“FOR CMS (MEDICARE) MEMBERS ONLY”

Coverage Indications, Limitations, and/or Medical Necessity

Selective Internal Radiation Therapy (SIRT) is one of several treatment options for treatment of metastatic liver disease and hepatocellular carcinoma (HCC). In patients with surgically unresectable liver disease with or without extrahepatic disease, systemic chemotherapy has become the standard for first and second-line treatment. Combination therapy with angiogenesis inhibitors and surgical resection has now become an integral part of first and second-line therapies. Patients with liver-dominant disease in which standard first- and second-line therapies have failed may be considered for treatment with yttrium-90 (Y-90). The liver is the most frequent site of metastases, primarily as a result of the spread of cancer cells through the portal circulation. In fact, approximately 60% of patients with colorectal carcinoma eventually have liver disease as the predominant site. Similarly to HCC, surgical resection of metastatic hepatic disease is the treatment of choice. However, surgical resection is feasible in fewer than 20% of patients.

In HCC available treatment options depend on the size, number, and location of tumors; presence or absence of cirrhosis; operative risk based on extent of cirrhosis and comorbid diseases; overall performance status; patency of portal vein; and presence of metastatic disease. Before instituting definitive therapy, it is best to treat the complications of cirrhosis with diuretics, paracentesis for ascites, lactulose for encephalopathy, ursodiol for pruritus, sclerosis or banding for variceal bleeding, and antibiotics for spontaneous bacterial peritonitis. Since there is a paucity of liver allografts for transplantation, transplant is a limited option. Thus the main goal currently is disease control. Methods of disease control include:

- **surgical resection** partial hepatectomy which in the United States, is possible in only 5% of patients

- **liver transplantation** (Many patients are not candidates for partial hepatectomy due to extent of underlying liver disease. Some of these patients are good candidates for liver
transplantation since it has the potential for eliminating the cancer as well as curing the underlying liver disease.)
Partial hepatectomy and transplantation are the only chances of cure.

- **Systemic chemotherapy** (however HCC is a relatively chemotherapy resistant tumor)
- **Chemoimmunotherapy** (a combination of chemotherapy and immunomodulatory agents)
- **Chemoembolization** - Hepatic Arterial Chemotherapy (HAC), Embolizing agents such as cellulose, microspheres, lipoidal, and gelatin foam particles are used to deliver intraarterial chemotherapy (Other terms: Transarterial embolization and transarterial chemoembolization (TACE)
- **Local tumor ablation** Intratumoral injections of ethanol or acetic acid, heat (via radiofrequency, microwave, or laser ablation), or cold (cryoablation with liquid nitrogen), laser photocoagulation
- **Radiation therapy** (radiation therapy is limited by dose-related radiation hepatitis, which precludes the administration of external beam radiation in doses effective for tumor eradication. It is sometimes used for palliation)
- A new technology that uses a combination of robotics and image guidance to deliver concentrated and highly focused beams of radiation to the tumor while minimizing radiation exposure to the surrounding healthy liver tissue. (i.e. CyberKnife, SBRT)

Bridging therapy with local therapies, such as chemoembolization or radiofrequency ablation (RFA) is sometimes considered for patients on the transplant waiting list.

The main objectives for management of unresectable liver tumor are to control pain, to prolong survival and, if possible, to try to convert unresectable tumor to resectable tumor. Neoadjuvant therapy has been used clinically to downstage unresectable liver tumor. This can be achieved in 20%-66% of these patients depending on the study.

**Procedure:**
The radioactive isotope yttrium-90 is delivered via embolic spheres directly to the tumor. An interventional radiologist injects these beads through a catheter from the femoral artery in the groin to the liver artery supplying the tumor. The beads become lodged within the tumor vessels where they exert their local radiation that causes cell death. A very high dose of radiation is delivered to the liver without damaging other organs. Small microspheres (diameter 20-40 µm) containing a radioactive isotope are delivered directly into the hepatic (liver) artery by way of a catheter inserted through the femoral artery. The spheres get stuck in the capillary bed of the liver (they embolize), not only restricting the tumor blood flow, but also emitting localized radiation. The isotope emits beta-radiation with a limited range of about 1cm in soft tissue. This greatly reduces the chance that any neighboring tissue will be damaged.
Y-90 microsphere liver brachytherapy is the implantation of tiny spheres (microspheres) that contain, within their matrix, a therapeutic dose of a beta-emitting radionuclide. It is a type of permanent brachytherapy. Arteries convey the microspheres into the microvasculature of the tumor. Once in the periphery of the tumor, the microspheres lodge permanently in the tumor tissue, where they deliver a high dose of radiation before becoming inert. Selective targeting occurs because metastatic and primary tumors in the liver derive 80-100% of their blood supply from the arterial system. The diameter (32.5 ± 5 micron) of the microspheres prevents them from entering the venous capillary bed (normal diameter is 8 microns) or on into the lungs. In other words, the microspheres are small enough to embed preferentially in the tumor vasculature and not "upstream" of the tumor in normal liver tissue or “downstream” in the lung or other normal tissues.

The physical half-life of Y-90 microsphere is 64.1 hours. It decays 99.8% as beta particles, and 0.2% as gamma radiation with an average energy of 0.97 MeV. The effective range for cell destruction is 3mm from the microsphere. The radiation source is physically embedded within the tumor tissue so it is highly targeted. It delivers a high tumor dose and simultaneously spares nearby normal liver tissue from radiation damage. A diagnostic particle distribution precedes actual treatment delivery. Beta-emitting radioactive spheres are too small to be seen on CT or MRI scans, and beta radiation does not result in useful information on conventional nuclear scans. Instead, a surrogate albumin particle (macro-aggregated albumin, MAA) combined with the gamma emitter 99mTc scan is performed. This simulation procedure demonstrates the particle distribution and it is needed to ensure safe and effective brachytherapy. Since the albumin particles are metabolized by the liver in a few hours, they do not block the therapeutic microspheres' access to the tumor. The gamma emissions are of sufficient quantity and quality to enable single photon emission computed tomography (SPECT) image acquisition in a few minutes, producing three dimensional image data sets for review and brachytherapy treatment planning.

This radioembolization is a palliative treatment but patients benefit by extending their lives and improving their quality of life. It is a relatively new therapy that has been effective in treating primary and metastatic liver cancers. It is usually performed as an outpatient treatment.

To ensure safety, certain criteria must be met, including the use of the device with experienced users who have a comprehensive understanding of microsphere technology and are trained in qualified centers within the context of a team. The team includes: interventional radiology, nuclear medicine, medical physics, and radiation oncology specialists.

**Evaluation**

Before SIRT, a comprehensive history of the patient is obtained. All previous findings must be reviewed to establish the indication and any possible contraindications. Cross-sectional imaging is necessary. In any case, a CT of chest and abdomen with contrast should be obtained and an MRI may also be useful in some cases. A PET scan (Positron Emission Tomography) is useful in looking for tumor manifestations outside the liver. The indication
is established in close cooperation with the oncology and nuclear medicine teams.

The workup of the patient in preparation for intra-arterial yttrium therapy includes the following parameters:

1. Liver function tests including total bilirubin, ggt, alkaline phosphatase, AST, ALT, INR, as well as CBC with differential and CEA level.

   For HCC, other parameters that should be evaluated before treatment of liver cancers include tumor markers, most commonly: fetoprotein for hepatoma; carcinoembryonic antigen for colorectal malignancies; cancer antigen 19-9 for tumors of pancreaticobiliary origin, and serotonin/5-hydroxyindole acetic acid/chromogranin A for some neuroendocrine tumors.

2. A nuclear medicine study, macro-aggregated albumin scan with the diagnostic gamma emitter 99mTc, is performed prior to microsphere therapy and it shows that the majority of delivered particles will remain in the liver and will not pass into the next organ’s (i.e. the lung) vascular bed.

3. All pertinent imaging studies need to be reviewed by the interventional radiology team; these studies need to be scrutinized for disease burden in the liver, pulmonary nodules, patency of the portal vein, presence of the gallbladder and presence or absence of the biliary dilatation.

If these tests deem the patient a suitable candidate for radioembolization, the patient will need to undergo an extensive visceral arteriogram. This exam will determine the presence and location of the proper hepatic artery, right hepatic artery, left hepatic artery and their respective normal variations i.e. replaced right hepatic artery off the superior mesenteric artery, accessory replaced left hepatic artery off the left gastric artery. Additionally, a detailed assessment for the location of the right gastric artery, gastroduodenal artery, supraduodenal artery, retroduodenal artery and inferior phrenic arteries needs to be completed. It is imperative during this detailed visceral arteriogram to select and embolize the gastroduodenal artery and right gastric artery. These are the two major branch arteries that may inadvertently receive yttrium microspheres during definitive therapy. If yttrium microspheres embolize to these vessels, gastritis, gastric ulcer, duodenitis, duodenal ulcer, GI bleeding or pancreatitis may occur. Thus these two vessels need to be embolized if at all possible before definitive therapy with yttrium. Additionally, at the time of this arteriographic assessment, a vascular tracer such as technetium macroaggregated albumin (Tc-MAA) is selectively injected in the hepatic artery branch supplying the lobe of the liver being treated. In most instances, two separate treatments one to two months apart are done since metastatic disease in most instances is present in both right and left lobes of the liver. The purpose of this exam is to determine the degree of shunting between the liver and lung. If an excessive amount of shunting to the lungs occurs (greater than 20%), then the dose of yttrium-90 microspheres will need to be reduced or catheter placement modified to minimize toxicity and risk of resultant radiation pneumonitis and pulmonary fibrosis or the patient may not be a suitable candidate.
In summary, since colorectal cancer is in most instances, metastatic to both lobes of the liver, the patient will need to undergo at least two staging arteriograms (right lobe, left lobe with embolization of the right gastric artery and gastroduodenal artery) as well as two additional arteriograms during which selective treatment of the right and left lobes are done respectively.

For HCC
In contrast to metastatic tumors to the liver, one of the angiographic characteristics of HCC, other than portal vein thrombosis, is direct arteriovenous shunting bypassing the capillary bed. As a result, one of the concerns with administration of 20-40 µm Y-90 microspheres is direct shunting to the lungs, possibly resulting in radiation pneumonitis. Lung shunting is assessed with planar and/or single photon emission CT (SPECT)-cameras.

The final consideration in the angiographic evaluation of HCC and metastatic disease is the presence of flow to the gastrointestinal tract. During each step of visceral angiography, assessment for potential gastric or small-bowel flow must be made.

The topic of alteration in vascular anatomy to optimize Y-90 delivery is quite complex.

There are instances when patients could have vascular anatomy that may be altered percutaneously to achieve more favorable anatomy.

Dosimetry
Irrespective of the Y-90 microsphere agent used, it is imperative that dosimetry calculations be based on the volume of the target vascular bed supplied by the artery to be catheterized. The volume used for dose calculation is determined by the volume of the liver segment(s) being supplied by the artery to be infused.

The delivery of microspheres occurs on a separate day, typically a week later, and uses all the data acquired from the angiogram, MAA, and radiation treatment planning to safely deliver Y-90 microspheres to the affected lobes of the liver, or whole liver as needed. Immediately after treatment an additional gamma scan is obtained in both planar and SPECT to confirm the location of the majority of microspheres.

With respect to Theraspheres, the dosimetry is based on volume of liver being treated, i.e. HCC tumor in the right lobe, calculate from CT the volume of the right lobe and calculate the dose.

With respect to SIR-Spheres, dosimetry is based on body surface area optimal method or by estimating tumor burden present throughout the liver as follows:

Activity of SIR-Spheres in GBq = (BSA-0.2) + (volume of tumor/volume of tumor + volume normal liver)
BSA is calculated from weight/height chart
**Basic Method for SIR-Spheres for metastatic colorectal cancer**

<table>
<thead>
<tr>
<th>Estimated tumor burden of the liver</th>
<th>Recommended yttrium-90 amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;50%</td>
<td>3GBq (whole liver)</td>
</tr>
<tr>
<td>25-50%</td>
<td>2.5GBq (whole liver)</td>
</tr>
<tr>
<td>&lt;25%</td>
<td>2GBq (whole liver)</td>
</tr>
</tbody>
</table>

Two diagnostic angios and two therapeutic angios

Split dose

Assume right lobe is 70% of the total liver volume
Assume left lobe is 30% of the total liver volume

**U.S. Nuclear Regulatory Commission**

Authorized users must meet the training and experience requirements of either §CFR 35.490 or, until October 25, 2005, §CFR 35.940 as well as the specific vendor training in the use of the microspheres and the microsphere delivery system and any other requirements under this Commission.

**Devices**

**SIR-Spheres**

For yttrium-90 microsphere radioembolization for metastatic colorectal cancer to the liver, one yttrium preparation is FDA approved. This agent is SIR-Spheres which is marketed by SIRTEX Medical in Lane Cove, Australia. This agent was approved as a local interstitial brachytherapy device. This device consists of resin microspheres 35 microns in size.

Yttrium-90 emits a beta particle that has a maximum tissue penetration of 1.1cms.

**Indications:**

1. Per the FDA approved package insert, SIR-Spheres is indicated for the treatment of unresectable metastatic liver tumors from primary colorectal cancer with adjuvant intra-hepatic artery chemotherapy (IHAC) of FUDR (Flouxuridine). Patients are indicated for treatment with SIR-Spheres when the metastatic colorectal cancer in the liver is considered non-resectable. In any of the following circumstances, patients would generally be considered non-resectable:
   a. multiple liver metastases together with involvement of both lobes;
   b. tumor invasion of the hepatic confluence where the three hepatic veins enter the inferior vena cava such that none of the hepatic veins could be preserved if the metastases were resected; tumor invasion of the porta hepatis such that neither origin of the right or left portal veins could be preserved if resection were undertaken; and widespread metastases such that resection would require removal of more liver than is necessary to maintain life.
2. It is also covered for patients with unresectable hepatocellular cancer (HCC) who can have appropriately positioned hepatic arterial catheters. (See below (under TheraSphere) for post treatment and complication information)

**Contraindications:**
1. Contraindications to SIR-Spheres yttrium microsphere therapy for metastatic colorectal cancer to the liver:
   a. previous external beam radiation to the liver
   b. ascites or liver failure
   c. markedly abnormal liver function tests; specifically, an increased total bilirubin indicates reduced hepatic reserve
   d. greater than 20% shunting to the lungs on hepatic arterial administration of Tc-MAA scan
   e. assessment visceral arteriogram that demonstrates abnormal vascular anatomy that would result in increased chance of gastrointestinal complication
   f. widely disseminated extrahepatic disease
   g. received capecitabine within the previous two months or who will be treated with capecitabine at any time following treatment with SIR-Spheres microspheres.
   h. total portal thrombosis or circulatory reversal
   i. technical obstacle with securely placing catheter

2. Relative Contraindications:
   a. evidence of bone metastases which show no activity during systemic therapy
   b. shunt Volume between liver and lung of 10-20%; a reduced dose therapy is still possible
   c. partial thrombosis of the portal vein

**TheraSphere**
TheraSphere, consisting of millions of microscopic radioactive glass microspheres; (MDS Nordion, Kanata, ON, Canada) was approved in 1999 by the U. S. Food and Drug Administration (FDA) under a humanitarian device exemption for the treatment of unresectable hepatocellular carcinoma (HCC) in patients who can have appropriately positioned hepatic arterial catheters. It is subject to the FDA requirements for use under a humanitarian device exemption protocol.

**Indications:**
1. TheraSphere is indicated for radiation treatment or as a neoadjuvant to surgery or transplantation in patients with unresectable HCC who can have placement of appropriately positioned hepatic arterial catheters. The device is also indicated for HCC patients with partial or branch portal vein thrombosis (PVT)/occlusion, when clinical evaluation warrants the treatment.

2. TheraSphere is indicated for the treatment of unresectable metastatic liver tumors from primary colorectal cancer with adjuvant intra-hepatic artery chemotherapy (IHAC) of
FUDR (Floxuridine). Patients are indicated for treatment when the metastatic colorectal cancer in the liver is considered non-resectable. In any of the following circumstances, patients would generally be considered non-resectable:

- multiple liver metastases together with involvement of both lobes;
- tumor invasion of the hepatic confluence where the three hepatic veins enter the inferior vena cava such that none of the hepatic veins could be preserved if the metastases were resected; tumor invasion of the porta hepatis such that neither origin of the right or left portal veins could be preserved if resection were undertaken; and widespread metastases such that resection would require removal of more liver than is necessary to maintain life.

Contraindications:
1. TheraSphere is contraindicated in patients with:
   - uncorrectable yttrium-90 microsphere deposition to the gastrointestinal tract
   - shunting to the lungs, in a single treatment, exceeding 16.5mCi (or 30Gy) of yttrium-90 microspheres to the lungs
   - contraindication to hepatic artery catheterization
   - severe liver dysfunction or pulmonary insufficiency
   - complete occlusion of the main portal vein

Post treatment
Although nonspecific, levels of albumin and total bilirubin and other markers such as lactate dehydrogenase and C-reactive protein may be helpful in post-treatment monitoring. C-reactive protein has also been shown to have prognostic value in patients with HCC. Blood tests, including albumin, bilirubin, alkaline phosphatase (ALP), alanine transaminase (ALT), and aspartate transaminase (AST) are performed prior to and at 24 and 48 hours following SIRT in the majority of patients

Yttrium-90 microsphere Complications
Complications associated with this treatment can include: bone marrow toxicity, radiation gastritis, pulmonary fibrosis, and gangrenous cholecystitis. There is one report of extensive fibrosis of liver resulting in portal hypertension related to microspheres therapy with Y-90 after microsphere treatment. Gastrointestinal ulceration is a known and relatively common complication that is not often reported following Y-90 microsphere embolization with potentially life-threatening consequences. Since vague upper abdominal discomfort is common after radiation therapy and often not thoroughly evaluated, the true incidence of occult ulceration is not known but occurs in at least 11% of patients despite comprehensive pre-treatment angiographic evaluation when empiric gastroduodenal artery embolization is not performed.

Non-covered Conditions
There is insufficient evidence in the peer-reviewed literature to support the safety and efficacy of Y-90 microsphere radioembolization for liver metastases from any site other than colorectal or neuroendocrine including but not limited to breast cancer, cholangiocarcinoma,
Discussion

Metastatic Liver Disease Hepatocellular Carcinoma (HCO)

The liver is also the dominate site of metastatic disease for a number of malignancies, including neuroendocrine, ocular melanoma and colorectal cancer. Colorectal cancer accounts for approximately 50% of patients with metastatic disease. If left untreated, these patients have a poor prognosis with a median survival of 4-21 months, a three-year survival rate of three percent, and virtually no five-year survival. “The liver is the most frequent site of metastases, primarily as a result of spread of cancer cells through the portal circulation. In fact, approximately 60% of patients with colorectal cancer eventually have liver disease as the predominant site.” Surgical resection is possible in only 20% of these patients. In most situations in which surgery is not a viable option, patients undergo first and second line chemotherapy with additional modification with the administration of anti-angiogenesis drugs. When drug side effects or toxicity become significant, these patients can be assessed for other treatment options.

Hepatocellular Carcinoma (HCC)

Hepatocellular carcinoma is cancer that arises from hepatocytes, the major cell type of the liver. Hepatocellular carcinoma is relatively rare in the United States. Although HCC is uncommon, comprising only 2% of all malignancies, since the mid-1980s the incidence of HCC has been rising at an alarming rate. It is either the number one or number two cause of cancer death worldwide. It is especially prevalent in parts of Asia and Africa. About 80% of people with hepatocellular carcinomas have cirrhosis. Chronic infection with the hepatitis B virus and hepatitis C virus also increases the risk of developing hepatocellular carcinoma. Aflatoxins, which are produced by a mold that is a contaminant of nuts (most commonly peanuts), grains, and beans, have also been implicated as a major risk factor for causing hepatocellular carcinoma. Although virtually non-existent in the United States, aflatoxins, are common in other parts of the world and often contaminate food.

HCC is the most common liver cancer diagnosed in adults and has a high prevalence in Asian and African populations. The rate of new HCC cases has been rising over the past 10 years in the United States. HCC is a very aggressive disease; patients usually survive less than one year after diagnosis. HCC occurs twice as often in men as in women. In 2006, an estimated 18,500 Americans will be newly diagnosed with liver cancer and an estimated 16,200 will die of the disease. (NCI)

A major impact on the incidence of HCC should be achieved through current vaccination strategies for hepatitis B virus (HBV) infection, screening and treatment for hepatitis C virus (HCV) infections, and from the reduction of alcoholic liver disease. However, because the latency period from hepatic damage to HCC development is very long, it may be many years until the incidence of HCC decreases as a result of these interventions.

Incidence of hepatitis B induced cirrhosis has been somewhat blunted by the availability of
the vaccine. However, there is a pandemic of hepatitis C worldwide; the incidence of subsequent hepatoma will lag between 15 and 20 years after infection. Not all people with Hepatitis C will suffer the consequences of cirrhosis and or hepatoma. Yet, the pandemic nature of hepatitis C now dating back to the early 1980s when it was called “non A, non B” viral hepatitis, emphasizes that there will be an ever increasing number of patients developing hepatoma.

Alternatively, since there is a paucity of liver allografts for transplantation, transplant is a limited option. Thus the main goal currently is disease control. In summary, in treating hepatoma nodules with yttrium-90 microspheres, the patient will need to undergo at least two arteriograms consisting of:

1. a "mapping" arteriogram in which the right gastric and gastroduodenal arteries are embolized and the liver lung shunting nuclear medicine exam with Tc-MAA is assessed, and
2. then the definitive arteriogram in which the calculated dose of yttrium-90 microspheres are injected into the liver.

When using either yttrium product, it is important to embolize important nontarget vessels e.g. gastroduodenal artery, right gastric artery prior to definitive treatment. Importantly, a nuclear medicine scan with Tc-MAA is injected in the branch hepatic artery supplying the primary hepatoma or multiple mets. The purpose of this is to define the degree of shunting between the liver and lung. If an excessive amount of shunting occurs (i.e. 20% or more), the patient is often times not a candidate due to excessive radiation exposure to the lung.

**Bill Type Codes:**
Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

999x Not Applicable

**Revenue Codes:**
Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A
N/A
CPT/HCPCS Codes

Group 1 Paragraph: CPT Codes
There are no specific CPT codes for SIRT. The following nonspecific codes may be used:

Group 1 Codes:

VASCULAR EMBOLIZATION OR OCCLUSION, INCLUSIVE OF ALL RADIOLOGICAL SUPERVISION AND INTERPRETATION, INTRAPROCEDURAL ROADMAPPING, AND IMAGING GUIDANCE NECESSARY TO COMPLETE THE INTERVENTION; VENOUS, OTHER THAN HEMORRHAGE (EG, CONGENITAL OR ACQUIRED VENOUS MALFORMATIONS, VENOUS AND CAPILLARY HEMANGIOMAS, VARICES, VARICOCELES)
37241

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 INFARCTION
37243

TRANSCATHETER THERAPY, EMBOLIZATION, ANY METHOD, RADIOLoGICAL SUPERVISION AND INTERPRETATION
77263

BASIC RADIATION DOSIMETRY CALCULATION, CENTRAL AXIS DEPTH DOSE CALCULATION, TDF, NSD, GAP CALCULATION, OFF AXIS FACTOR, TISSUE INHOMOGENEITY FACTORS,
77290

CALCULATION OF NON-IONIZING RADIATION SURFACE AND DEPTH DOSE, AS REQUIRED DURING COURSE OF TREATMENT,
77300

Group 2 Paragraph: Radiation Therapy codes

Group 2 Codes:

THERAPEUTIC RADIOLOGY TREATMENT PLANNING; COMPLEX
77263

THERAPEUTIC RADIOLOGY SIMULATION-AIDED FIELD SETTING; COMPLEX
77290

BASIC RADIATION DOSIMETRY CALCULATION, CENTRAL AXIS DEPTH DOSE CALCULATION, TDF, NSD, GAP CALCULATION, OFF AXIS FACTOR, TISSUE INHOMOGENEITY FACTORS,
77300

UNLISTED PROCEDURE, MEDICAL RADIATION PHYSICS,
77399

DOSIMETRY AND TREATMENT DEVICES, AND SPECIAL SERVICES
77399
ONLY WHEN PRESCRIBED BY THE TREATING PHYSICIAN

SPECIAL MEDICAL RADIATION PHYSICS CONSULTATION

SPECIAL TREATMENT PROCEDURE (EG, TOTAL BODY IRRADIATION, HEMIBODY RADIATION, PER ORAL OR ENDOCAVITARY IRRADIATION)

INTERSTITIAL RADIATION SOURCE APPLICATION: COMPLEX

SUPERVISION, HANDLING, LOADING OF RADIATION SOURCE

**Group 3 Paragraph: HCPCS Codes**
The following code is available for Outpatient billing only.

**Group 3 Codes:**

- C2616    BRACHYTHERAPY SOURCE, NON-STRANDED, YTTRIUM-90, PER SOURCE

*Please refer to the CMS website for the ICD-10 Codes that Support Medical Necessity.*

**Documentation Requirements**

Documentation in the medical record should support the medical need for the service and

1. The reasonable and necessary requirements as outlined under the "Coverage and Limitations" sections of this policy and must be available to the carrier for review upon request.

2. The prescription must define the goals and requirements of the treatment plan, including the specific dose constraints for the target(s) and nearby critical structures.

3. A statement by the treating physician, documenting the special need for performing Y-90 microsphere liver brachytherapy on the patient in question.

4. A signed Y-90 microsphere liver brachytherapy written directive by an authorized user that meets prescribed dose constraints for the normal liver and surrounding normal tissue, including the lungs.

5. The quantity of radioactivity to be implanted, target volume in liver, liver to lung shunt, and written directive that is included in the treatment plan must be independently checked before the patient’s treatment.

The following documentation should be maintained in the patient record with a humanitarian device exemption (HDE). No information need be sent for prior approval.
1. The HDE number.
2. The name of the device.
3. A signed patient consent clearly stating risks vs benefits and why the benefits out weigh the risk for this individual case.

Note: If the IRB requires a signed patient informed consent, that document satisfies the documentation requirements noted in this list and should therefore be the only document required to remain in the patient record. The informed consent includes the HDE number, the name of the device, identifies the IRB providing approval for the HDE and should clearly state the risks vs benefits and why the benefits out-weigh the risk for this individual case.