800) 978-4334.

Recipient Information

Recipient Name: The name reported in Waitlist displays. Verify the last name, first name and middle initial of the transplant recipient is correct. If the information is incorrect, corrections may be made on the recipient's Transplant Recipient Registration (TRR) record.

DOB: The date of birth reported in Waitlist displays. Verify the date is the recipient's date of birth. If the information is incorrect, corrections may be made on the recipient's TRR record.

Transplant Date: Verify that the displayed transplant date is correct. The transplant date is determined by the start of the organ anastomosis during transplant or the start of the islet infusion. Organ transplants include solid organ transplants and islet infusions. An organ transplant procedure is complete when *any* of the following occurs:

The chest or abdominal cavity is closed and the final skin stitch or staple is applied.

The transplant recipient leaves the operating room, even if the chest or abdominal cavity cannot be closed.

The islet infusion is complete

Birth Sex: The Birth Sex reported in Waitlist displays. Verify recipient's sex (Male or Female), based on biologic and physiologic traits at birth. If sex at birth is unknown, report sex at time of registration as reported by recipient or documented in medical record. The intent of this data collection field is to capture physiologic characteristics that may have an impact on recipient size matching or graft outcome. If the information is incorrect, corrections may be made on the recipient's TCR record.

SSN: The SSN reported in Waitlist displays. Verify the recipient's Social Security number is correct. If the information is incorrect, contact the Help Desk at 1-800-978-4334.

Clinical Information

Was evidence of HCC (viable or non-viable tumor) found in the explant? If there was any evidence of hepatocellular carcinoma (HCC), click Yes and complete the following

questions. If there **is not** any evidence, click **No** and answer the **Pre-transplant treatment for HCC** question only. This field is **required**.

Note: If **No** is clicked, a message displays containing the following information: If the candidate's explant pathology report does not show evidence of HCC, the transplant center must submit documentation and/or imaging studies used to support the HCC diagnosis at the time of listing. You may submit documentation by fax to (804) 782-4680, Attention: RRB Admin Supervisor, or by e-mail to <u>LiverPolicy@unos.org</u>.

Number of Tumors: If Yes was selected for Was evidence of HCC (viable or non-viable tumor) found in the explant, in the Number of Tumors list, click the appropriate option.

Options: 1, 2, 3, 4, 5, >5, Infiltrative (a large HCC lesion without distinct margins diffusely involving the liver parenchyma)

Note: If the **Number of Tumors** is > **5**, you are required to enter tumor size, location or tumor necrosis for the 5 largest tumors. If the **Number of Tumors** is **Infiltrative**, you are not required to enter tumor size, location or tumor necrosis.

Tumor: For each tumor, complete the following fields.

Size: Enter the size of the tumor in centimeters (cm). If **Number of Tumors** is 1 or more, this field is **required**. The largest dimension of each tumor must be reported (e.g., 3.2 cm x 5.1 cm must be reported as 5.1 cm).

Range: 0.01 to 99.99

Location: In the **Location** list, click the appropriate option. If **Number of Tumors** is 1 or more, this field is **required**.

Options: Right Lobe, Left Lobe

Tumor Necrosis: In the **Tumor Necrosis** list, click the appropriate option. If **Number of Tumors** is 1 or more, this field is **required**.

Options: None, Incomplete (any amount of viable tumor remains), Complete (no viable tumor remains)

Worst Tumor Differentiation: If Yes was selected for Was evidence of HCC (viable or non-viable tumor) found in the explant, in the Worst Tumor Differentiation list, click the appropriate option. If Number of Tumors is 1 or more, this field is required.

Options: Well, Moderate, Poor, Complete Tumor Necrosis

Vascular Invasion: If Yes was selected for Was evidence of HCC (viable or non-viable tumor) found in the explant, in the Vascular Invasion list, click the appropriate option. If Number of Tumors is 1 or more, this field is required. This does not include bland thrombus.

Options: None, Microvascular (vascular invasion seen only under microscopic inspection, synonymous with angiolymphatic or lymphovascular invasion), Macrovascular (any involvement of large vessels noted on gross pathological inspection)

Lymph Node Involvement: If Yes was selected for Was evidence of HCC (viable or non-viable tumor) found in the explant, in the Lymph Node Involvement list, click the appropriate option. If Number of Tumors is 1 or more, this field is required.

Options: Yes. No

Other Extrahepatic Spread: If Yes was selected for Was evidence of HCC (viable or non-viable tumor) found in the explant, in the Other Extrahepatic Spread list, click the

appropriate option. If **Number of Tumors** is 1 or more, this field is **required**. This is separate from nodal involvement.

Options: Yes, No

Satellite Lesions: If **Yes** was selected for **Was evidence of HCC (viable or non-viable tumor) found in the explant**, in the **Satellite Lesions** list, click the appropriate option. If **Number of Tumors** is 1 or more, this field is **required**. Satellite lesions are defined as a tumor nodule which is < 4 cm in diameter, < 2 cm in proximity from the primary tumor, and < 50% of the primary tumor's diameter.

Options: Yes, No

<u>Did recipient receive any pre-transplant liver-directed therapy for HCC?</u>: If the recipient received any pre-transplant treatment for HCC, click **Yes**. If the recipient **did not** receive any pre-transplant treatment for HCC, click **No**. This field is **required**. Examples of loco-regional therapy include TACE (trans-arterial chemoembolization) RFA (radiofrequency ablation), and radiolabeled microsphere treatment.

Public Burden Statement: The private, non-profit Organ Procurement and Transplantation Network (OPTN) collects this information in order to perform the following OPTN functions: to assess whether applicants meet OPTN Bylaw requirements for membership in the OPTN; and to monitor compliance of member organizations with OPTN Obligations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0915-0157 and it is valid until XX/XX/202X. This information collection is required to obtain or retain a benefit per 42 CFR §121.11(b) (2). All data collected will be subject to Privacy Act protection (Privacy Act System of Records #09-15-0055). Data collected by the private non-profit OPTN also are well protected by a number of the Contractor's security features. The Contractor's security system meets or exceeds the requirements as prescribed by OMB Circular A-130, Appendix III, Security of Federal Automated Information Systems, and the Departments Automated Information Systems Security Program Handbook. The public reporting burden for this collection of information is estimated to average 0.27 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Information Collection Clearance Officer, 5600 Fishers Lane, Room 14N39, Rockville, Maryland, 20857 or paperwork@hrsa.gov.