Radioembolization for Hepatic Tumors

Policy Number:	**M20180212005**
Effective Date:	**4/1/2018**
Sponsoring Department:	**Health Care Services**
Impacted Department(s):	**Health Care Services**

Type of Policy: ☒ Internal ☒ External

Data Classification: ☐Confidential ☐Restricted ☒Public

Applies to (Line of Business):

☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒MediSource; ☒ MediSource Connect; ☒Child Health Plus ☒Essential Plan
☒ Medicare, if yes, which plan(s): ☒MAPD; ☐PDP; ☒ISNP; ☒CSNP
☒ Commercial, if yes, which type: ☒Large Group; ☒Small Group; ☒Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes ☒ No☐

Purpose and Applicability:

To set forth Independent Health's coverage policy for the use of **radioembolization** utilizing Theraspheres or Sir-Spheres for hepatic tumors.

Policy:

Commercial, Self-Funded and Medicare Advantage:
Radioembolization utilizing Theraspheres or Sir-Spheres may be considered medically necessary for members with the following criteria:

- Unresectable, pathology proven, primary **Hepatocellular Carcinoma (HCC)** that is limited to the liver; **or**
- Unresectable, pathology proven, liver tumors from primary colorectal cancer with a Child-Pugh score A or B; **or**

- As a bridge to transplant for patients with hepatocellular carcinoma who meet liver transplant criteria and are waiting liver transplantation; **or**
- Treatment of unresectable, pathology proven, liver-only or liver dominant metastases from neuroendocrine cancers when other systemic therapies have failed to control symptoms; **and**
- Eastern Cooperative Oncology Group performance status of 0 - 2; **and**
- A life expectancy of at least 3 months.

All other indications are non-covered.

Contraindications:

- Inability to catheterize the hepatic artery;
- exaggerated hepatopulmonary shunting;
- fulminant liver failure, severe liver dysfunction, or pulmonary insufficiency;
- technetium-99m macroaggregated albumin (99Tc MAA) hepatic arterial perfusion scintigraphy demonstrating significant reflux or nontarget deposition to the gastrointestinal organs that cannot be corrected by angiographic techniques;
- portal vein occlusion;
- any contraindication for hepatic artery catheterization; and
- pregnancy.

MediSource, MediSource Connect, Child Health Plus, Essential Plan:
MediSource, MediSource Connect, Child Health Plus and Essential Plan cover radioembolization with Theraspheres or Sir-Spheres utilizing the Commercial criteria above.

Background:
Radioembolization, also known as Selective Internal Radiation Therapy (SIRT), involves the use of intra-hepatic microspheres which are radio-labeled particles composed of glass (TheraSphere) or resin (SIR-sphere) particles. The goal of the procedure is to destroy tumors while sparing normal liver tissue. Candidates for radioembolization with **Yttrium-90** microspheres include patients with unresectable and/or inoperable primary or secondary liver malignancies, where the tumor burden is liver dominant, with a performance status allowing benefit from radioembolization and a life expectancy of ≥ 3 month. Microspheres target liver tumors by taking advantage of their hypervascularity. Metastatic liver tumors larger than 3 mm receive 80% to 100% of their blood supply from the hepatic artery while normal liver tissue is predominantly fed by the portal vein. The microspheres are delivered via a fluoroscopic embolization procedure in which millions of 30-micron beads are infused through a catheter into the hepatic artery. The beads become embedded in the liver, and the therapeutic dose is delivered over a period of about two weeks.

Before radioembolization, a comprehensive history of the member is obtained. Cross-sectional imaging is necessary. A CT of the chest, and abdomen with contract should be obtained, and an MRI or PET scan may be useful. The workup of the member in preparation for radioembolization therapy includes liver function tests; CBC, CEA level, and macro-aggregated albumin scan which should show the majority of the delivered particles will remain in the liver and not pass into the next organ's vascular bed.

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined above.

Pre-Authorization Required? Yes ☐ No ☒

Pre-authorization is not required at the present time. Criteria above will be utilized upon retro-review.

Definitions

Childs-Pugh: A scoring system for severity of liver disease and likelihood of survival based on the presence of: degenerative disease of the brain (encephalopathy), the escape or accumulation of fluid in the abdominal cavity (ascites), laboratory measures of various substances in the blood (see table below), and the presence of other co-existing diseases; after calculating the CTP score using a table similar to the one below, candidates can be classified into 1 of 3 categories:

- Childs A (5-6 points): 10 year survival 80-90%
- Childs B (7-9 points): 5 year survival 60-80%
- Childs C (10-15 points): 2 year survival less than 50%

Variable	1 Point	2 Points	3 Points
Encephalopathy	None	Moderate	Severe
Ascites	None	Mild	Moderate
Albumin (mg/dL)	Greater than 3/5	2.8-3.5	Less than 2.8
Prothombin time (International Normalized ratio) prolonged	Less than 4	4-6	Greater than 6
Bilirubin (mg/dL) Primary biliary cirrhosis Cirrhosis/primary Primary sclerosing cholangitis	1-4	4-10	Greater than 10
All other diseases	Less than 2	1-3	Greater than 3

ECOG Performance Status

Developed by the Eastern Cooperative Oncology Group, Robert L. Comis, MD, Group Chair. *

GRADE	ECOG PERFORMANCE STATUS
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
3	Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
4	Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
5	Dead

*Oken M, Creech R, Tormey D, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. *Am J Clin Oncol.* 1982; 5:649-655.

Hepatocellular Carcinoma (HCC) is an aggressive tumor that frequently occurs in relation to cirrhosis. Treatment options include surgical options such as resection and transplantation, and non-surgical

therapies including radiofrequency ablation, radioembolization, cryoablation, transarterial chemoembolization, radiation therapy, and external beam radiation therapy.

Radioembolization uses intraarterial injection of yttrium-90 labeled microspheres to induce extensive tumor necrosis by implanting in the liver and delivering the therapeutic dose.

Yttrium-90 is a beta-emitting radionuclide that acts locally due to its relatively low energy, allowing the beta particles travel at most 11 mm in the liver.

References

Related Policies, Processes and Other Documents
N/A

Non-Regulatory references

American College of Radiology (ACR) [web site]. Radiologic Management of Hepatic Malignancy Appropriateness Guidelines. Last Reviewed 2022. Available at: https://acsearch.acr.org/docs/69379/Narrative/. Accessed January 10, 2024.

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Venook AP. Nonsurgical Local Treatment Strategies for Colorectal Cancer Liver Metastases. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed January 10, 2024.

Regulatory References

New York State Department of Health, Division of Managed Care Response to Coverage Question (CovQuest) January 16, 2018.

This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No☐

Revision Date	Owner	Notes
3/1/2024	Health Care Services	Reviewed
1/1/2024	Health Care Services	Revised
3/1/2023	Health Care Services	Revised
3/1/2022	Health Care Services	Revised
3/1/2021	Health Care Services	Reviewed
3/1/2020	Medical Management	Revised
4/1/2019	Medical Management	Revised