

Liver and Biliary Tract Cancer

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

Note: For Medicaid members/enrollees, circumstances when state Medicaid coverage provisions conflict with the coverage provisions within this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

DISCUSSION

Hepatobiliary cancers are highly lethal cancers including a spectrum of invasive carcinomas arising in the liver (hepatocellular carcinoma, also called HCC), gall bladder, and bile ducts (intrahepatic and extrahepatic cholangiocarcinoma). Gallbladder cancer and cholangiocarcinomas are collectively known as the biliary tract cancers. In 2020, it was estimated that 42,810 people in the United States would be diagnosed with liver cancer and intrahepatic bile duct cancer and an additional 11,980 people would be diagnosed with gallbladder cancer or other biliary tract cancer. Approximately 30,160 deaths occurred from liver or intrahepatic bile duct cancer. 4,090 deaths were anticipated in 2020 due to gallbladder cancer or other biliary tract cancer.¹

Due to the unique characteristics of HCC which vary with geographic region, many different staging systems are utilized. The Child-Pugh score and Tumor, Nodes and Metastases (TNM) staging system is currently utilized following an initial workup.² Patients are stratified into one of the following four categories²:

- Potentially resectable or transplantable, operable by performance status or comorbidity
- Unresectable disease
- Liver-confined disease, inoperable by performance status, comorbidity, or with minimal or certain extrahepatic disease
- Metastatic disease

External beam radiation or stereotactic body radiation can be considered as a treatment alternative to ablation and or liver embolization techniques.^{4,5} Image guidance should be considered in this clinical setting to improve treatment accuracy.^{4,5} Palliative radiation can be considered for symptom control or to prevent complications.

DEFINITIONS

- **Definitive radiation therapy** - Radiation therapy used with curative intent.
- **External beam radiation therapy (EBRT)** - External radiation (or external beam radiation) is the most common type of radiation therapy used for cancer treatment. A machine is used to aim high-energy rays (or beams) from outside the body into the tumor.
- **Fractions** - A way of dividing a total dose of radiation into separate doses to be administered over a period of time.
- **Gray (Gy)** - One of the two units used to measure the amount of radiation absorbed by an object or person, known as the absorbed dose. One gray (Gy) is the international system of units (SI) equivalent of 100 rads, which is equal to an absorbed dose of 1 Joule/kilogram.
- **Image-guided radiation therapy (IGRT)** - Image-guided radiation therapy (IGRT) is the use of imaging during radiation therapy to improve the precision and accuracy of treatment delivery. IGRT is used to treat tumors in areas of the body that move, such as the lungs. Radiation therapy machines are equipped with imaging technology to allow your doctor to image the tumor before and during treatment. By comparing these images to the reference

images taken during simulation, the patient's position and/or the radiation beams may be adjusted to more precisely target the radiation dose to the tumor. To help align and target the radiation equipment, some IGRT procedures may use fiducial markers, ultrasound, MRI, X-ray images of bone structure, CT scan, 3D body surface mapping, electromagnetic transponders, or colored ink tattoos on the skin.

- **Intensity-modulated radiotherapy (IMRT)** - Intensity-modulated radiation therapy (IMRT) is an advanced mode of high-precision radiotherapy that uses computer-controlled linear accelerators to deliver precise radiation doses to a malignant tumor or specific areas within the tumor. IMRT allows the radiation dose to conform more precisely to the three-dimensional shape of the tumor by controlling the intensity of the radiation beam in multiple small volumes. IMRT also allows higher radiation doses to be focused to regions within the tumor while minimizing the dose to surrounding normal critical structures.
- **National Comprehensive Cancer Network® (NCCN)** - An alliance of 32 leading cancer centers devoted to patient care, research, and education. The NCCN guidelines are utilized for Radiation Therapy and Medical Oncology standards. NCCN consensus clinical standards are periodically updated and NantHealth, Inc. reviews these and updates its policies within a timely manner.
- **Palliative Radiation Therapy** - Treatment given to help relieve the symptoms and reduce the suffering caused by cancer or other life-threatening diseases. Palliative therapy may help a person feel more comfortable, but it does not treat or cure the disease. Palliative therapy may be given with other treatments from the time of diagnosis until the end of life.
- **Selective internal radiation therapy (SIRT)** - Selective internal radiation therapy (sometimes called radioembolization (RE)) is an arterially directed treatment that's used to destroy liver tumors. During SIRT treatment, tiny radioactive beads are sent directly to the tumor through the arteries (blood vessels) in the liver. The beads give off radiation over a very short distance. The beads facilitate the transportation of the radiation inside the tumor, helping to reduce the amount of radiation that is transmitted to the remainder of the liver and of the body.
- **Stereotactic body radiation therapy (SBRT)** - Treatment outside the brain is called stereotactic body radiation therapy (SBRT). SBRT may be used for certain lung, spine, and liver tumors.
- **Three dimensional conformal radiation therapy (3D-CRT)** - A procedure that uses a computer to create a three dimensional picture of the tumor. This allows doctors to give the highest possible dose of radiation to the tumor, while sparing the normal tissue as much as possible.

POLICY

The following table outlines the criteria that must be met for the number of fractions and dosing relative to liver and biliary tract cancer radiation treatments. This dosing table represents evidence-based doses and fractions for the designated type of cancer treatment. Variations outside of the ranges may indicate a deviation from standard treatment.

Liver Cancer			
	Number of Fractions	Total Dose	Technique
Definitive - Conventional	10-30	30-60 Gy	3D-CRT, EBRT, IMRT, IGRT
Definitive - Stereotactic Body Radiotherapy (SBRT)	3-5	30-50 Gy	SBRT, IGRT
Stereotactic Body Radiotherapy (SBRT) (Oligometastases)	1-5	16-60 Gy	SBRT, IGRT
Palliative Radiotherapy	1-15	10-45 Gy	3D, IGRT

Biliary Tract Cancers (Cholangiocarcinoma and Gall Bladder)

	Number of Fractions	Total Dose	Technique
Definitive	23-33	45-60 Gy	3D-CRT, IMRT, EBRT, IGRT
Adjuvant	23-33	45-60 Gy	3D-CRT, IMRT, EBRT, IGRT
Stereotactic Body Radiotherapy (SBRT) (Unresectable)	3-5	30-50 GY	SBRT, IGRT
Palliative Radiotherapy	1-15	8-37.5 Gy	3D-CRT, EBRT

REFERENCES

1. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Hepatobiliary Cancers. (Version 1.2022). Available at https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf. ©National Comprehensive Cancer Network, 2022.
2. Tisoris A, Marlar CA. Use of The Child Pugh Score in Liver Disease. Nih.gov. <https://www.ncbi.nlm.nih.gov/books/NBK542308/>. Accessed May 5, 2022.
3. Hawkins MA, Dawson LA. Radiation therapy for hepatocellular carcinoma. Cancer. 2006;106(8):1653-1663.
4. Hoffs SE, Finkelstein SE, Russell MS, Shridhar R. Nonsurgical Options for Hepatocellular Carcinoma: Evolving Role of External Beam Radiotherapy. Cancer Control. 2010;17(2):100-110.

Please see all related radiation therapy treatment policies for additional information on the treatment modalities. (3D-CRT, EBRT, IGRT, IMRT, PBT, SIRT, SBRT and SRS)

CODING [ICD-10, HCPCS]*

*Procedure codes appearing in medical policy documents are only included as a general reference. This list may not be all-inclusive and is subject to updates. In addition, codes listed are not a guarantee of payment. CPT codes are available through the AMA.

Code	Description
C22.0	Hepatocellular carcinoma
C22.1	Cholangiocarcinoma
C24.0	Malignant neoplasm extrahepatic bile ducts
C78.7	Secondary malignancy, liver
G0339	Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment
G0340	Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum 5 sessions per course of treatment
G6015	Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session
G6016	Compensator-based beam modulation treatment delivery of inverse planned treatment using 3 or more high resolution (milled or cast) compensator convergent beam modulated fields, per treatment session
Z51.5	Encounter for palliative care
Z92.3	Personal history of irradiation

REVISION AND REVIEW HISTORY

No.	Description	Metadata
1	Original Effective Date:	5/2022
2	Policy Review Dates:	5/17/2022, 5/18/2022, 5/24/2022, 5/25/2022, 5/31/2022, 7/20/2022
3	Policy Revision Dates:	5/17/2022, 5/18/2022, 5/24/2022, 5/25/2022, 5/31/2022, 7/20/2022
4	Department Owner:	Medical Affairs
5	NH Advisory Committee Approval Dates:	5/18/2022, 5/25/2022, 5/31/2022,
6	Revision Changes:	5/31/2022 - Included PBT in the cross reference section, added SIRT definition to definition section