



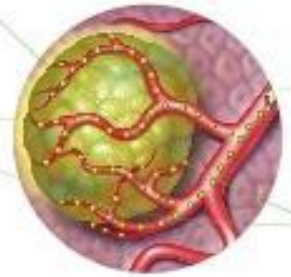
January 2019

Coding Guide

Pretreatment Mapping and
Microspheres Administration

Hospital Outpatient, ASC
OBIS and Physician Services





What are SIR-Spheres[®] yttrium-90 resin microspheres?

SIR-Spheres[®] Y-90 resin microspheres are microscopic spheres that are delivered via Selective Internal Radiation Therapy (SIRT) to liver tumors. The polymer microspheres with an average diameter of approximately 32.5 microns, are loaded with yttrium-90 (Y-90). After administration to the hepatic artery, SIR-Spheres yttrium-90 resin microspheres lodge preferentially in the vasculature of the tumor. The beta radiation remains localized, penetrating a mean of 2.5 mm in the tissue, destroying the tumor cells. Due to the half-life of 64.1 hours, most radiation (94%) is delivered in 11 days. The microspheres are biologically inert, and are not metabolized or excreted. Each vial is for a single patient use.

SIR-Spheres yttrium-90 resin microspheres are the ONLY fully FDA PMA approved yttrium-90 microspheres for the treatment of mCRC in the liver. The only yttrium-90 microspheres backed by randomized controlled trial (RCT) data, SIR-Spheres yttrium-90 resin microspheres can be used alone or in combination with chemotherapy.^{1,2,3}

SIR-Spheres yttrium-90 resin microspheres are the ONLY yttrium-90 microspheres administered using contrast imaging, ensuring visualization, and confirmation of distribution. Coupled with personalized dosing, and precise infusion, complete procedural control is assured.

Delivered through the hepatic artery, SIR-Spheres yttrium-90 resin microspheres directly target liver tumors with yttrium-90 beta radiation, minimizing healthy tissue exposure. Because these are the ONLY microspheres with a specific gravity similar to blood, infusion efficiency is enhanced, resulting in a homogeneous distribution, optimizing tumor coverage.

SIR-Spheres Y-90 resin microspheres

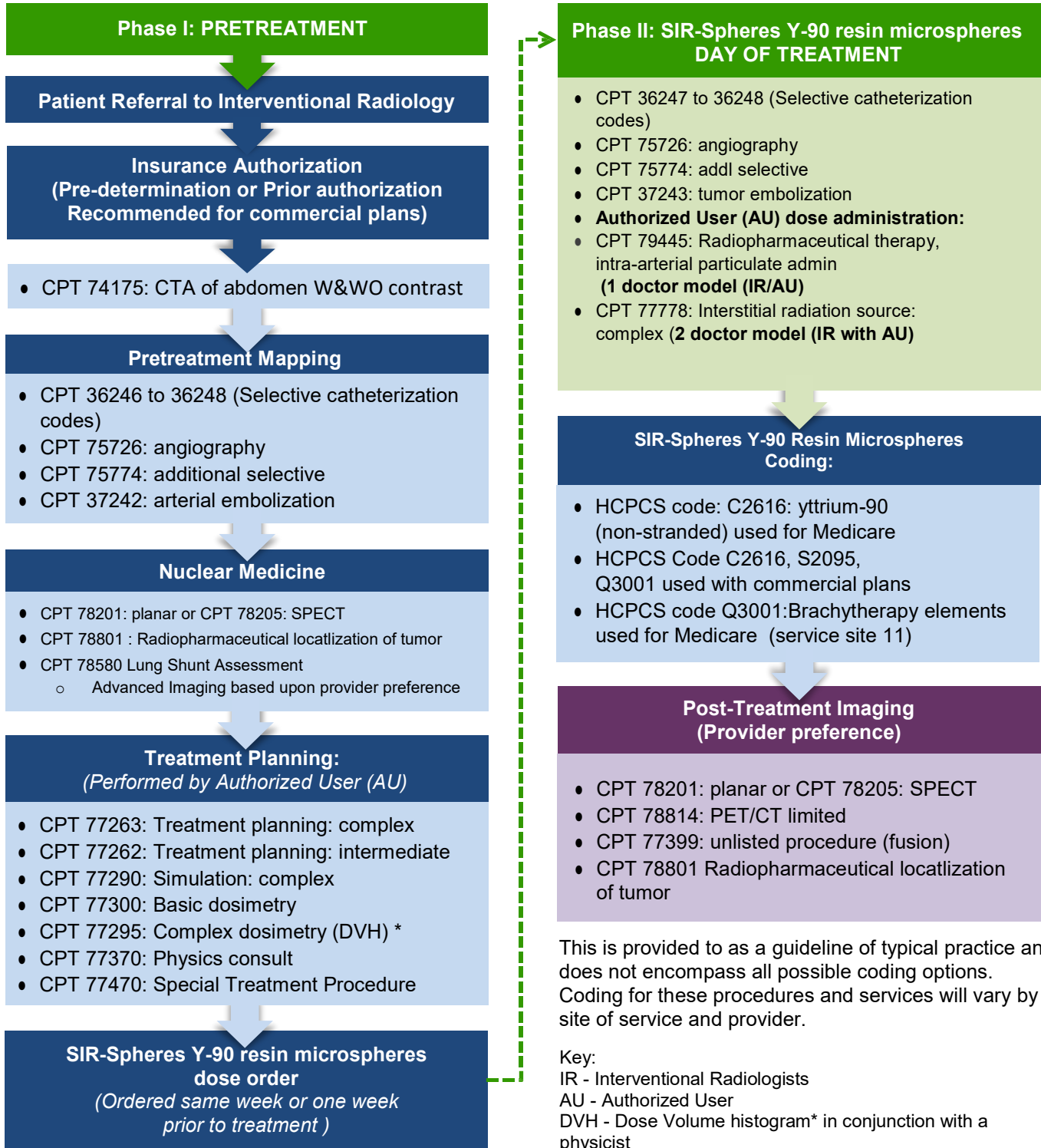
Microsphere material	Biocompatible Polymer
Isotope	Yttrium-90 permanently bound to the microspheres
Diameter	~32.5 µm
Penetration in tissue	2.5mm mean; 11mm maximum range
Half life	64.1 hours; 94% of the radiation decayed in 11 days
How supplied	3 GBq or 81 mCi per vial +/- 10% at the time of calibration
Number of particles per vial	40-80 million

1. Gray et al. *Ann Oncol* 2001;**12**:1711–20 2. van Hazel et al. *J Surg Oncol* 2004;**88**:78–85 3. Hendlisz et al. *J Clin Oncol* 2010;**28**:3687–94

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. SIR-Spheres Y-90 resin microspheres may only be distributed to a duly licensed or accredited facility capable of handling therapeutic medical isotopes. This product is radioactive and should thus be handled in accordance with all applicable standards and regulations. **Intended Use / Indications For Use:** SIR-Spheres Y-90 resin microspheres are approved for use in Argentina, Australia, Brazil, Canada, the European Union (CE Mark), Switzerland, Turkey, and several countries in Asia for the treatment of unresectable liver tumors. In the US, SIR-Spheres Y-90 resin microspheres have a Pre-Market Approval (PMA) from the FDA and are indicated for the treatment of unresectable metastatic liver tumors from primary colorectal cancer with adjuvant intra-hepatic artery chemotherapy (IHAC) of FUDR (Floxuridine). **Warnings / Precautions:** Inadvertent delivery of the microspheres to locations other than the intended hepatic tumor may result in local radiation damage. Due to the radioactivity and the significant consequences of misplacing the microspheres in situ, this product must be implanted by physicians who have completed the Sirtex TEC training program. A SPECT scan of the upper abdomen immediately after implantation is recommended. Patients may experience abdominal pain immediately after administration and pain relief may be required. H-2 blocking agents may be administered the day before implantation and continued as needed to reduce gastric complications. **Side Effects:** Common side effects are fever, transient decrease of hemoglobin, mild to moderate abnormality of liver function tests, abdominal pain, nausea, vomiting, and diarrhea. Potential serious effects due to exposure to high radiation include acute pancreatitis, radiation pneumonitis, acute gastritis, radiation hepatitis, and acute cholecystitis. **Contraindications:** SIR-Spheres Y-90 resin microspheres should not be implanted in patients who have either had previous external beam radiation therapy to the liver, ascites, or are in clinical liver failure. This device is contraindicated in patients with markedly abnormal synthetic and excretory liver function tests, greater than 20% lung shunting of the hepatic artery blood flow, disseminated extra-hepatic malignant disease, and portal vein thrombosis. This device should not be implanted in patients determined via angiogram to have an abnormal vascular anatomy that would result in significant reflux of the hepatic arterial blood flow to the stomach, pancreas or bowel. **Reference the Package Insert (www.sirtex.com) for a complete listing of indications, contraindications, side effects, warnings, and precautions.**

SIR-Spheres[®] yttrium-90 resin microspheres Patient Flow and Coding Reference Guide

The following patient flow and coding reference for SIR-Spheres yttrium-90 resin microspheres treatment



This is provided to as a guideline of typical practice and does not encompass all possible coding options. Coding for these procedures and services will vary by site of service and provider.

Key:
IR - Interventional Radiologists
AU - Authorized User
DVH - Dose Volume histogram* in conjunction with a physicist
CT - Computed tomography
CPT - Current Procedural Terminology
HCPCS - Healthcare Common Procedure Coding

**SIR-Spheres® yttrium-90 resin microspheres
Coding and Medicare National Average Reimbursement
2019 Hospital Outpatient (OPPS), Ambulatory Surgery Center (ASC) and
2019 Physician Services (MPFS)**

The SIR-Spheres yttrium-90 resin microspheres coding guide is designed to assist you with coding and billing for the SIRT yttrium-90 procedures. The codes and national average payments are based upon CY2019 Medicare OPPS Final Rule, Addendum B, published November 2, 2018. Medicare physician payment rates included in this coding guide are based on current law, including the Pathway for SGR Reform Act of 2013 and the MPFS payment rates reflecting policies adopted in CY2019 Medicare Physician Fee Schedule Final Rule that appeared in the Federal Register on November 2, 2018. Medicare physician payment rates are based on conversion factor \$36.0391 through December 31, 2019.

Coding for administration of SIR-Spheres yttrium-90 microspheres can be complex. There is no consensus or consistency in the Coding/billing for the administration of SIR-Sphere microspheres. This coding guide provides SIR-Spheres resin microspheres Pre-Treatment and Day of Treatment coding options. Payer policies should be reviewed for coverage & coding guidelines.

FDA LABELED INDICATIONS FOR USE

SIR-Spheres yttrium-90 resin microspheres: Colorectal cancer metastasized to the liver in combination with hepatic arterial chemotherapy (FUDR) – Full PMA approval

Payment:

Centers for Medicare and Medicaid Services (CMS)

SIR-Spheres yttrium-90 resin microspheres are eligible for payment under the Medicare Hospital Outpatient Prospective Payment System (OPPS). Effective, January 1st each year, the OPPS reimbursement rate may be adjusted based upon hospital cost reports. SIR-Spheres Y-90 resin microspheres are paid separately from the facility technical charges as mandated by the 2003 Medicare Modernization Act.

HCPCS	Descriptor	APC / Status Indicator	Hospital Outpatient APC Payment (Jan 1, 2019)	Ambulatory Surgery Center Payment (Jan 1, 2019)
C2616	Yttrium-90 non-stranded	2616 / U	\$16,626.00	\$16,626.00

Medicare Overview and Coverage Policies:

Medicare patients have the option of enrolling in either traditional fee-for-service Medicare or Medicare Advantage plans. Traditional fee-for-service Medicare provides eligible beneficiaries with medical benefits through Medicare Parts A and B. Medicare Part B covers medically necessary services rendered in hospital outpatient facilities and freestanding physician offices. Medicare’s managed care option, or Medicare Advantage (MA), is also known as Medicare Part C. Commercial plans contract with the Medicare program to offer coverage to Medicare enrollees. MA plans must provide coverage that is equal to or greater than the coverage offered by the beneficiary’s local traditional fee-for-service Medicare Administrative Contractor (MAC). SIR-Spheres® resin microspheres are eligible for Medicare reimbursement. Local Medicare contractors have the ability to approve or deny coverage based on medical necessity, coding, and appropriate procedural documentation.

Commercial Payers:

Reimbursement for SIR-Spheres® yttrium-90 resin microspheres by private payers will depend upon the payers coverage policy, medical necessity criteria and by your facilities contracted rates for individual plans. Private or commercial insurance coverage varies between payers and their respective health plans. Coverage, coding, and reimbursement for SIR-Spheres® Y-90 resin microspheres and related procedures should be confirmed with the payer to determine any applicable coverage policies or criteria prior to performing a procedure. Many national, regional, and local companies have determined SIR-Spheres® Y-90 resin microspheres to be medically necessary. Pre-determination / prior authorization is recommended for most private insurance plans.

Medicaid:

Medicaid is a public insurance program funded jointly by federal and state governments that provides safety-net coverage mainly to low-income and disabled Americans. Medicaid is run at the state level, and coverage and benefit requirements vary from state to state. Some states structure Medicaid as a fee-for-service program or contract with private companies that administer individual Medicaid managed care plans. Medicaid coverage for SIR-Spheres® Y-90 resin microspheres and actual coverage amounts will vary by state and plan type (Managed Medicaid vs. State Medicaid). Many states publish fee schedules on their websites for fee for service plans. Most Managed Medicaid plans will determine reimbursement based upon the terms of the contracts with individual providers. You will need to contact your patient's state or Managed Medicaid plan to determine the actual reimbursement for the office or facility.

Hospital Pre-determination Process / Prior Authorization:

Medicare Advantage, private commercial, and Medicaid plans may require providers to obtain a pre-determination or prior authorization for SIR-Spheres® Y-90 resin microspheres coverage and related procedures. It is recommended that the coverage policies of your payer mix be researched and that applicable pre-determination requirements be understood prior to treating the patient. **Note: Obtaining a pre-determination / prior authorization is not a guarantee of coverage or payment. Coverage and payment determination can only be made at the time a claim is adjudicated.**

Medicare Place of Service Payment Methodology

Provider of Service	Place of Service Code	Medicare Payment Methodology
Hospital Outpatient	22	Hospital Outpatient Prospective Payment System (OPPS) payments made based on CPT codes under Ambulatory Payment Classifications (APC)
Ambulatory Surgery Center (ASC)	24	ASC Payment System is linked to the OPPS, paying ~65% of the APC payment
Office Based Interventional Suite	11	Medicare Physician Fee Schedule (MPFS) payments are based on relative values assigned to CPT codes (work, practice and malpractice expense)

ICD-10 Diagnosis Codes:

The following diagnosis code range is specific to colorectal cancer (SIR-Spheres microspheres is approved for colorectal cancer that has metastasized to the liver). If the cancer is other than colorectal metastases, consult your ICD-10-CM codebook for appropriate coding.

C18.0 – C18.9	Malignant neoplasm of colon
C19.0 – C21.1	Malignant neoplasm of rectum
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct

Microspheres Revenue Code:

Revenue Code: 0278 (Medical/Surgical Supplies – Other Implants)

Microspheres Coding:

The HCPCS codes used to report use of SIR-Spheres® Y-90 resin microspheres to payers, may vary by plan type and the site of service where treatment is rendered. The following codes may be appropriate depending on payer

HCPCS	Descriptor	Payer(s)	Place of Service
C2616	Brachytherapy source, non-stranded, Yttrium-90, per source	Medicare; some private payers	Hospital outpatient 22 ASC 24
S2095	Transcatheter occlusion or embolization for tumor destruction, percutaneous, any method, using yttrium-90 microspheres	Not used by Medicare; Used by Blue Cross and Blue Shield and some UHC plans	Hospital outpatient 22 ASC 24 Office Based Interventional Suite 11
Q3001	Radioelements for brachytherapy, any type, each	Medicare; some private payers	Office Based interventional Suite 11

Important Provider Notice:

National Correct Coding Initiative (CCI) Edits may result in coding conflicts for various treatments and procedures. Providers should carefully review each quarter’s CCI edit updates. CCI edits may be downloaded from the CMS website at: <http://www.cms.gov/NationalCorrectCodInitEd/>. Questions, concerns or comments regarding specific NCCI edits, may be submitted in writing to:

National Correct Coding Initiative
 Correct Coding Solutions LLC (Fax #: 317-571-1745)
 P.O. Box 907
 Carmel, IN 46082-0907
 Attention: Niles R. Rosen, MD, Medical Director

Pretreatment and Mapping – Medicare January 2019

CPT	APC	CPT Description ¹ <i>See 2018 CPT Guide for full descriptions</i>	Facility Payment		Physician Payment	
			Hospital Outpatient	Ambulatory Surgery Center	Physician (Facility) ²	Physician (Non-Facility) ³
E&M CODES – E&M codes will vary; consult your most recent CPT Coding Guide for E&M coding options and guidelines						
PHASE I: PRE-PLANNING – MAPPING CODING⁴						
Selective Catheterizations for Diagnostic Procedure						
36246	NA	Selective catheter placement; initial second order	\$00	\$00	\$266	\$858
36247	NA	; initial third order or more	\$00	\$00	\$316	\$1,535
36248	NA	; addl second order, third order and beyond	\$00	\$00	\$51	\$148
Hepatic Angiogram						
75726	5184	Angiography, visceral, radiological S&I	\$4,377	\$00	\$56	\$147
75774	NA	Angiography, selective, radiological S&I	\$0	\$00	\$18	\$84
Embolization (if indicated)						
37242	5193 (J1*)	Arterial embolization or occlusion, inclusive of all radiological S&I; arterial other than hemorrhage or tumor	\$9,669.00	\$5,787	\$500	\$7,622
*NOTE: The APC J1 status indicator for CPT 37242 provides one bundled payment for all services provided in the facility setting considered integral, ancillary, supportive and/or adjunctive to the primary service (CPT 37242). If embolization is performed, all services provided on the same day of service will be packaged into the J1 APC payment for 37242.						
Treatment Planning – AU (Authorized User) Work						
77262 ⁵	NA	Treatment Planning; intermediate OR	\$0	\$0	\$110	\$110
77263 ⁶	NA	Treatment Planning; complex	\$0	\$0	\$172	\$172
77290	5612	Complex Simulation	\$322	\$166	\$84	\$520
77300	5611	Basic Dosimetry Calculation	\$124	\$34	\$34	\$68
77370 ⁶	5611	Special Medical Radiation Physics Consultation	\$124	\$64	\$0	\$127
77470 ⁷	5623	Special Treatment Procedure	\$520	\$26	\$109	\$135
77295 ⁸	5613	3D Rad plan	\$1,192	\$270	\$231	\$502
77399	5611	External radiation dosimetry	\$124	\$64	Carrier Determined	
78814	5594	PET/CT limited	\$1,376	\$708	\$109	\$109
78811	5594	PET limited (if PET/MRI) MRI code provider dependent	\$1,376	\$633	\$77	\$77

¹ Some CPT descriptors have been shortened for purposes of brevity. See your CPT Guide for full descriptors and coding guidelines.

² “Facility payment” refers to professional services rendered in a facility setting such as hospital or ASC.

³ “Non-Facility payment” refers to professional services provided in the physician freestanding office, surgical or cancer center.

⁴ The possible coding options listed in this section are based on Medicare guidelines and society recommendations. Medicare base case coding scenarios typical for one mapping and one treatment in the hospital outpatient or ASC setting follow this section.

⁵ Treatment planning should be billed and dictated separately prior to microspheres administration,

⁶ Use of this code requires a written order by the physician.

⁷ Used for brachytherapy and in circumstances requiring extra work over and above basic dosimetry calculation: Patient with previous chemo, is receiving concurrent chemo, or external beam radiation to the body/liver. AU must review current CT scan, liver function studies and ECOG performance status to determinate % yttrium-90 dose to be adjusted taking into account previous treatments. Often used as a re-treatment code. Should be supported by clinical treatment note.

⁸ 3 DVH calculations may be performed for the procedure with a Physicist.

Coding Options for SIR-Spheres® yttrium-90 resin microspheres Therapy

Pretreatment and Mapping (continued) – Medicare January 2019

CPT	APC	CPT Description ⁹ <i>See 2018 CPT Guide for full descriptions</i>	Facility Payment		Physician Payment	
			Hospital Outpatient	Ambulatory Surgery Center	Physician (Facility) ²	Physician (Non-Facility) ³
3-D Post-Processing (for liver volume)						
76376	N	3D Post Scan, not requiring image post-processing	\$0	\$0	\$10	\$23
76377	N	Cone Beam CT (<i>Medicare NCCI edit with 78580</i>)	\$0	\$0	\$41	\$72
CT Acquisition (may be billed in conjunction with CPT code 76377)						
74150	5522	CTA without contrast material	\$113	\$58	\$61	\$152
74160	5571	CTA; with contrast material(s)	\$202	\$104	\$65	\$242
74170	5571	CTA; with and without contrast	\$202	\$104	\$72	\$275
74175	5571	CTA; abdomen & pelvis, with & without contrast	\$202	\$104	\$93	\$320
Pre-Treatment Imaging (coding options will vary based on provider preference)						
78201	5593	Liver imaging, static	\$1,229	\$633	\$22	\$198
78205	5593	Liver imaging (SPECT) <i>*(Medicare NCCI edit with C2616)</i>	\$1,229	\$633	\$34	\$219
78215	5591	Liver Spleen Imaging	\$353	\$182	\$25	\$202
78580	5591	Pulmonary perfusion imaging (<i>Medicare NCCI edit 76377</i>)	\$353	\$182	\$37	\$248
78800	5591	Radiopharmaceutical localization of tumor; limited are	\$353	\$182	\$35	\$202
78801	5591	Radiopharmaceutical locatioization of tumor	\$353	\$182	\$40	\$267
78802	5593	Radiopharmaceutical localization whole body, single day	\$1,229	\$633	\$43	\$335
78803	5592	Radiopharmaceutical localization of tumor (SPECT)	\$455	\$235	\$53	\$354
78811	5593	Optional Procedure - PET; limited area	\$1,229	\$633	\$77	\$77
A9540 ¹⁰		Technetium 99m macroaggregated albumin	\$0	\$0	NA	\$0

⁹ Some CPT descriptors have been shortened for purposes of brevity. See your CPT Guide for full descriptors and coding guidelines.

¹⁰ Do NOT code CPT 79445 for the injection of TC99 MAA on the mapping day as this is considered part of the nuclear medicine exam.

Day of Treatment - Medicare January 2019

CPT	APC	CPT Description ¹¹ <i>See 2018 CPT Guide for full descriptions</i>	Facility Payment		Physician Payment	
			Hospital Outpatient	Ambulatory Surgery Center	Physician (Facility) ²	Physician (Non-Facility) ³
PHASE II: Day of Treatment (Administration / Implant)						
Selective Catheterizations						
36247	NA	Selective catheter placement; initial third order or more	\$00	\$00	\$316	\$1,535
36248	NA	; additional second order, third order and beyond	\$00	\$00	\$51	\$148
Hepatic Angiogram						
75726	5183	Angiography, visceral, radiological S&I	\$4,377	\$00	\$56	\$147
75774	NA	Angiography, selective, radiological S&I	\$0	\$00	\$18	\$84
Coding Options for Billing of Sources (Yttrium-90 Microspheres – non stranded)						
C2616	2616	Brachytherapy source (yttrium-90 non stranded) <i>(Medicare - billed in OPPS/ASC)</i>	\$16,626	\$16,626	NA	Invoice
S2095	NA	Transcatheter embo for tumor destruction using yttrium-90 microspheres <i>(Private payer; billed in OPPS/ASC/OBIS)</i>	Private Payer Contract Price	Private Payer Contract Price	NA	Private Payer Contract Price
Q3001	NA	Brachytherapy Radioelements, any type <i>(billed In OBIS)</i>	NA	NA	NA	Invoice
Microspheres Administration						
37243	5193	Tumor embolization or occlusion, inc of all radiological (J1*) S&I; venous, for tumors, organ ischemia, or infarction	\$9,669	\$4,056	\$589	\$9,861
*Note: APC J1 status indicator for CPT 37243 provides one bundled payment for all services provided in the facility setting considered integral, ancillary, supportive and/or adjunctive to the primary service (CPT 37243).						
Microspheres Administration: Authorized User Codes						
77262 ⁵	NA	Treatment Planning; intermediate OR	\$0	\$0	\$110	\$110
77263 ⁶	NA	Treatment Planning; complex	\$0	\$0	\$172	\$172
77290	5612	Simulation: complex	\$322	\$166	\$84	\$520
77300	5611	Basic Dosimetry Calculation	\$125	\$34	\$35	\$68
77295 ⁸	5613	3D Rad plan	\$1,187	\$270	\$231	\$502
77370 ⁶	5611	Special Medical Radiation Physics Consultation	\$124	\$64	\$0	\$127
77470 ¹²	5623	Special Treatment Procedure	\$520	\$26	\$109	\$135
79445	5661	Radiopharmaceutical therapy, intra-arterial particulate Admin (1 doctor model (IR/AU) or 2 doctor model IR with separate AU) OR	\$231	\$119	\$117	\$117
77778 ¹³	5624	Interstitial radiation source application; complex (2 Doctor model IR with separate AU)	\$705	\$363	\$471	\$867
77790 ¹⁴	N	Supervision, handling, loading of radiation source	\$0	\$0	\$15	\$15

¹¹ Some CPT descriptors have been shortened for purposes of brevity. See your CPT Guide for full descriptors and coding guidelines.

¹² Used in circumstances requiring extra work over and above basic dosimetry calculation: Patient with previous chemo, is receiving concurrent chemo, or external beam radiation to the body/liver. AU must review current CT scan, liver function studies and ECOG performance status to determinate % yttrium-90 dose to be adjusted taking into account previous treatments. Often used as a re-treatment code.

¹³ Medicare NCCI edit with 37243

¹⁴ Medicare packages this service with CPT 79445

Coding Options for SIR-Spheres® yttrium-90 resin microspheres Therapy



Day of Treatment (continued) – Medicare January 2019

Physician Payment

CPT	APC	CPT Description ¹ <i>See 2018 CPT Guide for full descriptions</i>	Hospital Outpatient	Ambulatory Surgery Center	Physician (Facility) ²	Physician (Non-Facility) ³
Post Treatment Imaging (coding options will vary based on provider preference)						
74170	5571	CTA; with and without contrast	\$202	\$104	\$72	\$275
74175	5571	CTA abdomen & pelvis, with & without contrast	\$202	\$104	\$93	\$320
78201	5593	Liver imaging, static	\$1,229	\$633	\$22	\$198
78205	5593	Liver imaging (SPECT)* (Medicare NCCI edit with C2616)	\$1,229	\$633	\$34	\$219
78215	5591	Liver Spleen Imaging	\$353	\$182	\$25	\$202
78580	5591	Pulmonary perfusion imaging (Medicare NCCI edit 76377)	\$349	\$182	\$37	\$248
78800	5591	Radiopharmaceutical localization of tumor; limited area	\$353	\$182	\$35	\$202
78801	5591	Radiopharmaceutical localization of tumor	\$353	\$182	\$40	\$267
78802	5593	Radiopharmaceutical localization whole body, single day	\$1,229	\$633	\$43	\$335
78803	5592	Radiopharmaceutical localization of tumor (SPECT)	\$456	\$235	\$53	\$354

HOSPITAL CHARGE MASTER REMINDER

- The hospital's charge master should reflect the following codes for the microspheres
 - C2616 (Brachytherapy source, yttrium-90 – non-stranded) mapped to Revenue Code 0278 and/or
 - S2095 (Trans-catheter occlusion or embolization for tumor destruction, percutaneous, any method, using yttrium-90 microspheres: BC/BS)
 - Q3001 (radioelements for brachytherapy, any type, each)
 - For Use In Office Based Interventional Suite
- Coding of SIR-Spheres Y-90 resin microspheres is dependent upon the patient's health insurance coverage. Private payer guidelines should be consulted for appropriate coding and payment.

NOTE: It is important to consult with the hospital finance department to determine the appropriate charges for the microspheres.

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