MEDICAL POLICY

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Medical Policy Title	**Radioembolization (TARE) for Hepatic Tumors**
Policy Number	**7.01.69**
Current Effective Date	February 20, 2025
Next Review Date	February 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

This policy does not address Transarterial Chemoembolization (TACE).

I. Transarterial Radioembolization (TARE) using radioactive Yttrium-90 (90Y) microspheres is considered **medically necessary** as a treatment for **EITHER** of the following indications (Refer to Policy Guidelines):

A. Primary Hepatic Tumors

1. Treatment of unresectable or medically inoperable hepatic tumors including **ANY** of the following:

a. Hepatocellular carcinoma (HCC);

b. As a bridge to transplant for patients with HCC who:

i. meet liver transplant criteria and are waiting liver transplantation;

c. Intrahepatic cholangiocarcinoma (ICC)

OR

B. Metastatic Hepatic Tumors

1. Treatment of unresectable or medically inoperable hepatic metastases when **ALL** of the following criteria are met:

a. Individual is not a candidate for chemotherapy or other systemic therapies, or is refractory to chemotherapy; with **ANY** of the following indications:

i. neuroendocrine tumors (e.g., carcinoids, pancreatic islet cell tumors, endocrine tumors)

ii. colorectal carcinoma;

iii. breast carcinoma;

iv. melanoma (ocular or cutaneous).

II. A second (repeat) TARE is considered **medically necessary** when **ALL** of the following criteria are met (Refer to Policy Guidelines):

A. Treatment is for a new, progressive primary or metastatic hepatic tumor

B. A previous satisfactory response to an initial radioembolization treatment was attained as evidenced by **all** of the following criteria:
   1. Completion of a computed tomography (CT) scan or positron emission tomography (PET)-CT scan, performed 3 months following the previous procedure; and
   2. Response should be graded according to the revised Response Evaluation Criteria in Solid Tumors (RECIST) guideline (Version 1.1);

C. There are no other effective systemic or liver-directed treatment options available;

D. The individual has compensated liver function tests;

E. Estimated lung dose and combined lung dose from previous radiation are within acceptable dose volume constraints;

F. Treatment should be given to a targeted tumor volume.

III. A third TARE is considered **not medically necessary**.

IV. TARE as a treatment for all other metastatic or primary hepatic tumors is considered **investigational**.

RELATED POLICIES

This policy does not address arterially directed therapies other than TARE.

Corporate Medical Policy

11.01.10 Clinical Trials

11.01.03 Experimental or Investigational Services

7.02.07 Liver Transplantation

7.01.111 Thermal Ablation for Solid Tumor Treatment

POLICY GUIDELINE(S)

I. TARE should be reserved for patients with:
   A. An Eastern Cooperative Oncology Group (ECOG) performance status no greater than 2 or Karnofsky Performance Status (KPS) of 70 or above;
   B. Adequate liver function and reserve, and liver-dominant metastases;
   C. Life expectancy of greater than three (3) months.

II. Radioactive Yttrium-90 (90Y) microspheres treatment is allowed only in the outpatient setting unless the documentation supports the medical necessity of inpatient treatment.

DESCRIPTION

Hepatic tumors can arise either as primary liver cancer or by metastasis to the liver from other tissues or organs. At present, surgical resection with tumor-free margins and liver transplantation are

the only potentially curative treatments for hepatic cancer. Unfortunately, most hepatic tumors are not amenable to resection or transplantation at diagnosis, due to their anatomic location, tumor size, the number of lesions, concurrent nonmalignant liver disease, or insufficient hepatic reserve. Patients with hepatic tumors may require treatments to downstage disease in order to meet criteria for a liver transplant (Milan criteria, etc.) and those individuals who do meet become candidates often require bridge therapy due to the long wait times to obtain the transplant. Various minimally invasive ablative techniques have been investigated that seek to cure or palliate unresectable hepatic tumors by improving loco-regional control. Examples of these techniques include TARE, transarterial chemoembolization, and thermal ablative techniques such as radiofrequency ablation, cryotherapy, and microwave ablation.

The content of this policy addresses the use of TARE, is also known in the literature as Selective Internal Radiation Therapy (SIRT), and arterial radioembolization with yttrium-90 (^{90}Y). TARE relies on targeted delivery of small beads (microspheres) impregnated with ^{90}Y, a radioactive beta emitter with a short half-life of 64.2 hours (2.67 days). TARE uses local anesthesia and fluoroscopic guidance to inject the radioactive material into the left, right or common hepatic artery via a percutaneous (femoral or gastroduodenal) catheter. This allows the delivery of a concentrated dosage of radiation directly into the tumor bed, while conserving the normal liver tissue that surrounds the tumor. The size of the microspheres causes them to become entrapped within the tumor vasculature and retained. The treatment goals with TARE can include curative intent, bridging to transplant, downsizing disease to assist with resection, inform the treatment approach and to provide valuable information for radiation dosimetry. TARE can usually be performed in an outpatient setting, as there is no radiation exposure to others once the microspheres have been infused.

Eastern Cooperative Oncology Group (ECOG) Performance Status (Oken et al. 1982)

Performance Status	Description
0	Fully active; no performance restrictions
1	Strenuous physical activity restricted; fully ambulatory and able to carry out light work
2	Capable of all self-care but unable to carry out any work activities Up and about > 50% of waking hours.
3	Capable of only limited self-care; confined to bed or chair >50% of waking hours
4	Completely disabled; cannot carry out any self-care; totally confined to bed or chair

SUPPORTIVE LITERATURE

Hepatocellular Carcinoma (HCC)

TARE has been studied for its use in all stages of HCC and has demonstrated comparable outcomes to the historical therapies of choice, including transarterial chemoembolization for intermediate stage HCC, and systemic therapy in patients with advanced HCC.

In 2016, Salem and colleagues conducted a randomized phase II trial (PREMIERE) comparing TARE to TACE in 179 patients with HCC with a Barcelona Clinic Liver Cancer stage of A or B. There was no difference noted in overall survival (OS), but authors found that TARE provided significantly longer time to progression (TTP) over TACE, patients had fewer related adverse events, and improved quality of life. Authors concluded that given given these outcomes, TARE provides better tumor control, and further, that it could reduce the amount of patients who drop out of the liver transplant waitlists.

The LEGACY Study (Salem 2021) evaluated TARE as a primary treatment of naïve solitary HCC tumors less than or equal to 8cm in size. The retrospective single arm study evaluated the overall response (OR) rate and duration of response and determined an OR of 88.3% with 62.2% of the lesions having a duration of response greater than six months, which again, is critical for patients awaiting transplant. The patients that had received surgical resection or transplant had an overall survival of 86.6% and 92.8%. Authors concluded that radioembolization for solitary HCC is safe and efficacious when neoadjuvant to transplant or resection, or as a stand-alone treatment.

Trials have demonstrated that there is no difference in OS or progression free survival (PFS) when comparing TARE with the use of the use of tyrosine kinase inhibitor sorafenib (Vilgrain 2017) for the treatment of HCC. Additionally, better treatment tolerance, and less adverse effects were noted with TARE.

Neuroendocrine Tumors

While studies investigating TARE for neuroendocrine tumors have limitations such as heterogeneous patient populations, studies report relief of symptoms from carcinoid syndrome in a proportion of patients. Surgical debulking of liver metastases has shown palliation of hormonal symptoms; debulking by radioembolization may lead to symptom relief in some patients (e.g., Sato et al. 2008; Kennedy et al. 2009; Cao et al. 2010; Cramer et al. 2016).

Metastatic Colorectal Cancer

A major cause of morbidity and mortality in patients with colorectal disease when metastatic to the liver is liver failure, as this disease tends to progress to diffuse, liver-dominant involvement. The literature demonstrates that the use of TARE to decrease tumor bulk or halt TTP and liver failure, may lead to prolonged PFS and OS in patients with no other treatment options (e.g., those with chemotherapy refractory liver-dominant disease). Other uses include palliation of symptoms (e.g., Kennedy et al. 2009, 2016; Mulcahy et al. 2009; Hendlisz et al. 2010; Damm et al. 2016; Jakobs et al. 2017).

In a 2021 randomized phase III trial, Mulcahy et al. investigated the role of TARE when combined with standard-of care second-line systemic chemotherapy for the treatment of colorectal liver metastases. The study was conducted in over 95 centers internationally and included 488 patients whose disease had progressed despite first-line chemotherapy. The patients were randomly assigned

to chemotherapy with or without TARE. Primary end points were PFS and hepatic PFS (hPFS) from the time of group assignment using RECIST 1.1. Results demonstrated that the primary end points of PFS and hPFS were longer with the addition of TARE to second-line chemotherapy. Further, TTP was observed for tumors with KRAS mutation, left-side primary tumor, hepatic tumor burden of 10%-25%, ≤3 lesions, addition of a biologic agent, and resected primary disease. The study was limited by its design, in that it was not powered for OS, and higher rates of additional local therapy (including TARE) occurred in the control arm; which prevents the ability to draw strong conclusions based on the results. Authors determined that although the addition of TARE to systemic therapy improved PFS and hPFS in the second-line setting for colorectal liver metastases, further studies are needed to identify the optimal second-line patient population that would most benefit from treatment.

Bridge Therapy

Gabr et al. (2020) performed a retrospective review reporting the long-term outcomes of 207 liver transplantation patients with HCC who were bridged or down staged with TARE from 2004 to 2018. The median OS from liver transplant was 12.5 years, with a median time to liver transplantation of 7.5 months (interquartile range, 4.4 to 10.3). Overall, 169 patients were bridged and 38 were down staged. The OS rates at 3, 5, and 10 years were 84%, 77%, and 60%, respectively. Disease specific mortality was 6%, 11%, and 16% at 3, 5, and 10 years. No differences were noted in recurrence free survival and OS for patients who were bridged or downstaged. Recurrence free survival was greater in patients with complete/extensive tumor necrosis vs. partial. Authors came to the concluded TARE is an effective treatment for HCC in the setting of bridging/downstaging to liver transplant.

Lopez et al. conducted a systematic literature review (2023) to analyze relevant data regarding patient selection, HCC features and outcomes after TARE for downstaging or bridging in liver transplant. A total of 14 studies representative of 204 patients were included in the analysis, which was made up of the following treatments included in the studies: downstaging (n=7), bridging (n=3), and mixed (downstaging and bridging, n=4). For patients with remaining viable tumor after imaging, or for those who had planned staged procedures due to bilobar disease, multiple TARE interventions were required (16.7% to 28% of patients). A total of 55 patients were transplanted after undergoing TARE for downstaging. The percentage of patients who received a response, by study group and type is as follows:

Study Group	Complete Response	Partial Response	Stable Disease	Progressive Disease
Downstaging	26.7%	49.2%	13.4%	10.7%
Bridging	41.8%	34.1%	17.6%	6.6%
Mixed	30.8%	35.9%	33.3%	0%

Despite limitations including study design, high dropout rates due to death or tumor progression, and authors believing comparisons to be underpowered, they concluded that the use of TARE is an alternative treatment in patients with advanced HCC who were not initially suitable for resection or liver transplant.

Other Hepatic Metastases

A 2024 study (NCT 02685631) by Zhou et al. aimed to evaluate the response and survival outcomes of TARE on unresectable liver-dominant metastases from primary neoplasms other than colorectal carcinoma (m-non-CRC). The study included 1474 patients from the Radiation-Emitting Society of Interventional Radiology SIR-Spheres in Nonresectable Liver Tumor registry (RESiN). Of the study participants, 33% had liver metastases of non-colorectal origin, 34% had metastatic colorectal cancer, 34% had HCC). Responses were identified in 12 unique cancer types, most of which were identified as refractory to several lines of systemic therapies. Outcomes provided within the study were as follows:

Study Group	Complete Response	Partial Response	Stable Disease	Progressive Disease	Objective Response Rate	Disease Control Rate	Median Duration of Response
m-CRC n=248	Not Available	Not Available	Not Available	31%	31%	69%	9 months (95% CI, 6–13 months)
m-non-CRC n=250	6%	39%	28%	27%	46%	73%	11.5 months (95% CI, 8–19 months) for m-non-CRC (P = .04 for comparison between mCRC and m-non-CRC groups).
HCC n=255	Not Available	Not Available	Not Available	21%	50%	79%	16 months (95% CI, 11–19 months) for HCC

The study demonstrated better outcomes with the m-non-CRC group for duration of response, PFS, TTP, and OS when compared to the reference standard for metastatic colorectal cancer. Metastatic neuroendocrine tumor, sarcoma, ovarian, renal, prostate, and breast cancers were associated with superior treatment outcomes. Worse treatment outcomes were observed in metastatic lung, gastric, pancreatic, and esophageal cancers. Although promising for certain indications, this study did have

several limitations including its design which did not include a control arm or predefined number of patients for each cancer type. The patient population was heterogeneous and obtained from RESiN, a non- randomized observational registry and therefore, differences in patient's extent of disease, treatment timing and use of other therapies does not allow for applicability to the general population. Authors concluded that despite its limitations, the use of TARE in m-non-CRC patients may provide an important option for some patients with late-stage disease whose malignancies are rarer.

Melanomas

A 2017 systematic review by Jia et al. aimed to assess the effectiveness of TARE in the treatment of unresectable liver metastases from melanoma. A total of 12 reports were included in the analysis, of which, 7 were observational studies and 5 were conference abstracts. The reports represented 255 patients with primary sites of melanoma consisting of cutaneous (8.6%), ocular (77.3%), rectal (1.2%) and unknown (12.9%). Among the 207 patients, complete response was seen in 1.0% (2/207), partial response was seen in 19.3% (40/207), stable disease was seen in 46.9% (97/207), and progressive disease was seen in 32.9% (68/207). The median survival was 10 months (range, 7-13.4 months), and the median 1-year survival rate was 34.6% (range, 23%-80%). Authors concluded that TARE is a promising alternative therapy with encouraging effects on disease control and survival in patients with melanoma, given the lack of alternative treatments for this patient population.

A prospective phase II trial (NCT01473004) from Gonsalves and colleagues (2019) aimed to assess the safety and effectiveness of TARE for the treatment of uveal melanoma hepatic metastases by studying the level of response, PFS, and OS after TARE, comparing treatment naïve participants (Group A, n=23) to patients who progressed after immmunoembolization, who had less than a 50% tumor burden (Group B, n=24). Patients were followed for 1 month and then every 3 months for toxicities, with MRI, CT and PET performed every 3 months. Patients were followed for a minimum of 2 years or until death. A median OS of 18.5 months and 19.2 months with a 1-year survival of 60.9% and 69.6% was achieved in treatment Groups A and B, respectively. Survival outcomes were attributed to the stabilization of hepatic tumors in 87.0% and 58.3% of participants in groups A and B, respectively. Additionally, PFS was 8.1 months and 5.2 months for group A and B participants, respectively. Despite the stabilization noted, greater than 90% of participants developed new hepatic and extrahepatic metastases following treatment. The treatment was well tolerated with no instances of radiation-induced liver disease and clinically significant treatment-related toxicities were temporary and uncommon. The authors concluded that given there are no effective systemic treatments available for metastatic uveal melanoma, radioembolization is a safe and effective first-or second-line treatment for uveal melanoma hepatic metastases.

A retrospective analysis (Ponti et al. 2020) of a prospectively collected cohort was conducted evaluating 22 patients with uveal melanoma metastatic to the liver and treated with first-line TARE. Authors set to investigate the safety and efficacy of TARE as a first-line therapy, given data were lacking when compared to its use as salvage therapy. According to the European Association of the Study of Liver Disease (EASL) Criteria, disease control at 6 months after TARE was achieved in 15 of the 29 TARE patients and was predictive of survival. Median overall survival from the first TARE was 18 months (95% confidence interval [CI], 8–28 months). At the time of the analysis, 5 patients

(23%) had survived. In multivariate analysis, largest lesion size (hazard ratio [HR], 1.22; 95%CI, 0.98–1.53], liver tumor volume (HR, 1.002; 95%CI, 1.0004–1.003), subsequent systemic therapy (HR, 0.04; 95%CI, 0.006–0.24), and liver-directed locoregional therapy (HR, 0.204; 95%CI, 0.04–0.94) were predictive of survival. The authors concluded that based on study results, TARE is safe and produced promising outcomes in patients with uveal melanoma metastatic to the liver, but that prospective trials using first-line TARE are desirable.

Intrahepatic Cholangiocarcinoma (ICC)

To investigate the efficacy and survival profile of TARE for unresectable ICC, Schartz et al. 2022 conducted a systematic review and meta-analysis of 21 studies representing 921 patients using a random effects model. The study measured for disease control rate (DCR), down staged-to resectable rate, cancer antigen CA 19-9 response rate, pooled median OS, pooled median PFS, and mean reported survival rates from 3 to 36 months. The overall DCR was 82.3%. In 11% of the cases, patients were down staged to being surgically resectable. The CA 19-9 response rate was 67.2%. From the time of radioembolization, PFS was 7.8 months and median OS was 12.7 months. The mean overall reported survival proportions were 84% at 3 months, 69% at 6 months, 47% at 12 months, 31% at 18 months, 30% at 24 months, 21% at 30 months, and 5% at 36 months. The authors conclude that TARE for unresectable ICC results in substantial downstaging, disease control, and survival.

In an effort to identify factors associated with an improved median OS in ICC patients receiving radioembolization, Schaarschmidt and colleagues (2023) conducted a retrospective study of five major tertiary care centers. The study analyzed outcomes of 138 radioembolizations conducted in 128 patients with ICC. Radioembolization was performed as first-line treatment in 25.4%, as second-line treatment in 38.4%, and as salvage treatment in 36.2%. The disease control rate was 68.6%, 52.8%, and 54.0% respectively, after 3 months; 31.4%, 15.1%, and 12.0% after 6 months; and 17.1%, 5.7%, and 6.0% after one year. In patients receiving radioembolization as first-line, second-line, and salvage treatment, Median OS was 12.0 months for patients receiving radioembolization as first-line treatment, 11.8 months for patients receiving second-line treatment, and 8.4 months for those with salvage treatment. No significant differences were observed between the three groups (P=0.15). Limitations of the study were noted, including its retrospective design, with selection bias potential due to a highly probability that radioembolization was reserved for patients ineligible for surgery or chemotherapy, and the likelihood that patients with comorbidities were included in the cohort for a first-line radioembolization. Given the limitations, authors conclude that second-line and salvage radioembolization may be an important option for advanced ICC, and that its use as a first-line therapy requires further investigation.

Breast

Liu et al. (2022) published a systematic review and meta-analysis assessing the evidence for TARE in liver metastatic breast cancer. A total of 24 studies (N=412) were included, most of which were retrospective or non-comparative. Patient demographic information was not summarized. The median survival time after TARE was 9.8 months. The cumulative OS rates at 6 months and one, two, and three years were 65.6% (95% CI, 60.8% to 70.0%), 39.0% (95% CI, 34.3% to 43.7%), 13.3% (95% CI,10.3% to 16.8%), and 4.4% (95% CI, 2.7% to 6.6%), respectively. Patients who had a

hepatic metastatic burden exceeding 25% experienced a median survival time of 6.8 months, while those with a burden less than 25% had a median survival time of 10.5 months (p<.0001).

PROFESSIONAL GUIDELINE(S)

The National Comprehensive Cancer Network's (NCCN) V. 3. 2024 Guidelines for Hepatocellular Carcinoma recommends TARE as bridge therapy to decrease tumor progression and the dropout rate from the liver transplantation waiting list.

The NCCN's V.6.2024 Guidelines for Intrahepatic Cholangiocarcinoma recommends arterially directed therapies alone or followed by systemic chemotherapy with the intention to prolong survival or downstage ICC to curative resection.

The NCCN's Guidelines for Uveal Melanoma V.1.2024 recommends TARE. Recommendations are based upon disease control rates being consistently greater than 50% in retrospective studies. Additionally, the treatment is well tolerated, with most toxicities being grade 1-2 and self-limiting, with no treatment related deaths.

The American Association for the Study of Liver Diseases (AASLD), in an updated 2023 practice guideline regarding the prevention, diagnosis, and treatment of individuals with HCC, states that the use of TARE with Yttrium-90 has been established as an acceptable treatment for solitary unresectable HCC, and there are increasing data for its utilization to enhance the future liver remnant size. Enhancing the future liver remnant size before resection ensures the remaining liver can adequately function after diseased tissue removal. Additionally, regarding use of TARE as a bridge to transplant, the AASLD highlights that due to the mandatory 6-month wait time prior to the awarding of Model for End-Stage Liver Disease (MELD) exception, neoadjuvant treatment is typically used as a bridge to control tumor growth and reduce the risk of waitlist dropout (Singal et al., 2023).

A joint practice parameter on the use of TARE for the treatment of liver malignancies was published by the American College of Radiology (ACR), American Brachytherapy Society (ABS), American College of Nuclear Medicine (ACNM), American Society for Radiation Oncology (ASTRO), Society of Interventional Radiology (SIR), and Society of Nuclear Medicine and Molecular Imaging (SNMMI) (Hong et al., 2021). The practice parameter defines indications for TARE which include the following:

- The presence of unresectable or inoperable primary or secondary liver malignancies (particularly colorectal cancer and neuroendocrine tumor metastases).
- The tumor burden should be liver dominant, not necessarily exclusive to the liver.
- Patients should also have a performance status that will allow them to benefit from such therapy.
- Life expectancy of at least 3 months

The American College of Radiology (ACR) (Koepsel et al., 2022) published ACR Appropriateness Criteria for the Management of Liver Cancer stating that TARE is appropriate for the treatment of the following indications:

<u>HCC</u>

- Solitary tumor less than 3 cm, cirrhotic
- Solitary tumor 3 to 5 cm, cirrhotic
- Multifocal, bilobar disease, at least 1 tumor greater than 5cm, cirrhotic
- Solitary or multifocal disease with vascular invasion, cirrhotic

Intrahepatic Cholangiocarcinoma

- Peripheral hepatic lobar cholangiocarcinoma, less than 3cm; no biliary ductal dilatation, macroscopic vascular invasion, regional lymphadenopathy, or distant metastases.

Ductal Cholangiocarcinoma

- Hilar cholangiocarcinoma, greater than 3 cm with poorly defined margins, vascular invasion, and periportal lymphadenopathy

Metastatic Liver Disease

- Multifocal metastatic neuroendocrine tumor (includes carcinoid tumors as well as islet cell tumors of the pancreas)
- Multifocal bilobar colorectal carcinoma (liver dominant or isolated)

REGULATORY STATUS

There are currently two types of Yttrium microspheres (glass and resin) that have been approved by the FDA and are classified as brachytherapy devices: TheraSpheres (Theragenics; Atlanta, GA) and SIR-Spheres (Sirtex Medical Limited; Lake Forest, IL). The FDA granted premarket approval of SIR-Spheres in 2002 for use in combination with 5-floxuridine (5-FUDR) chemotherapy to treat unresectable hepatic metastases from colorectal cancer. In contrast, the FDA approved TheraSpheres under the humanitarian device exemption (HDE) in 1999 for use as monotherapy to treat unresectable HCC. In January 2007, the HDE for TheraSpheres was expanded to include patients with HCC who have partial or branch portal vein thrombosis. In March of 2021, the FDA granted approval of the TheraSphere Y-90 Glass Microspheres, developed for the treatment of patients with HCC expanding access to this which previously could only have been used under an HDE.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
No CPT codes specific to TARE, but the following could be used*: *This policy does not address arterially directed therapies other than TARE.	
37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infraction
75894	Transcatheter therapy, embolization, any method, radiological supervision and interpretation
77778	Interstitial radiation source application, complex, includes supervision, handling, loading of radiation source, when performed
79445	Radiopharmaceutical therapy, by intra-arterial particulate administration

HCPCS Codes

Code	Description
A9543	Yttrium Y-90 ibritumomab tiuxetan, therapeutic, per treatment dose, up to 40 mCi
C2616	Brachytherapy source, nonstranded, yttrium-90, per source
S2095	Transcatheter occlusion or embolization for tumor destruction, percutaneous, any method, using yttrium-90 microspheres

ICD10 Codes

Code	Description
C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of colon

Code	Description
C18.9	Malignant neoplasm of colon, unspecified
C22.0	Liver cell carcinoma
C22.1	Intrahepatic bile duct carcinoma
C22.2	Hepatoblastoma
C22.3	Angiosarcoma of liver
C22.4	Other sarcomas of liver
C22.7	Other specified carcinomas of liver
C22.8	Malignant neoplasm of liver, primary, unspecified as to type
C22.9	Malignant neoplasm of liver, not specified as primary or secondary
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
Z76.82	Awaiting organ transplant status

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SEARCH TERMS

Sir-Spheres, Theraspheres, Selective Internal Radiation Therapy (SIRT), TARE-Y90

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Based on our review, Selective Internal Radiation Therapy is not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid

guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.

- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION	
Committee Approval Dates	
12/21/06, 12/20/07, 07/17/08, 08/20/09, 06/17/10, 06/16/11, 08/18/11, 08/16/12, 07/18/13, 06/19/14, 05/28/15, 04/21/16, 06/15/17, 08/16/18, 07/18/19, 08/20/20, 08/19/21, 02/17/22, 02/16/23, 02/22/24, 02/20/25	
Date	**Summary of Changes**
02/20/25	• Annual review, policy title change, policy statements added for primary intrahepatic cholangiocarcinoma, and metastatic hepatic tumors related to cutaneous melanoma as medically necessary when criteria are met.
01/01/25	• Summary of changes tracking implemented.
12/15/05	• Original effective date