OncoHealth

Radiation Oncology Medical Policies

Table of Contents

SERVICE: High Dose Rate (HDR) Electronic Brachytherapy (also known as electronic brachytherapy)

PRIOR AUTHORIZATION: Required

POLICY:

According to the American Brachytherapy Society[26] and the National Comprehensive Cancer Network, high dose rate electronic brachytherapy remains experimental, investigational and unproven for breast cancer, non-melanomatous skin cancers or gynecologic cancers.

EXCLUSIONS:

According to the American Brachytherapy Society consensus statement for electronic brachytherapy: High dose rate electronic brachytherapy "has been utilized to deliver accelerated partial breast irradiation with, thus far acceptable local control and toxicity rates including a randomized trial that used electronic brachytherapy to deliver intraoperative radiotherapy; however, prospective data with large patient numbers and long-term follow up are needed. Increasing numbers of patients have been treated with electronic brachytherapy for non-melanomatous skin cancers; although, preliminary data are promising, there is a lack of data comparing electronic brachytherapy to traditional radiotherapy techniques as well as a lack of long-term follow up. For treatment of the vaginal cuff with electronic brachytherapy, small retrospective studies have been reported without long-term follow up. In light of a randomized trial in breast showing higher rates of recurrence and the lack of prospective data with mature follow up with other sites, as well as concerns regarding dosimetry, it is not recommended that electronic brachytherapy be utilized for accelerated partial breast irradiation, non-melanomatous skin cancers, or vaginal cuff brachytherapy outside prospective clinical trials at this time."[26]

With regard to non-melanoma skin cancer, the National Comprehensive Cancer Network (NCCN) Guidelines© state: "There is insufficient long-term efficacy and safety data to support the routine use of electronic brachytherapy." Instead, the NCCN Guidelines recommend either electron beam radiotherapy or, in highly selected cases, remote afterloading HDR radionuclide brachytherapy for non-melanoma skin cancer patients who are non-surgical candidates, do not wish to undergo surgery or prefer radiotherapy. Consequently, treatment of non-melanoma skin cancer with a 50-150 kV device (i.e., an Esteya®, Intrabeam®, SRT-100™ or Xoft® device) should not be billed as electronic brachytherapy. Instead, it should be billed as superficial radiation therapy using CPT codes 77280 (one unit), 77300 (one unit) and 77401 (use the number of fractions in the radiotherapy prescription).

The ASTRO Clinical Practice Guideline states that "because of its relative novelty, there are no long-term follow-up studies (>10 years) involving electronic brachytherapy which evaluate local control and toxicity. Therefore, caution should be made in extrapolating electronic brachytherapy local control and toxicity from the other older modalities within electronically generated, low-energy radiation sources.."[27]

OVERVIEW:

Brachytherapy is a form of radiotherapy that delivers a high dose of radiation inside of or very close to a cancer. The term brachytherapy was originally derived from the Greek words βραχύς (brachys) and θεραπεία (therapeía) which means "short" and "curing or healing," respectively. Brachytherapy dates

back to the 1910s. Traditionally, brachytherapy involves the use of sealed radioactive sources. It is extensively used in the treatment of brain, eye, base of tongue, floor of mouth, tongue, oropharynx, lip, nasopharynx, trachea, esophagus, breast, cervix, endometrium, prostate, rectum, skin, sarcoma and other treatment sites. Brachytherapy can be used alone or in conjunction with conventional external beam radiation therapy. Based on the type of sources, high dose rate (HDR) brachytherapy can be classified as either radionuclide or electronic. High dose rate (HDR) electronic brachytherapy involves the use of electricity, a miniaturized X-ray tube, a computerized controller, and an applicator to deliver a radiation treatment (fraction) at a high dose rate over several minutes. HDR electronic brachytherapy devices in the United States deliver superficial (50-100 kV) x-rays. HDR electronic brachytherapy is typically used to treat keloids, soft tissue sarcomas, and cancers of the breast, skin, vaginal cuff, cervix, endometrium and rectum.

a. Breast Cancer

The TARGIT (TARGeted Intraoperative radioTherapy)-A trial is the largest intraoperative radiation therapy (IORT) trial to date using electronic brachytherapy in conjunction with breast conservation surgery.[20] This trial studied a total of 3,451 patients wherein 1,721 subjects were randomized to single-dose, targeted IORT and 1,730 to fractionated external beam radiation therapy (EBRT). The 5-year risk for local recurrence in the conserved breast was 3.3% (95% CI 2.1-5.1) for TARGIT versus 1.3% (0.7-2.5) for EBRT (p=0.042). Overall mortality was 3.9% (2.7-5.8) for TARGIT versus 5.3% (3.9-7.3) for EBRT (p=0.099). Wound-related complications were much the same between groups, but grade 3 or 4 skin complications were significantly reduced with TARGIT (four of 1,720 vs 13 of 1,731, p=0.029).

b. Non-Melanoma Skin Cancer

Bhatnagar et al. summarized electronic brachytherapy results obtained by multiple groups.[24] Median follow-up ranged from only 4 to 16 months, and the local recurrence rate for 1,822 treated lesions was 0.97%. Interim results of NCT03024866 (a retrospective chart review with prospective follow-up) was presented by Dr. Rakesh Patel at the 2017 ASTRO Annual Meeting.[25] In that presentation, 369 non-melanoma skin cancer patients had been treated with electronic brachytherapy or Mohs surgery. Based on a mean follow-up of 3.4 years, 99.5% of electronic brachytherapy patients and 100.0% of Mohs surgery patients remained recurrence-free. The overall incidence of toxicity was similar in both treatment groups, and physician-rated cosmetic outcomes were either “excellent” or “good” in 97.6% of electronic brachytherapy-treated lesions, compared to 95.7% of Mohs surgery-treated skin cancers. Based on the absence of electronic brachytherapy studies with >10 years of follow-up, conclusions cannot be drawn about its long-term efficacy and safety.[27] For example, the NCCN Guidelines® state that “there are insufficient long-term efficacy and safety data to support the routine use of electronic surface brachytherapy” for non-melanoma skin cancer. Also, the ASTRO Clinical Practice Guidelines on non-melanoma skin cancer state that “because of its relative novelty, there are no long-term follow-up studies (>10 years) involving electronic brachytherapy which evaluate local control and toxicity. Therefore, caution should be made in extrapolating electronic brachytherapy local control and toxicity from the other older modalities within electronically generated, low-energy radiation sources..”[27] Moreover, in light of the lack of prospective data with mature follow up and concerns regarding dosimetry, the American Brachytherapy Society consensus statement for electronic brachytherapy does not recommend that electronic brachytherapy be used for non-melanoma skin cancer outside prospective clinical trials at this time.[26]

MEDICARE ADVANTAGE:

There is no NCD for HDR electronic brachytherapy. Also, there are LCDs for MA, CT, NH and ME. Consequently, this commercial policy will also apply to Medicare Advantage.

BILLING CODES AND DESCRIPTIONS:

Billing codes and their descriptions are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list is not all-inclusive. Billing codes that are not in effect at the time that a service is rendered may not be eligible for reimbursement.

0394T High dose rate electronic brachytherapy, skin surface application, per fraction, includes basic dosimetry, when performed. Electronic brachytherapy is not medically necessary for skin cancer according to the NCCN and ABS. Also, CPT code 0394T should not be billed with 77300.
0395T High dose rate electronic brachytherapy, interstitial or intracavitary treatment, per fraction, includes basic dosimetry, when performed. CPT code 0395T should not be billed with 77300.

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POLICY HISTORY:

Date	Action
January 3, 2020	Original policy

November 18, 2021	An update is highlighted in yellow on page 2.

SERVICE: Hyperthermia

PRIOR AUTHORIZATION: Required

POLICY:

The use of hyperthermia and concurrent radiation therapy is medically necessary for any of the following:

Primary or metastatic cutaneous or subcutaneous superficial (≤4 cm in depth) malignancies, e.g., melanomas, squamous or basal cell carcinomas, adenocarcinomas or sarcomas. This includes recurrent, superficial melanoma. Also, it includes cervical lymph node metastases from head and neck cancer. In addition, it includes a chest wall recurrence of breast cancer.

Treatment of the above conditions will be approved in the absence of both of the following:

A. Metastatic disease for which chemotherapy or hormonal therapy is being given concurrently or planned
B. Evidence of tumor recurrence exceeding 4 cm in depth

EXCLUSIONS:

Hyperthermia is unproven and not medically necessary due to insufficient evidence of efficacy for treating **all** other indications. For example, the use of intraluminal, endocavitary, interstitial, regional deep tissue hyperthermia exceeding 4 cm in depth and whole-body hyperthermia are considered experimental, investigational or unproven. Also, hyperthermia is not covered when used alone or in connection with chemotherapy.

OVERVIEW:

Local hyperthermia for treatment of cancer consists of the use of heat to make tumors more susceptible to radiation therapy. Currently, in the United States, the Food and Drug Administration (FDA) has approved hyperthermia for use in the treatment of cancer when combined with radiation therapy for the "…palliative management of certain solid surface and subsurface malignant tumors (i.e. melanoma, squamous or basal cell tumors, adenocarcinoma, or sarcoma) that are progressive or recurrent despite conventional therapy." Following FDA approval, Medicare approved coverage for local hyperthermia when used together with radiation therapy. A National Coverage Determination (NCD 110.1) was issued by Medicare (CMS) in December 1984 and remains unchanged. It states, "Local hyperthermia is covered under Medicare when used in conjunction with radiation therapy for the treatment of primary or metastatic cutaneous or subcutaneous superficial malignancies. It is not covered when used alone or in connection with chemotherapy." The National Cancer Center Network (NCCN) recommends "…that the use of hyperthermia be limited to treatment centers with appropriate training, expertise and equipment..."

Although research into hyperthermic treatments at depths greater than 4 cm is ongoing in the US, it is currently recognized only as investigational as are intraluminal, endocavitary, and interstitial applications. On May 15, 2009, the FDA granted humanitarian use device (HUD) status to the BSD2000 and on November 18, 2011, the FDA granted humanitarian device exemption (HDE) to the BSD-2000 for the treatment of cervical cancer patients ineligible for chemotherapy (treatment population less than 4,000). This is the only approval for deep heating, and only actual costs incurred in the research may be billed. Other applications for deep heating are pending for both BSD and Medifocus devices. In the US, only the BSD-500 has FDA commercial clearance for superficial heating (less than a 4 cm depth). It operates at the microwave range of 915 MHz with different applicators and power setting ranging from 20 to 250 watts. The standard recommended treatment regimen for use with radiation therapy is a "…total of 10 hyperthermia treatments delivered two times per week at 72-hour intervals, with each heat treatment preceded or followed by a standard prescribed dose of ionizing radiation within 30 minutes of the heat treatment." A sustained intratumoral temperature of 42.5 degrees centigrade for 60 minutes is recommended.

The FDA granted pre-market approval for the Sonotherm® 1000 Ultrasound Therapy System on September 29, 1989. This approval was for hyperthermia to treat tumors at a depth of 8 cm. Although FDA approval was granted, the device remains in clinical study and is designated experimental, investigational or unproven.

There are three randomized studies that have documented that have shown a benefit to local hyperthermia in conjunction with radiotherapy:

a. Recurrent, Superficial Melanoma
One-hundred and thirty-four metastatic or recurrent melanoma lesions in 70 patients were randomly assigned to receive radiation therapy (three fractions of 8 or 9 Gy over 8 days) alone or followed by hyperthermia (43 degrees C for 60 minutes). There was a beneficial local effect in 28% of cases for radiation alone, and 46% of cases for combined treatment. Toxicity was not higher with hyperthermia (Overgaard, 1995)

b. Cervical Lymph Node Metastases Due to Head and Neck Cancer
A randomized study of 44 nodes in 41 patients demonstrated improved, 5-year actuarial nodal control with combined treatment. In addition, the study reported a statistically significant improvement in survival at 5 years and no increased toxicity from combined modality therapy (Valdagni, 1994).

c. Chest Wall Recurrence of Breast Cancer
Five randomized trials were combined to demonstrate the benefit of combined treatment for superficial, localized breast cancer. The control rate for radiation therapy alone was 41%, while that for combined treatment was 59%. The greatest effect was observed in patients with recurrent lesions (Vernon, 1996).

MEDICARE ADVANTAGE:

There is a Medicare NCD for hyperthermia entitled "National Coverage Determination (NCD) Hyperthermia for Treatment of Cancer 110.1."

The above NCD on hyperthermia will apply to Medicare Advantage.

BILLING CODES AND DESCRIPTIONS:

Billing codes and their descriptions are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list is not all-inclusive. Billing codes that are not in effect at the time that a service is rendered may not be eligible for reimbursement.

77600 Hyperthermia, externally generated; superficial (i.e., heating to a depth of 4 cm or less)
77605 Hyperthermia, externally generated; deep (i.e., heating to depths greater than 4 cm)
77610 Hyperthermia generated by interstitial probe(s); 5 or fewer interstitial applicators
77615 Hyperthermia generated by interstitial probe(s); more than 5 interstitial applicators
77620 Hyperthermia generated by intracavitary probe(s)

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POLICY HISTORY:

Date	Action
January 3, 2020	Original policy

SERVICE: Image Guided Radiation Therapy (IGRT)

PRIOR AUTHORIZATION: Required

POLICY:

Image guided radiation therapy (IGRT) in conjunction with three-dimensional (3D) conformal radiation therapy is medically necessary in the following circumstances:

- When the planning target volume (PTV) is in close proximity to a previously irradiated area
- Treatment of the hepatobiliary tract
- Treatment of head and neck cancer
- Treatment of Hodgkin's and non-Hodgkin's lymphoma
- Treatment of lung cancer
- Treatment of prostate cancer
- Treatment of esophageal cancer
- Treatment of gastric cancer
- Treatment of pancreatic cancer
- Treatment of pelvic cancer (e.g., rectal cancer) when the individual is in the prone position on a belly board
- During a breast boost involving photons
- During accelerated partial breast irradiation (APBI)
- During treatment of breast cancer when a deep inspiration breath hold (DIBH) technique is being utilized because there is clinically significant tumor motion with inspiration and expiration
- During a boost to the bladder
- Preoperative or postoperative treatment of a sarcoma

Also, IGRT is medically necessary when any one of the following conditions is met:

- Intensity modulated radiation therapy (IMRT) is being utilized
- Proton beam therapy is being utilized
- Use of IGRT will allow significant reduction of radiation doses to sensitive normal structures
- Implanted fiducial markers are indicated and have been placed
- Bony anatomy fails to accurately delineate a tumor location and fiducial markers are not indicated (e.g., head and neck cancer)
- The treatment field in question abuts a previously irradiated field
- There is significant setup variation affecting target coverage, for example:
    - Individual is morbidly obese (with a body mass index (BMI) > 35) and is receiving radiotherapy for a tumor in the mediastinum, abdomen or pelvis
    - There is significant tumor and organ movement due to respiration and the treatment plan addresses tumor motion, e.g., using a four-dimensional (4D) computed tomography (CT) scan at the time of simulation to address significant tumor and organ movement motion inspiration and expiration

EXCLUSIONS:

IGRT not medically necessary for all other indications. Examples would be that IGRT is not medically necessary for electron beam therapy, high dose rate electronic brachytherapy or superficial radiation therapy. Also, DIBH, where the target is stationary during treatment, does not warrant CPT code 77293.

OVERVIEW:

Image guided radiation therapy (IGRT) refers to pre-treatment imaging used to verify correct patient positioning in cases where sub-centimeter accuracy is needed. There are multiple different technologies which can be utilized for IGRT, including ultrasound guidance, stereoscopic x-ray guidance, CT-based guidance and continuous intra-fraction position monitoring. Both the American Society for Radiation Oncology (ASTRO) and the American College of Radiology (ACR) have published descriptive overviews related to IGRT.

IGRT is an integral part of the delivery of highly conformal treatments such as IMRT, stereotactic radiosurgery (SRS) and stereotactic body radiotherapy (SBRT). Recognition of this fact has resulted in changes to the current procedural terminology (CPT) definitions such that the technical aspect of IGRT is now bundled with IMRT, SRS and SBRT and may not be billed separately.

When highly tailored dose distributions such as IMRT, SRS and SBRT are not being utilized, sub-centimeter precision is not generally needed and patient setup can be achieved with other techniques. These include patient immobilization with custom treatment devices like body molds or thermoplastic masks, placement of tattoos aligned to 3D lasers in the treatment room and offline review of port verification films. Small daily setup uncertainties exist, and these are considered in the target expansion process where an additional margin is added to the gross tumor volume (GTV) to create the clinical target volume (CTV) and ultimately the planning target volume (PTV) during the treatment planning process.

With brachytherapy, imaging is medically necessary to verify source position in all but the simplest of cases. Images may also be used to perform dosimetry calculations. Use of applicable simulation and/or field verification codes is appropriate, including CPT code 77280 (set radiation therapy field).

The ACR-ASTRO practice parameter for IGRT indicates that “when the target is not clearly visible and bony anatomy is not sufficient for adequate target alignment, fiducial markers may be needed.” For soft tissue targets such as the prostate, implanted fiducial markers have been validated as an accurate way to localize the target when using orthogonal imaging. In general, the use of implanted fiducial markers for other soft tissue targets located in close proximity to critical structures is appropriate when needed to safely reduce PTV margins and reduce the risk of late complications.

IGRT can also help identify patients who would benefit from adaptive re-planning to prevent overdosing of critical structures such as the spinal cord if significant weight loss occurs during treatment. Essentially all of the research around IGRT for head and neck cancer has been performed in the setting of IMRT.

The current National Comprehensive Cancer Network (NCCN) Guidelines© recommend using IGRT with SBRT and when 3D conformal radiation therapy or IMRT is used with steep dose gradients around the target, organs at risk are in close proximity to target tissues, and when utilizing gating or other motion management techniques.

Pre-treatment image acquisition and isocenter shifting has been suggested as a strategy to allow a safe reduction in planning target volume (PTV) margins. By decreasing the volume of normal tissue exposed to radiation, the use of IGRT with 3D conformal radiation therapy or IMRT has been suggested as a way to reduce toxicity, allow an increase in the radiation dose, or both. This has been most extensively studied in prostate cancer, where evidence of a dose response and improved freedom from failure with dose escalation from 70 Gy to 78 Gy was demonstrated in a randomized trial.[27] Higher-dose treatment was associated with increased rectal toxicity and this correlated with the proportion of the rectal volume receiving ≥ 70 Gy. These findings prompted efforts to escalate doses beyond 78 Gy and simultaneously decrease normal tissue toxicity by using IGRT in combination with IMRT.

When used with 3D conformal radiation therapy, IGRT reduces the risk of late toxicities due to prostate cancer radiotherapy. For example, Singh et al.[32] reported that treatment with IGRT significantly decreased post-treatment rectal pain, urgency, diarrhea and change in bowel habits.

In the setting of head and neck cancer, IGRT allows for a safe reduction of margin expansion and the ability to detect significant anatomic changes which might benefit from re-planning. Chen et al.[4] have reported a series of 225 consecutively treated head and neck cancer patients treated with image-guided IMRT. IGRT was performed with volumetric imaging prior to each treatment. The first 95 patients were treated with a 5 mm CTV to PTV expansion and the following 130 patients were treated with a 3 mm expansion. Two-year local control was equal for the two groups. Examination of the treatment failures did not reveal any marginal recurrences in either cohort. The authors concluded that when IGRT is used, the CTV to PTV margin can safely be reduced from 5 mm to 3 mm. A subsequent report[5] included 264 patients with a 3 mm margin expansion and found that the 3-year locoregional control was equal in the 5 mm and 3 mm margin groups. Compared to the 5 mm margin group, the 3 mm margin patients had a lower incidence of gastrostomy-tube dependence at 1 year (10% vs. 3%, p=0.001) and esophageal stricture (14% vs. 7%, p=0.01).

IGRT in the non-IMRT setting can be justified in cases where the use of surface tattoos and standard immobilization techniques are known to be inadequate. In obese patients with deep-seated tumors within the abdomen and/or pelvis, surface landmarks are known to be inaccurate. Wong et al.[36] have reported that, using CT-based IGRT, shifts of greater than 10 mm were needed 21% of the time to correctly position the prostate in moderately to severely obese patients (BMI > 35). This was significantly more than shifts needed in normal weight, overweight, and mildly obese patients.

Tumor motion during the breathing cycle needs to be evaluated and managed when highly conformal radiation techniques are used to treat lung cancer. Liu et al.[20] evaluated respiratory related tumor motion in 152 patients with lung cancer and found that motion in the superoinferior (SI) axis was > 5 mm in 39% of patients and > 10 mm in 11% of patients. The degree of respiratory cycle related motion was more pronounced with smaller lesions and with tumors that were farther from the lung apex.

MEDICARE ADVANTAGE:

There is no NCD for IGRT. Also, there are no LCDs for MA, CT, NH or ME for IGRT. Consequently, this commercial policy will also apply to Medicare Advantage.

BILLING CODES AND DESCRIPTIONS:

Billing codes and their descriptions are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list is not all-inclusive. Billing codes that are not in effect at the time that a service is rendered may not be eligible for reimbursement.

77014 CT guidance for placement of radiation therapy fields. CPT code 77014 for a CT scan during simulation is included in CPT code 77301 (radiotherapy dose plan IMRT). Consequently, one unit of CPT code 77014 should not be reported for CT simulation in addition to one unit of CPT code 77301. Also, effective 2014, CPT code 77014 should not be reported with CPT code 77295 (3D radiotherapy plan). However, CPT code 77014 may be used for IGRT with CT-based systems, i.e., integrated cone beam CT, CT/linear accelerator on rails or tomotherapy.

77387 Guidance for localization of target volume for delivery of radiation treatment delivery, includes intrafraction tracking, when performed. There should be a note stating why IGRT is medically necessary.

G6001 Ultrasonic guidance for placement of radiation therapy fields. There should be a note stating why IGRT is medically necessary.

G6002 Stereoscopic x-ray guidance for localization of target volume for the delivery of radiation therapy. There should be a note stating why IGRT is medically necessary.

G6017 Intra-fraction localization and tracking of target or patient motion during delivery of radiation therapy (e.g., 3D positional tracking, gating or 3D surface tracking), each fraction of treatment. Do not report other IGRT billing codes when intrafraction tracking is used. There should be a note stating why IGRT is medically necessary.

IGRT codes may not be billed separately for SRS or SBRT because they are bundled in with the daily treatment codes. Also, CPT codes 77370 and 77470 should not be billed based on the use of IGRT.

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POLICY HISTORY:

Date	Action
January 3, 2020	Original policy

SERVICE: Intensity Modulated Radiation Therapy (IMRT)

PRIOR AUTHORIZATION: Required

POLICY:

Intensity modulated radiation therapy (IMRT) is reasonable and medically necessary when highly conformal dose planning is required. IMRT planning may be clinically indicated when one or more of the following conditions are present:

- An immediately adjacent area has been previously irradiated and abutting portals must be established with high precision.
- Dose escalation is planned to deliver radiation doses in excess of those commonly utilized for similar tumors with conventional treatment.
- The target volume is concave or convex, and the critical normal tissues are within or around that convexity or concavity.
- The target volume is in close proximity to critical structures that must be protected.
- The volume of interest must be covered with narrow margins to adequately protect immediately adjacent structures.

On the basis of the above conditions demonstrating medical necessity, disease sites that may support the use of IMRT include the following:

- Primary, metastatic or benign tumors of the central nervous system including the brain, the brain stem and spinal cord.
- Primary or metastatic tumors of the spine where the spinal cord tolerance may be exceeded with conventional treatment or where the spinal cord has previously been irradiated.
- Primary, metastatic, benign or recurrent head and neck malignancies, including: orbits, sinuses, skull base, aero-digestive tract and salivary glands.
- Thoracic malignancies.
- Abdominal malignancies when dose constraints to small bowel or other normal abdominal tissue are exceeded and present administration of a therapeutic does.
- Pelvic malignancies including: prostatic, gynecological and anal cancers.
- Other pelvic or retroperitoneal malignancies.

Other malignancies not listed above can be supported with submission of documentation for medical necessity should a denial occur. The determination of appropriateness and medical necessity for IMRT for any site must be found in the documentation, e.g., dose-volume histograms, submitted by the radiation oncologist.

Indications for IMRT include stage I-III lung cancers treated with curative intent to reduce the risk of severe pneumonitis and cardiac doses compared with three-dimensional (3D) conformal radiation therapy.[130] Based on the results of NRG Oncology RTOG 0617, the National Comprehensive Cancer Network (NCCN) Guidelines© state that IMRT is preferred over 3D conformal radiation therapy for stage III non-small-cell lung cancer. IMRT is considered medically necessary for small cell lung cancer in the following situations:

1. Where there is disease in the bilateral mediastinum or bilateral hilar regions
2. Where there is disease in the paraspinal region
3. For superior sulcus tumors
4. Documentation that a 3D plan does not meet the normal tissue constraints using standard metrics published by the Radiation Therapy Oncology Group (RTOG)/National Comprehensive Cancer Network (NCCN). This documentation must describe the specific OARs (organs at risk) whose tolerance has been exceeded.

IMRT may be medically necessary for breast cancer when **any** one of the 5 following conditions is met:

1. For individuals with left-sided breast lesions where the risk of cardiac exposure would be excessive with three-dimensional conformal radiation therapy (3DCRT) and when **all** of the following are met**:**
    A. 3D planning has been done, with appropriate techniques to limit toxicity such as a "field-in-field" technique ± breathing management such as deep inspiration breath-hold (DIBH)
    B. Despite the use of all appropriate techniques, the dose-volume constraints would lead to unacceptable risk of cardiac toxicity such that greater than 10 cc of the heart would receive 25 Gy or more (V25 > 10 cc)
    C. The IMRT plan demonstrates a reduction in the volume of heart receiving 25 Gy by at least 20% when compared to the 3D plan
2. For individuals who will receive internal mammary node irradiation if **any** one of the following is met:
    B. Enlarged internal mammary nodes based on imaging
    C. Pathologically involved internal mammary lymph node(s) based on tissue biopsy
    D. For individuals at high risk of internal mammary lymph node involvement based on any one of the following:
        a. Four or more pathologically positive axillary lymph nodes
        b. Medial quadrant pT1-2 tumor and pN1-N3
        c. Medial quadrant pT3-4 tumor, any pN
3. For individuals where the 3D conformal plan would result in more than 10 cc of the ipsilateral lung receiving 25 Gy or more (V25 > 10 cc) despite breathing management
4. For individuals where the 3D conformal plan would result in more than 200 cc of the breast receiving more than 105% of the prescription dose or a hot spot (> 2 cc) would receive more than 107% of the prescription dose despite the use of forward planned field-in-field blocking and/or mixed beam energies
5. To treat a previously-irradiated field

Also, IMRT may be medically necessary for supradiaphragmatic lymphomas because their location gives rise to a need for special care to avoid adjacent critical structures. Subdiaphragmatic presentations will be reviewed on a case-by-case basis. Moreover, IMRT may be appropriate for esophageal cancer in a clinical setting where reduction in dose to organs at risk such as the lungs and heart is required and cannot be achieved with 3D conformal radiation therapy. Furthermore, hippocampal avoidance using IMRT for whole brain radiation therapy may be medically necessary for brain metastases patients with a Karnofsky performance status of at least 70, a life expectancy of at least 4 months and brain metastases that are at least 5 mm outside the hippocampus based on the results of the phase III NRG-CC001 trial. However, IMRT for prophylactic cranial irradiation remains experimental, investigational and unproven.

IMRT is only justified to treat a basal or squamous cell carcinoma of the skin when there is large nerve involvement or there is a high risk of regional nodal involvement. Also, according to ASTRO and NCCN Clinical Practice Guidelines, IMRT should only be used to treat rectal cancer in the setting of a clinical trial or in unique clinical situations such as reirradiation of previously-treated patients with recurrent disease, unique anatomic situations or T4 disease.

There must be a documented, clinically significant advantage for IMRT versus another radiation therapy method such as 3D conformal radiation therapy in the medical record of each patient in whom IMRT is requested.

EXCLUSIONS:

IMRT not medically necessary for all other indications.

The American Society for Radiation Oncology (ASTRO) IMRT Model Policy outlines clinical scenarios that would not typically support IMRT. These include:

- Where IMRT does not offer an advantage over 3D conformal radiation therapy techniques that deliver good clinical outcomes and low toxicity.
- Clinical urgency, such as spinal cord compression, superior vena cave syndrome, or airway obstruction.
- Palliative treatment of metastatic disease where the prescribed dose does not approach normal tissue tolerances.
- Inability to accommodate for organ motion, such as for a mobile lung tumor.
- Inability of the patient to cooperate and tolerate immobilization to permit accurate and reproducible dose delivery.

OVERVIEW:

IMRT is a computer-based method of planning for, and delivery of patient-specific, spatially and often temporally modulated beams of radiation to tumors. IMRT uses an approach for obtaining highly conformal dose distributions needed to irradiate complex, e.g., convex or concave, targets positioned near sensitive normal tissues. IMRT delivers a more precise radiation dose to the tumor than 3D conformal radiation therapy while sparing the surrounding normal tissues by using nonuniform radiation beam intensities that are determined by computer-based optimization techniques. This process is referred to as "inverse planning." Inverse planning develops a dose distribution based on the input of specific dose constraints for the clinical target volume (CTV), planning treatment volume (PTV), and nearby clinical structures (which are also known as organs at risk). The gross tumor volume (GTV), CTV, PTV, and nearby normal tissues are identified by a contouring procedure on a computed tomography (CT) scan or magnetic resonance imaging (MRI) scan. IMRT uses non-uniform and customized fluence distributions for treatment delivery. Delivery of IMRT requires either the use of a multi-leaf collimator (MLC) with leaves that project to a nominal 1 cm or less at the isocenter or the use of compensator-based beam modulation using three or more high resolution compensator-modulated fields. The use of an MLC does not, by itself, constitute IMRT. For example, it is possible to use an MLC to deliver 3D

conformal radiation therapy. Also, a traditional "field-in-field technique" is not considered IMRT but rather 3D conformal radiation therapy. IMRT delivery imposes a more stringent requirement than 3D conformal radiation therapy in terms of accounting for patient position and organ motion. Methods that account for organ motion include, but are not limited to:

- Image guided adaptive radiotherapy (e.g., ultrasound-guided or portal-image guided setup based on implanted fiducial markers)
- Respiratory gating of diaphragmatic movement for thoracic and upper abdominal sites.

MEDICARE ADVANTAGE:

There is no NCD for IMRT. Also, there are no LCDs for MA, CT, NH or ME. Consequently, this commercial policy will also apply to Medicare Advantage.

BILLING CODES AND DESCRIPTIONS:

Billing codes and their descriptions are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list is not all-inclusive. Billing codes that are not in effect at the time that a service is rendered may not be eligible for reimbursement.

a. Treatment Planning and Delivery

77293 Respiratory motion management simulation. A 4D simulation must be performed showing clinically significant tumor motion with inspiration and expiration. DIBH, where the target is stationary during treatment, does not warrant CPT code 77293. Report CPT code "+77293" in conjunction with 77295 or 77301 as it is an add-on-code. CPT code "+77293" cannot be billed as a stand-alone code.
77301 Intensity Modulated Radiation Therapy (IMRT) plan, including dose-volume histograms for target and critical structure partial tolerance specifications. A request for a second IMRT dose plan (77301) would require that an additional CT scan be performed for planning purposes and that a medical necessity statement be provided from the requesting physician. The new CT data set must demonstrate a significant change in patient size or tumor volume to necessitate utilization of the new data for planning.
77385 Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple. CPT code 77385 may be used for a diagnosis of breast cancer or prostate cancer if you will not be using compensator-based IMRT. Also, CPT code 77385 may be used for all sites if you will be using compensator-based IMRT. If you are requesting CPT code 77385, then you cannot request CPT code 77371, 77372 or 77373. In addition, if you are requesting CPT code 77385 for compensator-based IMRT to any site in the body, then you cannot request CPT code 77338.
77386 Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex. CPT code 77386 may be used for diagnoses other than breast cancer or prostate cancer if you will not be using compensator-based IMRT. If you are requesting CPT code 77386, then you cannot request CPT code 77371, 77372 or 77373.

G6015 Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session. Report in freestanding centers under the Medicare Physician Fee Schedule to payers that do not accept CPT codes 77385 or 77386.
G6016 Compensator-based beam modulation treatment delivery of inverse planned treatment using three or more high resolution (milled or cast) compensator convergent beam modulated fields, per treatment session. Report in freestanding centers under the Medicare Physician Fee Schedule to payers that do not accept CPT codes 77385 or 77386.

b. Basic Radiation Dosimetry and Treatment Devices

i. Basic Radiation Dosimetry

Basic radiation dosimetry is a separate and distinct service from IMRT planning and should be reported accordingly. The radiation dose delivered by each IMRT beam must be individually calculated and verified before the course of radiation treatment begins. Thus, multiple basic dosimetry calculations (up to 10) are typically performed and reported on a single day. Supporting documentation should accompany a claim for more than ten (10) calculations
on a single day.

77300 Basic radiation dosimetry calculation central axis depth dose calculation, TDF, NSD, gap calculation, off axis factor, tissue inhomogeneity factors, calculation of non-ionizing radiation surface and depth dose, as required during course of treatment, only when prescribed by the treating physician. This code can generally be billed once for each IMRT beam or arc up to a limit of ten. This code is used to report dosimetry calculations that arrive at the relationship between monitor units (or time) and dose, and the physician's verification, review and approval. The documentation should contain the independent check of each field, separate from the computer-generated IMRT plan. CPT code 77300 should not be billed separately from 77307. As of January 1, 2015, CPT code 77307 includes the work associated with the basic dosimetry calculation(s) (77300).

ii. Treatment Devices

There are several categories of treatment devices used in conjunction with the delivery of IMRT radiotherapy. Immobilization treatment devices are commonly employed to ensure that the beam is accurately on target. In addition, the radiation oncologist is responsible for the design of treatment devices that define the beam geometry. The beam or arc aperture, the dose constraints per beam, the couch and gantry angles for each beam position or arc start/stop location, and the coverage requirements all must be evaluated to guide the generation of the multi-leaf collimator (MLC) segments. CPT® code 77338 was established to report multiload collimator (MLC) design and construction for IMRT. It captures the physician work associated with design and fabrication of the device, the practice expense associated with staff (physicists and dosimetrists) and the equipment used to design, analyze and fabricate the device. While 77334 was previously billed once for each gantry angle, 77338 is billed only once per IMRT plan. There is no separate accounting for gantry

angles or other beam arrangements. CPT code 77334 may be used in the IMRT process of care to report the immobilization device constructed at time of the simulation. Additional IMRT plans during a course of care merit additional reporting of 77338.

77332 Treatment devices, design and construction; simple. Simple treatment devices include simple multi-use shaped blocks, bolus and passive, multiuse devices. If an allowed quantity of 10 is exceeded, then documentation must be provided to support why a quantity greater than 10 should be approved.
77333 Treatment devices, design and construction; intermediate
Intermediate treatment devices include pre-cast or pre-made standard-shaped blocks, stents, and special bolus and bite blocks. If an allowed quantity of 10 is exceeded, then documentation must be provided to support why a quantity greater than 10 should be approved.
77334 Treatment devices, design and construction; complex. Complex treatment devices include custom-fabricated cast blocks, immobilization devices, wedges, compensators and eye shields. If an allowed quantity of 10 is exceeded, then documentation must be provided to support why a quantity greater than 10 should be approved.
77338 Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan. Do not report CPT code 77338 more than once per IMRT plan. Also, do not report CPT code 77338 in conjunction with G6016 (compensator-based IMRT) or with 77385 if IMRT will be compensator-based.

a. Image Guided Radiation Therapy

Image Guided Radiation Therapy (IGRT) utilizes imaging technology to modify treatment delivery to account for changes in the position of the intended target. IGRT is indicated for use in patients whose tumors are located near or within critical structures and/or in tissue with inherent setup variation. The new IMRT delivery codes (77385 and 77386) include the technical component of guidance and tracking if performed. The G-codes listed below can be used
to report the professional component of IGRT in instances where a payer does not accept 77387-26.

77014 Computed tomography guidance for placement of radiation therapy fields
Report under the Medicare Physician Fee Schedule to payers that do not accept CPT code 77387. For IGRT, a physician can bill the professional component of IGRT code 77014 with a -26 modifier (however, the hospital cannot bill for 77014) in a hospital setting. Also, an office can bill for 77014 globally in a freestanding setting for daily image guidance. There should be a note stating why IGRT is medically necessary. An allowed billable grouping is 77014, G6001 and G6002 but not 77387 for IGRT and 77385 or 77386 for IMRT.
77387 Guidance for localization of target volume for delivery of radiation treatment delivery, includes intrafraction tracking, when performed. There should be a note stating why IGRT is medically necessary.
G6001 Ultrasonic guidance for placement of radiation therapy fields
Report under the Medicare Physician Fee Schedule to payers that do not accept CPT code 77387. There should be a note stating why IGRT is medically necessary.

G6002 Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy. Report under the Medicare Physician Fee Schedule to payers that do not accept CPT code 77387. There should be a note stating why IGRT is medically necessary.

b. **Additional Information**

The following codes should not be reported with CPT® code 77301 when these services are performed as part of developing an IMRT plan, even if reported on a separate date of service. They may, however, be reported as needed during IMRT treatment (i.e., with CPT codes 77385 or 77386) if they are not performed in conjunction with the development of an IMRT plan.

77014 Computed tomography guidance for placement of radiation therapy fields. CPT code 77014 for a CT scan during simulation is included in CPT code 77301. Consequently, one unit of CPT code 77014 should not be reported for CT simulation in addition to one unit of CPT code 77301. Also, (effective 2014) CPT code 77014 should not be reported with CPT code 77295. CPT code 77014 may be used for IGRT treatment delivery with CT-based systems, i.e., integrated cone beam CT, CT/linear accelerator on rails or tomotherapy.
77280 Therapeutic radiology simulation-aided field setting; simple. Criteria for level: Single treatment area. CPT code 77280 should not be reported for a simple (verification) simulation of IMRT treatment. As of 2017, CPT code 77280 should not be reported with CPT code 77301 unless the simulation was performed in support of non-IMRT radiation therapy for a different tumor.
77285 Therapeutic radiology simulation-aided field setting; intermediate. Criteria for level: Two separate treatment areas. CPT code 77285 should be used for simulation of 2 different treatment areas. As of 2017, CPT code 77285 should not be reported with CPT code 77301 unless the simulation was performed in support of non-IMRT radiation therapy for a different tumor.
77290 Therapeutic radiology simulation-aided field setting; complex. Criteria for level: Any of these factors present: Three or more treatment areas, or any number of treatment areas
if the following are involved: particle therapy, rotation or arc therapy, complex blocking, custom shielding blocks, brachytherapy simulation, hyperthermia probe verification, and/or any use of contrast materials. As of 2017, CPT code 77290 should not be reported with CPT code 77301 unless the simulation was performed in support of non-IMRT radiation therapy for a different tumor.
77295 3-dimensional radiotherapy plan, including dose-volume histograms. May be reported once per treatment course per treatment volume. As of 2017, CPT code 77295 should not be reported with CPT code 77301.
77331 Special dosimetry (e.g., TLD, microdosimetry). There should be a physician's order for diodes, diode reading for date of service in question and a physician's note detailing why diodes were medically necessary. As of 2017, CPT code 77331 should not be reported with CPT code 77301.
77370 Special medical radiation physics consultation. As of 2017, CPT code 77370 may not be used with CPT code 77301. Also, CPT code 77370 is not approved for treatment planning summaries. However, CPT code 77370 may be used if requested by the physician to evaluate a clinical scenario separate from development of the IMRT treatment plan. Documentation of the physician's request and the physicist's report for a clinical scenario separate from the IMRT treatment plan should be provided.

77470 Special radiation treatment. There is no situation in which CPT code 77470 should be routinely used. CPT code 77470 may be requested under certain circumstances. According to the ASTRO Radiation Oncology Coding Resource Digital eBook, examples of where CPT code 77470 should be requested include: 1) patient is very difficult to set up; 2) external beam radiotherapy will be combined with brachytherapy; 3) reconstruction of a prior plan was required; 4) chemotherapy will be given concurrently with radiotherapy; 5) treatment will be given twice a day (BID); or 6) daily EKGs will be obtained because of a pacemaker. There should be a note from a physician stating why significant additional physician and facility work will be required for CPT code 77470 to be approved.

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Stomach

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POLICY HISTORY:

Date	Action

January 3, 2020	Original policy

SERVICE: Neutron Beam Therapy (NBT)

PRIOR AUTHORIZATION: Required

POLICY:

Neutron beam radiotherapy is considered medically necessary for salivary gland cancers that are inoperable, recurrent or resected with positive margins (R1 resection) or gross residual disease (R2 resection).

EXCLUSIONS:

All other indications are not covered because neutron beam therapy (NBT) is considered experimental, investigational, and/or unproven (EIU).

OVERVIEW:

Neutron beam radiotherapy differs from other forms of radiation particle treatment such as protons or electrons because neutrons have no electrical charge. The treatment effects result from energy deposition. There is high energy linear transfer (LET) that may offset the negative effects of low oxygen tension in tumors, leading to improved control in hypoxic tumors. There is limited information including prospective clinical trials addressing its clinical effectiveness, resulting in a lack of national guidelines. The lack of prospective data and comparative trials limits its designation to EIU, with the exception of salivary gland cancers where there have been retrospective case series. Currently, the University of Washington Medical Cyclotron Facility in Seattle is the only clinical neutron facility in the United States. The effectiveness of neutrons for salivary gland malignancies was assessed by Davis et al. The overview included 140 patients with salivary gland malignancies treated with neutron radiotherapy by the Radiation Oncology Department at the University of Washington from 1997 to 2006. The neutron dose for head and neck tumors was 1.15 neutron Gray (nGy) 4 times per week for 4 weeks (total, 18.4 nGy), which is an equivalent amount of radiation as the standard 60 to 70 Gy given for 6 to 7 weeks with conventional photon radiation. Adenoid cystic carcinoma of the submandibular gland was the most common tumor type and location. Post-treatment trismus occurred in 56%. Acute mucositis and xerostomia occurred in approximately 88 and 89% of patients, respectively. Osteoradionecrosis was reported in 6% of patients. The 6-year survival rate was 58% which compares favorably to the survival rate reported in the literature for traditional photon radiation treatment of advanced salivary gland tumors. Stannard et al. (2013) at IThemba Labs in South Africa reported results with NBT using a median dose of 20.4 nGy in 12 fractions over 4 weeks or 15 fractions over 5 weeks. The 335 patients had either unresectable malignant salivary gland tumors or had gross macroscopic residual disease. Local regional control was 61% at 5 years and 39.% at 10 years. Disease specific survival was 67% at 5 years and 54% at 10 years. In a multivariate analysis, tumors >6 cm, squamous carcinoma, unresectable tumors and nodal disease were associated with significantly worse locoregional control. The authors concluded that NBT appears to be the treatment of choice for incompletely excised and unresectable salivary gland tumors with improved survival rates. However, NBT does have limitations, especially at the skull base, which can result in an increased complication rate.

MEDICARE ADVANTAGE:

There is no NCD for neutron beam therapy. Also, there are LCDs for MA, CT, NH and ME. Consequently, this commercial policy will also apply to Medicare Advantage.

BILLING CODES AND DESCRIPTIONS:

Billing codes and their descriptions are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list is not all-inclusive. Billing codes that are not in effect at the time that a service is rendered may not be eligible for reimbursement.

77423 Neutron beam tx complex. The quantity should reflect the number of fractions in the prescription.

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POLICY HISTORY:

Date	Action

January 3, 2020	Original policy

SERVICE: Proton Beam Therapy (PBT)

PRIOR AUTHORIZATION: Required

POLICY:

Proton beam therapy (PBT) is reasonable and medically necessary for the commercial line of business when documentation confirms that **both** of the following indications are met:

1. There is an unresectable target where standard radiotherapy techniques, including intensity-modulated radiation therapy (IMRT), stereotactic body radiation therapy (SBRT) or stereotactic radiosurgery (SRS), are contraindicated based on the following:
    - The target is close enough to a critical normal structure for a steep dose gradient outside the target to be necessary for the avoidance of exposures above tolerance, OR
    - Decreased dose inhomogeneity is necessary for the avoidance of hotspots that would lead to excessive normal tissue toxicity within the target volume, OR
    - Photon-based techniques would result in unacceptable toxicity, OR
    - The clinical target volume is in close proximity to a previously irradiated volume and sculpting is necessary to keep the exposure below normal tissue tolerances such as those in the National Comprehensive Cancer Network (NCCN) Guidelines
2. **Any** of the following diagnoses:
    - Intracranial arteriovenous malformations
    - Ocular tumors, including intraocular/uveal melanoma after initial diagnosis, margin-positive enucleation or for intraocular or orbital recurrence
    - Skull-based tumors (e.g., chordomas or chondrosarcomas*)
    - Unresectable benign or malignant central nervous system tumors (e.g., acoustic neuroma, astrocytoma including glioblastoma multiforme, benign and atypical meningiomas, craniopharyngioma, medulloblastomas, pineal gland tumors or pituitary neoplasms)
    - Localized, unresectable hepatocellular carcinoma (HCC) in the curative setting when documentation is provided that sparing of the surrounding normal tissue cannot be achieved with standard radiotherapy techniques, including IMRT or SBRT
    - Intrahepatic cholangiocarcinoma in the curative setting when documentation is provided that sparing of the surrounding normal tissue cannot be achieved with standard radiotherapy techniques, including intensity-modulated radiation therapy (IMRT) or stereotactic body radiation therapy (SBRT)
    - Unresectable, non-metastatic retroperitoneal sarcoma
    - Advanced (T4) stage and/or unresectable malignant lesions of the head and neck including cancers of the paranasal sinuses and other accessory sinuses, thymomas and thymic carcinomas
    - Primary or benign solid tumors in patients younger than 21 years in age when treatment is performed with curative intent

*PBT following biopsy or partial resection of a skull base or cervical spine chordoma or chondrosarcoma is reasonable and medically necessary when there is residual, localized tumor with no evidence of metastatic disease.

Also, PBT is reasonable and medically necessary when documentation confirms that the patient is younger than 65 years and has prostate cancer that is defined as:

A. Very low risk (i.e., cT1c, Grade Group 1 (Gleason score 6), PSA <10 ng/mL), fewer than 3 prostate biopsy fragments/cores positive, ≤50% cancer in each fragment/core, AND PSA density <0.15 ng/mL/g), OR
B. Low risk (i.e., cT1-cT2a, Grade Group 1 (Gleason score 6), AND PSA <10 ng/mL) but does not qualify for very low risk, OR
C. Intermediate risk (i.e., no high risk OR very high-risk group features as defined below under Exclusions) AND has one or more intermediate risk factors:
    i. cT2b-cT2c, OR
    ii. Grade Group 2-3 (Gleason score 7), OR
    iii. PSA 10-20 ng/mL

    A very low risk, low risk or intermediate risk prostate cancer patient younger than 65 years has a life expectancy of more than 15 years based on the Roswell Park Estimator for Prostate Cancer Death: https://www.roswellpark.org/apps/prostate_cancer_estimator/
    PBT, when compared with IMRT, may result in more than 80% reduction in the risk of developing a second cancer among prostate cancer patients based on a retrospective cohort study using the National Cancer Database (Xiang M et al.). Based on randomized controlled trials (CHHiP, PROFIT, NRG 0415 and HYPRO) and the preferred approach in the current National Comprehensive Cancer Network (NCCN) Guidelines on prostate cancer, 20-28 fractions of PBT will be considered medically necessary when pelvic lymph nodes will not be electively irradiated. Twenty to 45 fractions of PBT will be considered medically necessary when pelvic lymph nodes will be electively irradiated in intermediate risk patients in accordance with the current NCCN Guidelines on prostate cancer.

In addition to the “Group 1” cancers included in section 2 on the previous page, the following “Group 2” cancers will be covered for the Medicare line of business when National Government Services Inc's Local Coverage Determination (LCD) #35075 entitled “Proton Beam Therapy” for Massachusetts considers PBT to be medically reasonable and necessary.

- Unresectable lung cancers and upper abdominal/peri-diaphragmatic cancers
- Advanced stage, unresectable pelvic tumors including those with peri-aortic nodes or malignant lesions of the cervix
- Breast cancers
- Unresectable pancreatic and adrenal tumors
- Skin cancer with macroscopic perineural/cranial nerve invasion of skull base
- Unresectable malignant lesions of the liver, biliary tract, anal canal and rectum
- Prostate cancer, without distant metastases (20-28 fractions is the preferred approach for low risk and intermediate risk prostate cancer where there is no plan to electively irradiate pelvic lymph nodes)
- Hodgkin or non-Hodgkin lymphoma involving the mediastinum or in non-mediastinal sites where PBT has the potential to reduce the risk of pneumonitis or late effects of radiation therapy (secondary malignancy, cardiovascular disease, or other chronic health conditions)

EXCLUSIONS:

In accordance with the current National Comprehensive Cancer Network Guidelines, PBT is not considered reasonable and necessary due to insufficient high-level evidence supporting its efficacy, safety and cost effectiveness for **all** other indications not listed above, including but not limited to:

- Age-related macular degeneration (AMD)
- Choroidal hemangioma or neovascularization
- Extrahepatic cholangiocarcinoma
- Gallbladder cancer
- Not advanced (i.e., T1-T3) and resectable head and neck cancers
- Testicular seminoma

Also, PBT is not covered in the following clinical scenarios:

- Where PBT does not offer an advantage over photon-based therapies that otherwise deliver good clinical outcomes and low toxicity
- Spinal cord compression, superior vena cava syndrome, malignant airway obstruction, poorly controlled malignant bleeding and other scenarios of clinical urgency
- Inability to accommodate for organ motion
- Palliative treatment in a clinical situation where normal tissue tolerance would not be exceeded in previously irradiated areas

OVERVIEW:

PBT is a type of radiation therapy which uses protons to deliver ionizing radiation to a target. In order for protons to penetrate the body and reach the intended target, they must be accelerated to about 60% of the speed of light using a cyclotron. Since PBT is still experimental for many types of cancer considering that the evidence supporting it is low-level and the cost associated with building a cyclotron is high, few centers in the United States offer this service.

With standard radiation therapy, the greatest energy release is near the surface of the tissue and decreases exponentially with the distance travelled. In contrast to standard radiation therapy, the greatest energy of a proton beam is released at the end of its path. This region is called the Bragg peak. Since the energy release of the proton beam is largely in the Bragg peak, the collateral damage to surrounding healthy tissues is reduced and an increased dose of radiation can be delivered to the target area. This physical property of PBT has led to the theory that PBT may be especially useful for targets where damage to nearby healthy tissue would result in an unacceptable risk.

a. Skull-Based Tumors

Amichetti et al. (2009) conducted a similar review on the use of proton therapy to treat chordoma and reported that the use of protons has shown better results compared to conventional photon RT, resulting in the best long-term outcome for this tumor with relatively few significant complications considering the high doses delivered. Amichetti et al. (2010) conducted a systematic review of published literature on the use of proton beam therapy to treat chondrosarcoma. There were no prospective trials, but 9 uncontrolled single-arm studies were identified. The reviewers found that the use of proton therapy following maximal surgical resection shows a very high probability of medium- and long-term cure with a relatively low risk of significant complications.

b. Intraocular/Uveal Melanoma

The safety and efficacy of PBT for the treatment of melanomas of the uveal tract is supported by systematic reviews, randomized controlled trials, prospective case series and retrospective reviews. Patient populations ranged from 21–2645 and follow-up ranged from 18 months to 15 years. Outcomes varied based on the tumor characteristics. Ten- and 15-year local control rates up to 98%, 15-year overall eye retention rates up to 84%, and subsequent enucleation rates as low as 9% have been reported. The rate of development of distant metastases following PBRT ranged from 7%–24.2%. Five-year tumor specific survival rates have been reported at 79%. Five-, 10- and 15-year survival rates have been reported at 86%, 77%, and 73% respectively.

BILLING CODES AND DESCRIPTIONS:

Billing codes and their descriptions are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list is not all-inclusive. Billing codes that are not in effect at the time that a service is rendered may not be eligible for reimbursement.

77520 Proton treatment delivery; simple, without compensation
77522 Proton treatment delivery; simple, with compensation
77523 Proton treatment delivery; intermediate**.** Intermediate proton beam therapy delivery to one or more treatment areas utilizing two or more ports or one or more tangential/oblique ports with custom blocks and compensators is billed using CPT code 77523
77525 Proton treatment delivery; complex. Complex proton beam therapy delivery to one or more treatment areas utilizing two or more ports per treatment area with matching or patching fields and/or multiple isocenters, with custom blocks and compensators is billed using CPT code 77525.

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POLICY HISTORY:

Date	Action
January 3, 2020	Original policy
November 18, 2021	Updates are highlighted in yellow on page 42.

[1]This policy applies to the products of Harvard Pilgrim Health Care and its affiliates—Harvard Pilgrim Health Care of Connecticut, Harvard Pilgrim Health Care of New England, and HPHC Insurance Company—for services performed by contracted providers. Payment is based on member benefits and eligibility, medical necessity review, where applicable, and provider contractual agreement. Payment for covered services rendered by contracted providers will be reimbursed at the lesser of charges or the contracted rate. (Does not apply to inpatient per diem, DRG, or case rates.) HPHC reserves the right to amend a payment policy at its discretion. CPT and HCPCS codes are updated annually. Always use the most recent CPT and HCPCS coding guidelines.
[2]The table does not include all possible CPT and HCPCS codes related to radiation oncology.

SERVICE: Stereotactic Body Radiation Therapy (SBRT)

PRIOR AUTHORIZATION: Required

POLICY:

From a billing standpoint, stereotactic body radiation therapy (SBRT) refers to the stereotactic delivery of 2-5 fractions of radiotherapy to cranial lesion(s) or 1-5 fractions of radiotherapy to non-cranial lesion(s). The aforementioned billing definition of SBRT is used in this medical policy. From a clinical standpoint, SBRT is sometimes referred to as "fractionated SRS" in situations where 2-5 fractions are given to cranial or spinal target(s).

From a billing standpoint, stereotactic radiosurgery (SRS) refers to the stereotactic delivery of single-fraction radiotherapy to cranial lesion(s). Please see the SRS Medical Policy if a provider is requesting the stereotactic delivery of single-fraction radiotherapy to cranial lesion(s).

SBRT will be considered medically reasonable and necessary for certain conditions as long as the following criteria are met:

- Either #1, #2, or #3 must be present, **and**
- Either #4 or #5 must be present, **and**
- #6 must always be present.

1) When dose constraints to normal tissues limit the total dose of radiation safely deliverable to the tumor with other indicated methods.
2) When there is a reason to believe that doses generally thought to be above the level otherwise attainable with other methods might improve control rates.
3) In circumstances when the higher levels of precision associated with SBRT as compared to other radiation methods are necessary, i.e., clinically relevant.
4) For the treatment of primary lesions, the intent of treatment is curative.
5) For the treatment of metastatic lesions, there must be:
    i. The expectation of a long-term (> 6 months) benefit that could not have been attained with conventional therapy.
    ii. The expectation of a complete eradication of the metastatic lesion that could not have been safely accomplished with conventional therapy, as evidenced by a dosimetric advantage for SBRT over other forms of radiation therapy.
6) The patient's record demonstrates why SBRT is considered the treatment of choice for the individual patient. Specifically, the record must address the lower risk to normal tissue, the lower risk of disease recurrence, and the advantages of SBRT over IMRT or 3D conformal radiation therapy. For example, there should be dosimetric evidence of more than 10% reduction in a dose-volume treatment planning constraint for a critical organ such as the lungs or heart.

SBRT will be considered medically reasonable and necessary only if the above criteria are met, as specified, for the following conditions:

Bony Vertebral Metastases

The patient has an ECOG Performance Status of 0-2, **and**:

- Metastatic disease requiring palliation cannot be treated by conventional methods due to proximity of adjacent prior irradiated volumes and other measures are not appropriate or safe for the patient, **or**
- The patient's general medical condition justifies aggressive local therapy to one or more deposits of metastatic cancer in an effort to achieve total disease clearance in the setting of oligometastatic (≤ 5 metastases) disease with no active disease elsewhere in the body, **and**
- The targeted tumor(s) can be completed encompassed with acceptable risk to nearby critical normal structures

For uncomplicated, previously untreated bone metastases in a patient with widespread progressive disease in the spine or elsewhere and where the prognosis is unfavorable, it is generally appropriate to use a less technically complex form of palliative radiation therapy rather than SBRT.

Brain Metastases

The patient has a Karnofsky Performance Status 40 or greater (and expected to return to 70 or greater with treatment), and otherwise reasonable survival expectations or an Eastern Cooperative Oncology Group (ECOG) Performance Status of 3 or less (or expected to return to 2 or less with treatment), **and:**

- Stable systemic disease, **and**
- Does not have leptomeningeal disease, **and**
- Has a cancer that is not germ cell tumor or lymphoma, **and**
- Has no lesion > 5 cm (the use of 2-5 fractions of SBRT rather than a single fraction of SRS may improve local control and reduce the risk of radionecrosis for brain metastases that measure 3-5 cm) and all lesions can be addressed in a single treatment plan, **and**
- Has not been treated with more than 2 courses of SRS/SBRT in the past 9 months, **and**
- Has a life expectancy of > 6 months **or**
- Has received prior whole brain irradiation and has a life expectancy > 3 months

The patient may be treated with SBRT alone or with SBRT in a postoperative setting.

Kidney or Adrenal Gland Cancer

The patient an ECOG Performance Status of 0-2, **and**:

- Primary kidney cancer ≤ 5 cm and is not a surgical candidate, **or**
- Oligometastatic (≤ 5 lesions) disease where the lesions are all ≤ 5 cm with no active disease elsewhere in the body, **and**
- Other forms of radiotherapy, including but not limited to IMRT, cannot be as safely or effectively utilized, and the tumor burden can be completely targeted with acceptable risk to critical normal structures.

- If the tumor histology is germ cell or lymphoma, effective chemotherapy regimens have been exhausted or are otherwise not feasible. Also, other forms of focal therapy, including but not limited to radiofrequency ablation and cryotherapy, cannot be as safely or effectively used.

Liver Cancer

The patient an ECOG Performance Status of 0-2, **and**:

- Primary hepatocellular carcinoma ≤ 5 cm and is not a surgical candidate, **or**
- As palliative treatment for individuals with liver-related symptoms **or**
- As treatment of up to 3 lesions, as an option to surgery or embolization when these therapies have been done and have failed, or are contraindicated, when the following conditions are met:
    1. Diameter ≤5 cm **and**
    2. No extrahepatic disease **and**
    3. Patients with Child-Pugh A or B liver disease **(**Note: SBRT has not been established as a safe treatment option in patients with Child-Pugh category C cirrhosis) **or**
    4. To treat a previously irradiated field

Non-Small Cell Lung Cancer

The patient an ECOG Performance Status of 0-2, **and**:

- Stage I-II non-small cell carcinoma of the lung in a medically inoperable patient or a patient who refuses surgery, **or**
- Oligometastatic (≤5 lesions) disease and:
    1. Has had or who will undergo curative treatment of the primary tumor (based on T and N stage), **and**
    2. Has one to 5 metastases in the synchronous setting, i.e., the metastases were found at the time of diagnosis of the primary tumor, **or**
    3. One to 5 adrenal gland, lung, liver or bone metastases in the metachronous setting, i.e., the metastases were found after the treatment of the primary tumor, when all the following criteria are met:
        i. Disease free interval of more than one year from the initial diagnosis, **and**
        ii. Primary tumor received curative therapy and is controlled, **and**
        iii. No prior evidence of metastatic disease (cranial or extracranial)

Also, SBRT may be considered medically necessary if it is being used to treat a previously irradiated field.

Pancreatic Cancer

The patient an ECOG Performance Status of 0-2, **and**:

- Palliative intent or curative intent where the primary tumor is borderline unresectable.

SBRT should be avoided where direct invasion of the bowel or stomach is observed on computed tomography scan, magnetic resonance imaging scan, or endoscopy.

Prostate Cancer

The patient an ECOG Performance Status of 0-2 and is being treated at a radiation oncology practice that has appropriate technology, physics, and clinical expertise with SBRT to treat:

- Very low risk to favorable intermediate risk prostate cancer as defined by the National Comprehensive Cancer Network.

Small Cell Lung Cancer

The patient an ECOG Performance Status of 0-2, **and**:

- cT1-T2,N0, M0 disease, **and**
- Is medically inoperable, **or**
- A decision is made not to pursue surgical resection

Also, SBRT may be considered medically necessary if it is being used to treat a previously irradiated field.

EXCLUSIONS:

SBRT will not be considered medically necessary for:

- Lesions involving organs not listed above as literature does not support an outcome advantage over other conventional radiation modalities. Lesions of bone, breast, uterus, ovary and other internal organs not listed under “Policy” above are not covered for definitive SBRT as literature does not support its use as standard of care at this time. However, SBRT may be appropriate in the setting where lesions have received prior radiotherapy or an immediately adjacent site has been irradiated.
- Patients in whom the tumor burden cannot be completely targeted with acceptable risk to nearby critical normal structures.
- Cases where it is unlikely to result in functional improvement or clinically meaningful cancer control that is not otherwise achievable, e.g., where a patient has widespread metastases.
- Patients with a poor performance status (Karnofsky Performance Status < 40; see Karnofsky Performance Scale* below) or an Eastern Cooperative Oncology Group (ECOG) Performance Status > 2 (see below).

***Karnofsky Performance Scale**

100 Normal; no complaints, no evidence of disease
90 Able to carry on normal activity; minor signs or symptoms of disease

80 Normal activity with effort; some signs or symptoms of disease
70 Cares for self; unable to carry on normal activity or to do active work
60 Requires occasional assistance but is able to care for most needs
50 Requires considerable assistance and frequent medical care
40 Disabled; requires special care and assistance
30 Severely disabled; hospitalization is indicated although death not imminent
20 Very sick; hospitalization necessary; active supportive treatment is necessary
10 Moribund, fatal processes progressing rapidly
0 Dead

***Eastern Cooperative Oncology Group Performance Scale**

0 Fully active, able to carry on all pre disease activities without restriction (Karnofsky 100)

1 Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, for example, light housework/office work (Karnofsky 80-90)

2 Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours (Karnofsky-70)

3 Capable of limited self-care, confined to bed or chair 50% or more of waking hours (Karnofsky 40-50)

4 Completely disabled; cannot carry on any self-care; totally confined to bed or chair (Karnofsky 10-30)

5 Dead (Karnofsky 0)

OVERVIEW:

SBRT uses externally-generated, high-dose ionizing radiation to eradicate ≤ 5 cm target(s). The target is defined by high-resolution stereotactic imaging. The process typically involves input from a radiation oncologist and a medical physicist. SBRT performed using immobilization technology and a stereotactic image-guidance system can be performed in up to 5 sessions. The adjective "stereotactic" describes a procedure during which a target lesion is localized relative to a known 3D reference system that allows for a high degree of anatomic accuracy. Examples of devices used for stereotactic guidance include a body frame with external reference markers in which a patient is positioned securely, a system of implanted fiducial markers that can be visualized with low-energy (kV) x-rays, and computed tomography (CT)-imaging-based systems used to confirm the location of a tumor immediately prior to treatment. SBRT is performed with at least one form of image guidance to confirm proper patient positioning and tumor localization. To minimize intra-treatment tumor motion associated with respiration, some form of motion control or "gating" should be used. SBRT may be given as a single treatment to a non-cranial target or “fractionated” whereby it is given in two to 5 treatments to a target anywhere in the body. Each fraction requires an identical degree of precision, localization and image guidance. Since the goal of SBRT is to complete an entire course of treatment within an accelerated time frame, any course of radiation treatment extending beyond five fractions is not considered SBRT. Five Gy is the minimum dose per fraction for the radiotherapy technique to be considered SBRT. A typical dose would be 12-24 Gy if SBRT were given in a single treatment to a non-cranial lesion such as a bone

metastasis. For patients with tumors of any type arising in or near a previously-irradiated region, SBRT may be appropriate when a high level of precision and accuracy is needed to minimize the risk of injury to surrounding normal tissues.

a. Bone Metastases

SBRT has been demonstrated to achieve durable tumor control when treating bone metastases. There is an important clinical distinction between the status of patients described above and a patient with widely metastatic disease for whom palliation is the major objective. In one setting, a patient with limited metastatic disease and good performance status is treated with the intention of eradicating all known active disease or greatly reducing the total disease burden in a manner that can extend progression-free survival. For such a patient, SBRT can be a reasonable therapeutic intervention. However, for uncomplicated, previously untreated bone metastases in a patient with widespread progressive disease and where the prognosis is unfavorable, it is generally appropriate to use a less technically complex form of palliative radiation therapy rather than SBRT.

b. Prostate Cancer

Many clinical studies supporting the efficacy and safety of SBRT in the treatment of localized prostate cancer have been published. At least one study has shown excellent five-year biochemical control rates with very low rates of serious toxicity. Additionally, numerous studies have demonstrated the safety of SBRT for prostate cancer after a follow-up interval long enough (two to three years) to provide an opportunity to observe the incidence of late genitourinary or gastrointestinal toxicity. While it is necessary to observe patients treated for prostate cancer for extended intervals to gauge the rate of long-term (e.g., beyond 10 years) biochemical control and overall survival, the interim results reported appear at least as good as other forms of radiation therapy administered to patients with equivalent risk levels followed for the same post-treatment duration. It is NCCN's opinion that data supporting the use of SBRT for prostate cancer have matured to a point where SBRT is considered an appropriate option for patients with very low, low or favorable intermediate risk disease.

c. Other Indications for SBRT

For patients with tumors of any type arising in or near previously irradiated regions, SBRT may be appropriate when a high level of precision and accuracy is needed to minimize the risk of injury to surrounding normal tissues. Also, in cases where a high dose per fraction, i.e., ≥ 5 Gy/fraction, and 1-5 fractions are indicated, SBRT may be appropriate. The medical necessity for SBRT should be documented in the patient's medical record.

MEDICARE ADVANTAGE:

There is no NCD for SBRT. However, there is "Local Coverage Determination (LCD): Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (L35076)" for MA, CT, NH and ME:
https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35076&ver=52&CoverageSelection=Local&ArticleType=All&PolicyType=Final&s=Massachusetts&KeyWord=SRS&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAAAAA&

The above Medicare LCD on SBRT will apply to Medicare Advantage.

BILLING CODES AND DESCRIPTIONS:

Billing codes and their descriptions are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list is not all-inclusive. Billing codes that are not in effect at the time that a service is rendered may not be eligible for reimbursement.

- **SBRT Treatment Planning**

  There are no specific codes for clinical treatment planning and simulation for SBRT. However, because of the complexity of SBRT and the need for three-dimensional conformal or IMRT dosimetric treatment planning, the following codes are usually appropriate for SBRT cases. Use of IMRT planning is based on medical necessity.

  77263 Therapeutic radiology treatment planning; complex Given the complexity of clinical decision-making for SBRT, a complex clinical treatment planning code is justified.
  +77293 Respiratory motion management. It may be reasonable to perform and report CPT code 77293 once per course of SBRT for cases in which target movement during respiration must be accounted for during treatment planning (e.g., tumors of the thorax and upper abdomen). A 4D simulation must be performed showing clinically significant tumor motion with inspiration and expiration. DIBH, where the target is stationary during treatment, does not warrant CPT code 77293. Report CPT code "+77293" in conjunction with 77295 or 77301 as it is an add-on-code. CPT code "+77293" cannot be billed as a stand-alone code.
  77295 3-dimensional radiotherapy plan, including dose-volume histograms**.**
  77301 Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications**.** (Dose plan is optimized using inverse planning technique for modulated beam delivery, e.g., binary, dynamic MLC, to create a highly conformal dose distribution. A second unit of CPT code 77301 can only be billed if medically necessary due to significant weight loss or changes in tumor anatomy during radiotherapy. The reason(s) for a repeat plan must be documented.
  77470 Special treatment procedure. Given the complexity and additional time and effort required of SBRT, CPT code 77470 may be justified with appropriate specific documentation.

- **Medical Radiation Physics, Dosimetry, Treatment Devices and Special Procedures**

  There are no SBRT specific codes for medical radiation physics, dosimetry, treatment devices and special services. However, the following codes can be used as described below.

  77300 Basic radiation dosimetry calculation, central axis depth dose calculation, TDF, NSD, gap calculation, off axis factor, tissue inhomogeneity factors, calculation of non-ionizing radiation surface and depth dose, as required during course of treatment, only when prescribed by the treating physician. One unit for each arc using a linear accelerator system. One unit for each shot with a cobalt-60 device. Maximum limit of 10 units.
  77334 Treatment devices, design and construction; complex (irregular blocks, special shields, compensators, wedges, molds or casts)**.** One unit for each unique combination of beam angle

and collimator pattern or each unique arc; certain carrier limitations may apply. One unit for each helmet with a cobalt-60 device. Maximum limit of 10 units.
77338 Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction, per IMRT plan**.** If IMRT planning code 77301 is used for coding treatment planning. then one CPT 77338 should be used to code for the devices. Maximum limit of one unit.
77370 Special medical radiation physics consultation. This may be reasonable and necessary if ordered by the radiation oncologist. Maximum limit of one unit.

- **SBRT Treatment Delivery**

  Historically, in the hospital outpatient environment, CMS has utilized G-codes to distinguish between robotic and nonrobotic SBRT and SRS. The agency recently reviewed current radiation therapy equipment technology and found that most linac-based treatment platforms incorporate some type of robotic capability. CMS therefore concluded that it is no longer necessary to continue distinguishing robotic and non-robotic linear accelerators.

  77373 Stereotactic body radiation therapy, treatment delivery**.** CPT code 77373 should be used for SBRT, 2-5 fractions to cranial lesion(s) or 1-5 fractions to non-cranial lesion(s)) including spinal lesion(s). You should not report CPT code 77371 or 77372 with 77373 (all of the fractions are billed using CPT code 77373 if this code is reported). Do not request CPT codes 77385, 77386, 77401, 77402, 77407 or 77412 in conjunction with CPT code 77373. For single fraction cranial lesion[s], use CPT code 77371 or 77372 for SRS delivery**.** CPT code 77373 is a technical code for up to but no more than 5 fractions. This code includes all image guidance on the days of treatment delivery; therefore, do not report 77373 in conjunction with 77014 on the days of treatment delivery. This code will be paid only once per day of treatment regardless of the number of sessions or lesions. When reporting SBRT delivery, it is not appropriate to bill more than one treatment delivery code on the same date of service, even though stereotactic therapy may be delivered using either three-dimensional conformal or intensity modulated radiation therapy techniques. Likewise, only one SBRT delivery unit is to be reported even if multiple targets are treated using different setup and field arrangement parameters on the same day.

- **Radiation Treatment Management**

  The physician work for 77435 can be summarized as follows: The radiation oncologist evaluates the patient prior to the procedure. Under the direct supervision of the radiation oncologist, the patient is set up on the treatment table and all the treatment parameters are verified. Image guidance and respiratory correlation, if required, may be achieved through a variety of methods, all of which are supervised, corrected and approved in real-time by the physician. The physician assesses and approves all of the ongoing images used for localization, tumor tracking and any gating application, as well as any complementary single (beam's eye) view localization images for any of the fields or arcs used to deliver a dose. The radiation oncologist remains available throughout SBRT treatment to manage the execution of the treatment and make real-time adjustments in response to patient motion, target movement or equipment issues to ensure accuracy and safety. The physician also evaluates the patient post-procedure. Work generally associated with CPT code 77427 (Radiation treatment management, five treatments) is included and should not be separately coded. Much of

the radiation oncologist's work in establishing the above treatment parameters is performed in conjunction with the qualified medical physicist.

77435 Stereotactic body radiation therapy, treatment management, per treatment course, to one or more lesions, including image guidance, entire course not to exceed 5 fractions. Do not request CPT codes 77427, 77431 or 77432 with 77435. The same physician should not report both stereotactic radiosurgery services (32701, 63620 and 63621) and radiation treatment management (77435)**.** CPT code 77435 is a professional charge for treatment management performed by a radiation oncologist. This code can be reported only once for the entire course of treatment and not per fraction. It will apply to all lesions treated during that entire course of treatment. It should not be reported in conjunction with any other treatment management codes (777472-77432).

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Bone Metastasis

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Lung – Primary and Metastatic Tumors

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POLICY HISTORY:

Date	Action
January 3, 2020	Original policy

SERVICE: Stereotactic Radiosurgery (SRS)

PRIOR AUTHORIZATION: Required

POLICY:

From a billing standpoint, stereotactic radiosurgery (SRS) refers to the stereotactic delivery of single-fraction radiotherapy to cranial lesion(s). The aforementioned billing definition of SRS is used in this medical policy.

From a billing standpoint, stereotactic body radiation therapy (SBRT) refers to the stereotactic delivery of 2-5 fractions of radiotherapy to cranial lesion(s) or 1-5 fractions of radiotherapy to non-cranial lesion(s). Please see the SBRT Medical Policy for situations where a provider is requesting 2-5 fractions of radiotherapy to cranial lesion(s) or 1-5 fractions of radiotherapy to non-cranial lesion(s). SBRT is sometimes referred to as "fractionated SRS" in situations where 2-5 fractions are given to cranial or spinal target(s).

SRS will be considered medically reasonable and necessary for the following indications:

- Primary central nervous system malignancies, generally used as a boost or salvage therapy for cranial or base of skull lesions < 5 cm.
- Primary and secondary tumors involving the brain parenchyma, meninges/dura or immediately adjacent bony structures.
- Benign brain tumors such as cranial meningiomas, acoustic neuromas, other schwannomas, pituitary adenomas, pineocytomas, craniopharyngiomas, glomus tumors or hemangioblastomas.
- Arteriovenous malformations and hemangiomas.
- Other cranial non-neoplastic conditions such as trigeminal neuralgia and select cases of medically refractory epilepsy, movement disorders such as Parkinson's disease and essential tremor, and hypothalamic hamartomas.
- Metastatic brain lesions with stable systemic disease, Karnofsky Performance Status 40 or greater (and expected to return to 70 or greater with treatment), and otherwise reasonable survival expectations or an Eastern Cooperative Oncology Group (ECOG) Performance Status of 3 or less (or expected to return to 2 or less with treatment).
- Relapse in a previously irradiated cranial field where the additional stereotactic precision is required to avoid unacceptable vital tissue radiation.

Additional Coverage Requirements for Brain Metastases

The patient:

- Has stable systemic disease, **and**
- Does not have leptomeningeal disease, **and**
- Has no lesion > 5 cm (the use of 2-5 fractions of SBRT rather than a single fraction of SRS may improve local control and reduce the risk of radionecrosis for brain metastases that measure 3-5 cm) and all lesions can be addressed in a single treatment plan, **and**
- Has not been treated with more than 2 courses of SRS/SBRT in the past 9 months, **and**
- Has a life expectancy of > 6 months

The patient may be treated with SRS alone or with SRS in a postoperative setting.

EXCLUSIONS:

SRS will not be considered medically necessary for:

- Treatment for anything other than a severe symptom or serious threat to life or critical functions, not responsive or reasonably amenable to another therapy.
- Treatment unlikely to result in functional improvement or clinically meaningful disease stabilization, not otherwise achievable.
- In general, SRS is not indicated for cancers that are widespread with regard to brain metastases. The intent of treatment should be curative, except in cases where SRS will provide the best palliation and significantly improve quality of life.
- Patients with poor performance status (Karnofsky Performance Status < 40; see Karnofsky Performance Scale* below) or Eastern Cooperative Oncology Group (ECOG) Performance Status 4 (see below).
- For ICD-10-CM code G25.0-G25.2, essential tremor, coverage should be limited to the patient who cannot be controlled with medication, has major systemic disease or coagulopathy, and who is unwilling or unsuited for invasive surgical procedure. If the preceding conditions are met, coverage will be limited to unilateral thalamotomy.
- Stereotactic cingulotomy as a means of psychotherapy. This is considered investigational per Medicare National Coverage Determinations (NCD) Manual, Publication 100-03, Chapter 1, Part 2, Section 160.4.

***Karnofsky Performance Scale**

100 Normal; no complaints, no evidence of disease
90 Able to carry on normal activity; minor signs or symptoms of disease
80 Normal activity with effort; some signs or symptoms of disease
70 Cares for self; unable to carry on normal activity or to do active work
60 Requires occasional assistance but is able to care for most needs
50 Requires considerable assistance and frequent medical care
40 Disabled; requires special care and assistance
30 Severely disabled; hospitalization is indicated although death not imminent
20 Very sick; hospitalization necessary; active supportive treatment is necessary
10 Moribund, fatal processes progressing rapidly
0 Dead

***Eastern Cooperative Oncology Group Performance Scale**

0 Fully active, able to carry on all pre disease activities without restriction (Karnofsky 100)

1 Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, for example, light housework/office work (Karnofsky 80-90)

2 Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours (Karnofsky-70)

3 Capable of limited self-care, confined to bed or chair 50% or more of waking hours (Karnofsky 40-50)

4 Completely disabled; cannot carry on any self-care; totally confined to bed or chair (Karnofsky 10-30)

5 Dead (Karnofsky 0)

OVERVIEW:

SRS requires computer-assisted, 3D or IMRT planning and delivery with stereotactic and convergent-beam technologies, including but not limited to: gamma rays from a multisource cobalt-60 unit (e.g., Gamma Knife®) or x-rays from a linear accelerator (e.g., XKnife®) or an image-guided robotic linear accelerator (e.g., CyberKnife®). SRS is delivered in a single treatment to cranial lesion(s) using a rigidly-attached stereotactic guidance device or other immobilization technology with stereotactic guidance. To promote high quality care, SRS should involve discussions within a multidisciplinary team consisting of a neurosurgeon, radiation oncologist and medical physicist. SRS uses radiation to eradicate small cranial target(s) without the need to make an incision.

MEDICARE ADVANTAGE:

There is no NCD for SRS. However, there is "Local Coverage Determination (LCD): Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (L35076)" for MA, CT, NH and ME:
https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35076&ver=52&CoverageSelection=Local&ArticleType=All&PolicyType=Final&s=Massachusetts&KeyWord=SRS&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAAAAA&

The above Medicare LCD on SRS will apply to Medicare Advantage.

BILLING CODES AND DESCRIPTIONS:
Billing codes and their descriptions are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list is not all-inclusive. Billing codes that are not in effect at the time that a service is rendered may not be eligible for reimbursement.

a. SRS Treatment Planning

There are no specific codes for clinical treatment planning and simulation for SRS. However, because of the complexity of SRS and the need for three-dimensional conformal or IMRT dosimetric treatment planning, the following codes are usually appropriate for SRS cases. Use of IMRT planning is based on the delivery system and medical necessity. Whether a physician treats one or more lesions, treatment planning CPT code 77295 or CPT code 77301 should only be used once for the entire episode.

77263 Therapeutic radiology treatment planning; complex. Given the complexity of SRS, a complex treatment planning code is justified. CPT code 77263 should not be reported with CPT code 77401.
77295 3-dimensional radiotherapy plan, including a dose-volume histogram. Report one unit for each course of SRS. Report one unit.
77301 Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications. A second unit of CPT code 77301 can only be billed if medically necessary due to significant weight loss or changes in tumor anatomy during radiotherapy. The reason(s) for a repeat plan must be documented.

b. Medical Radiation Physics, Dosimetry, Treatment Devices, and Special Services

There are no SRS specific codes for medical radiation physics, dosimetry, treatment devices, and special services. However, the following codes can be used as described below.

77300 Basic radiation dosimetry calculation, central axis depth dose calculation, TDF, NSD, gap calculation, off axis factor, tissue inhomogeneity factors, calculation of nonionizing radiation surface and depth dose, as required during course of treatment, only when prescribed by the treating physician. One unit for each arc and each lesion with a linear accelerator system. There is a maximum limit of 20 units. The quantity approved will equal the number of fields/portals/angles/arcs. For example, the approved quantity would be 16 if 4 arcs will be used to treat 4 cranial lesions.
77334 Treatment devices, design and construction; complex (irregular blocks, special shields, compensators, wedges, molds or casts). There should be one unit for each arc with linac-based SRS. Alternatively, there should be one unit for each collimator helmet size utilized with cobalt-60 based SRS. Provide documentation of immobilization device and/or each treatment device reported for date of service in question. If an allowed quantity of 10 is exceeded, then documentation must be provided to support why a quantity greater than 10 should be approved.
77338 Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction, per IMRT plan**.** If IMRT planning code 77301 is used for coding treatment planning, then typically one CPT 77338 would be used to code for the MLC devices. Treatment devices are billed separately from the planning and delivery codes. Report one unit, if applicable.
77370 Special medical radiation physics consultation (one unit). CPT code 77370 may be reasonable and necessary for SRS if a special medical radiation physics consultation is ordered by the radiation oncologist, e.g., for fusion of an MRI scan onto a CT scan. The physician's request and physicist's report for the date of service in question should be provided. Report a maximum of one unit, if applicable.

c. SRS Treatment Delivery

It is not appropriate to bill more than one treatment delivery code on the same day of service, even though some types of delivery may have elements of several modalities (e.g., a stereotactic approach with IMRT). Only one delivery code is to be billed.

77371 Radiation treatment delivery, stereotactic radiosurgery (SRS). CPT code 77371 should be used for single-fraction treatment of cranial lesion(s) using a cobalt-60 unit. If you are requesting 2-5 fractions of SRS, then you should report CPT code 77373 rather than CPT code 77371.

delivery using cobalt-60. Report one unit, if applicable.
77372 Radiation treatment delivery, stereotactic radiosurgery (SRS). CPT code 77372 should be used for single-fraction treatment of cranial lesion(s) using a linac. Report one unit, if applicable. If 2-5 fractions are planned, then you should report CPT code 77373 for SBRT rather than one unit of CPT code 77372 for SRS.

d. Radiation Treatment Management

There is one radiation treatment management code specific to SRS, CPT® code 77432. If 2-5 fractions are planned, then use CPT code 77435 (SBRT management). For spinal stereotactic radiotherapy involving one to five fractions, report the treatment as SBRT and use CPT code 77435 (SBRT management) once for the entire course of treatment. CPT code 77432 and CPT code 77435 cannot be billed for the same patient for the same episode of care, and Medicare does not reimburse CPT code 77432 and CPT code 77470 (Special treatment procedure) on the same day of service. A prolonged (more than 5 fractions) course of cranial radiation therapy should be reported using billing codes for 3DCRT or IMRT rather than SRS (or SBRT). SRS treatments are to be performed under the direct supervision of a qualified medical physicist and a radiation oncologist.

77432 Stereotactic radiation treatment management of cranial lesion(s) (complete course of treatment consisting of one session)**.** The same physician should not report both stereotactic radiosurgery neurosurgical services [61796-61800) and stereotactic radiation treatment management (77432) for cranial lesion(s).

e. Coding For A Neurosurgeon

Usually, a radiation oncologist will work with a neurosurgeon to perform SRS. Radiation oncologists and neurosurgeons have separate CPT® billing codes for SRS. CPT codes 61781–61783 or 61796–61800 are reported for the work attributed to the neurosurgeon. These codes are mutually exclusive with the radiation oncology CPT codes 77432 and 77435; therefore, the same physician should not bill for both of these codes. No one physician may bill both the neurosurgical codes 61781–83 or 61796–61800 and the radiation oncology 77xxx codes. If either the radiation oncologist or the neurosurgeon does not fully participate in the patient's care, that physician must take care to indicate this change by use of the appropriate -54 modifier (followed by any appropriate -55 modifier) on the global procedure(s) submitted. As the services are collegial in nature with different specialties providing individual components of the treatment, surgical assistants will not be reimbursed. The following codes may be used by the neurosurgeon to code for involvement in the procedure.

61796 Treatment of a simple cranial lesion by a neurosurgeon using cobalt-60 based SRS (Gamma Knife radiosurgery). No one physician may bill both the neurosurgical codes 61781-83, 61796-61800, 63620 or 63621 and the radiation oncology 77xxx codes. The physician billing the 77xxx codes must be physically present during the entire process of defining the target volume and structures at risk.
+**61797** Treatment of each additional simple cranial lesion by a neurosurgeon using cobalt-60 based SRS (Gamma Knife radiosurgery). No one physician may bill both the neurosurgical codes 61781-83, 61796-61800, 63620 or 63621 and the radiation oncology 77xxx codes. The physician billing the

77xxx codes must be physically present during the entire process of defining the target volume and structures at risk.
61798 Treatment of a complex cranial lesion by a neurosurgeon using cobalt-60 based SRS (Gamma Knife radiosurgery). No one physician may bill both the neurosurgical codes 61781-83, 61796-61800, 63620 or 63621 and the radiation oncology 77xxx codes. The physician billing the radiation oncology 77xxx codes must be physically present during the entire process of defining the target volume and structures at risk.

+**61799** Treatment of each additional complex cranial lesion by a neurosurgeon using cobalt-60 based SRS (Gamma Knife radiosurgery). No one physician may bill both the neurosurgical codes 61781-83, 61796-61800, 63620 or 63621 and the radiation oncology 77xxx codes. The physician billing the radiation oncology 77xxx codes must be physically present during the entire process of defining the target volume and structures at risk.
61800 Application of stereotactic headframe for stereotactic. No one physician may bill both the neurosurgical codes 61781-83, 61796-61800, 63620 or 63621 and the radiation oncology 77xxx codes. The physician billing the radiation oncology 77xxx codes must be physically present during the entire process of defining the target volume and structures at risk.

f. Additional Information

For Medicare claims, the HCPCS/CPT® code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing Medicare.

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POLICY HISTORY:

Date	Action
January 3, 2020	Original policy

SERVICE: ^{90}Y Microsphere Radioembolization (also known as ^{90}Y microspheres, selective internal radiation therapy (SIRT), implantable beta-emitting microspheres, intrahepatic microsphere radiation (IMR) therapy or transarterial radioembolization (TARE))

PRIOR AUTHORIZATION: Required

POLICY:

Yttrium-90 (^{90}Y) microsphere radioembolization is proven and medically necessary for the following indications:

- Unresectable liver only or liver dominant metastases from primary colorectal cancer (CRC) or neuroendocrine tumors, e.g., carcinoids or pancreatic islet cell tumors. Requests for the treatment of liver metastases from other primary malignancies, including breast carcinoma, ocular melanoma, cutaneous melanoma and intrahepatic cholangiocarcinoma, will be considered if there is a lack of any other systemic or liver-directed treatment options for the patient in an effort to relieve symptoms and/or possibly extend life expectancy
- Unresectable primary hepatocellular carcinoma (HCC)
- Unresectable primary intrahepatic cholangiocarcinoma

The patient should have an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2 or a Karnofsky Performance Status (KPS) of 70 or more and a life expectancy of at least 3 months.

A second radioembolization procedure is considered medically necessary for new or progressive primary or metastatic liver cancer when the patient has had a previous satisfactory response to the initial radioembolization treatment based on the results of a computed tomography (CT) scan or positron emission tomography (PET)-CT scan performed following the previous procedure.

Professional Societies

Radioembolization Brachytherapy Oncology Consortium

In 2007, the Radioembolization Brachytherapy Oncology Consortium (REBOC), an independent group of experts from the fields of interventional radiology, radiation oncology, nuclear medicine, medical oncology and surgical oncology, issued clinical guidelines for ^{90}Y microsphere radioembolization to standardize indications, techniques, multimodality approaches, and dosimetry. Patients with hepatic metastases from neuroendocrine tumors should be offered standard systemic treatment options with a known survival benefit before ^{90}Y treatment. In the case of primary liver tumors, patients should undergo a thorough evaluation to determine optimal treatment. Key findings include the following:

- Sufficient evidence exists to support the safety and effectiveness of ^{90}Y microsphere radioembolization in selected patients.
- Candidates for radioembolization are patients with unresectable primary or metastatic hepatic disease with liver-dominant tumor burden and a life expectancy > 3 months.

- In metastatic colorectal cancer, radioembolization can be given: 1) alone after failure of first-line chemotherapy; 2) with floxuridine (FUDR) during first-line therapy; or 3) during first- or second-line chemotherapy on a clinical trial.
- Initiation of clinical trials is essential to further define the role of ^{90}Y microspheres.

American College of Radiology / Society of Interventional Radiology

The American College of Radiology (ACR) and Society of Interventional Radiology (SIR) state that indications for radioembolization with ^{90}Y microspheres include, but are not limited to:

- The presence of unresectable and/or inoperable primary or secondary liver malignancies. 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, i.e., a Karnofsky Performance Status (KPS)* of 70 or more or an Eastern Cooperative Oncology Group (ECOG) Performance Status* of 0 or 1.
- A life expectancy of at least three months.

***Karnofsky Performance Scale**

100 Normal; no complaints, no evidence of disease
90 Able to carry on normal activity; minor signs or symptoms of disease
80 Normal activity with effort; some signs or symptoms of disease
70 Cares for self; unable to carry on normal activity or to do active work
60 Requires occasional assistance but is able to care for most needs
50 Requires considerable assistance and frequent medical care
40 Disabled; requires special care and assistance
30 Severely disabled; hospitalization is indicated although death not imminent
20 Very sick; hospitalization necessary; active supportive treatment is necessary
10 Moribund, fatal processes progressing rapidly
0 Dead

***Eastern Cooperative Oncology Group Performance Scale**

0 Fully active, able to carry on all pre disease activities without restriction (Karnofsky 100)

1 Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, for example, light housework/office work (Karnofsky 80-90)

2 Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours (Karnofsky-70)

3 Capable of limited self-care, confined to bed or chair 50% or more of waking hours (Karnofsky 40-50)

4 Completely disabled; cannot carry on any self-care; totally confined to bed or chair (Karnofsky 10-30)

5 Dead (Karnofsky 0)

EXCLUSIONS:

^{90}Y microsphere radioembolization is unproven and not medically necessary for all other indications.

Absolute contraindications:

A. Inability to catheterize the hepatic artery
B. Fulminant liver failure (Childs-Pugh status late B or C)
C. ^{99m}Technetium macro-aggregated albumin (^{99m}Tc-MAA) hepatic arterial perfusion scintigraphy demonstrating significant reflux or non-target deposition in gastrointestinal organs that cannot be corrected by angiographic techniques.
D. ^{99m}Tc-MAA hepatic arterial perfusion scintigraphy demonstrating the potential delivery of > 30 Gy to the lungs

Relative contraindications:

A. Excessive tumor burden in the liver with greater than 70% of the parenchyma replaced by tumor
B. Prior extensive liver resection
C. Total bilirubin greater than 2 mg/dL in the absence of a reversible cause (e.g., obstruction) that accounts for severe liver function impairment. Non-obstructive bilirubin elevations generally indicate that liver metastases have caused liver impairment to a degree where treatment-related risks outweigh benefits. In contrast, patients with hepatocellular carcinoma and an elevated bilirubin may be treated with ^{90}Y microsphere radioembolization if segmental or subsegmental infusion can be performed
D. Prior radiation therapy to the liver or upper abdomen that included a significant volume of the liver. The volume of liver exposed to > 30 Gy (V30) is the strongest predictor of hepatotoxicity. In one study, all patients with a liver V30 > 13% experienced hepatotoxicity
E. Concurrent or prior capecitabine chemotherapy (within the previous two months)
F. If the patient is known to be pregnant, the potential radiation risks to the fetus and clinical benefits of the procedure should be considered before proceeding

OVERVIEW:

The preferred treatment for liver tumors is surgical excision. However, many liver tumors are unresectable because they are located too close to blood vessels or other critical structures or are too advanced, making surgery potentially unsafe. For unresectable liver tumors, physicians may recommend palliative treatments to reduce pain and improve quality of life. Intrahepatic microsphere radiation (IMR) therapy or selective internal radiation therapy (SIRT) is a palliative treatment for unresectable liver tumors designed to inhibit tumor growth and preserve remaining liver function by delivering radiation locally. During IMR therapy, a physician threads a catheter inserted at the femoral artery into the hepatic artery and injects millions of microscopic beads that contain the radioisotope ^{90}Y. The microspheres become lodged in the liver's capillaries. The beta radiation, which penetrates about half an inch, is delivered directly to tumors and is less toxic to adjacent, healthy tissue than radiation delivered by other means. After about two weeks, ^{90}Y has decayed by over 95%; however, the beads remain in the liver permanently.

The FDA has approved two commercial forms of ^{90}Y microspheres for radioembolization: TheraSphere® (MDS Nordion) and SIR-Spheres® (Sirtex). TheraSphere is glass matrix particles with ^{90}Y and SIR-Spheres are resin particles with ^{90}Y.

a. **Unresectable Liver Metastases from Primary Colorectal Cancer or Neuroendocrine Tumors**
Van Hazel et al.[1] evaluated SIRFLOX, a randomized, multicenter trial designed to assess the efficacy and safety of adding ^{90}Y microsphere radioembolization to standard fluorouracil, leucovorin, and oxaliplatin (FOLFOX)-based chemotherapy in patients with previously untreated metastatic colorectal cancer. Chemotherapy-naïve patients with liver metastases were randomly assigned to receive either modified FOLFOX (mFOLFOX6; control) or mFOLFOX6 plus ^{90}Y microsphere radioembolization plus or minus bevacizumab. The primary endpoint was progression-free survival (PFS) at any site. Median PFS at any site was 10.2 v 10.7 months in the control group versus the ^{90}Y microsphere radioembolization group. Median PFS in the liver was 12.6 v 20.5 months in the control group and the ^{90}Y microsphere radioembolization group, respectively. Grade ≥ 3 adverse events were reported in 73.4% and 85.4% of patients in the control group and the ^{90}Y microsphere radioembolization group, respectively. The authors concluded that the addition of ^{90}Y microsphere radioembolization to FOLFOX-based first-line chemotherapy in patients with liver-dominant or liver-only metastatic colorectal cancer did not improve PFS at any site but significantly delayed disease progression in the liver.

A systematic review and meta-analysis of published literature was conducted by Devcic et al.[2] to evaluate the efficacy of ^{90}Y resin radioembolization in patients with liver-dominant metastatic neuroendocrine tumors. Of the 12 studies included, 6 were retrospective, 3 were prospective, 1 was prospectively collected but retrospectively reviewed, and 2 didn't specify. The total number of procedures with response data was 435 in 414 patients. The pooled data demonstrated a disease control rate of 86% and improved overall survival for patients responding to therapy. The authors concluded that ^{90}Y resin radioembolization is an effective treatment option for patients with liver-dominant metastatic neuroendocrine tumors.

b. **Unresectable Primary Hepatocellular Carcinoma**
There are no level 1 data comparing ^{90}Y microsphere radioembolization to other regional therapies. Considerations of efficacy and safety (given cirrhosis) must be made on an individual basis. NICE states that TheraSphere could be used to treat patients with operable and inoperable HCC, as an alternative or adjunct to one of several options currently offered (including liver resection, transplantation, local ablation, chemoembolization, and systemic therapies), depending on multiple factors including the patient's general health and tumor stage. The evidence from 11 studies summarized in the briefing is of mixed quality and shows that patients treated with TheraSphere do not show significantly different overall survival compared with those treated with conventional transarterial chemoembolization (TACE) with lipiodol.[3] The National Institute for Health and Care Excellence (NICE) states that current evidence on the efficacy and safety of ^{90}Y microsphere radioembolization for primary hepatocellular carcinoma is adequate for use with normal arrangements for clinical governance, consent and audit.[4]

c. **Unresectable Intrahepatic Cholangiocarcinoma**

Al-Adra et al.[5] systematically reviewed the literature surrounding treatment of unresectable intrahepatic cholangiocarcinoma (ICC) with yttrium-90 microspheres. A comprehensive search of electronic databases for ICC treatment was performed and 12 primary studies meeting the inclusion criteria were identified. These included seven prospective case series and five retrospective cohort studies with relevant data regarding ^{90}Y microsphere radioembolization. A total of 298 patients were assessed with a median follow-up of 10.8 months. The most common types of morbidity following radioembolization therapy with yttrium-90 microspheres were fatigue (33%), abdominal pain (28%), and nausea (25%). The authors concluded that the overall survival of patients with ICC after treatment with yttrium-90 microspheres is higher than historical survival rates and shows similar survival to those patients treated with systemic chemotherapy and/or trans-arterial chemoembolization therapy. They state that the use of yttrium-90 microspheres could be considered as a treatment option for ICC. Future randomized trials comparing systemic chemotherapy, TACE, and local radiation will be required to identify the optimal treatment for unresectable ICC.

MEDICARE ADVANTAGE:

There is no NCD for ^{90}Y microsphere radioembolization. Also, there are no LCDs for MA, CT, NH and ME. Consequently, this commercial policy will also apply to Medicare Advantage.

BILLING CODES AND DESCRIPTIONS:

Billing codes and their descriptions are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list is not all-inclusive. Billing codes that are not in effect at the time that a service is rendered may not be eligible for reimbursement.

37243 Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural road mapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction.
79445 Radiopharmaceutical therapy, by intra-arterial particulate administration.
S2095 Transcatheter occlusion or embolization for tumor destruction, percutaneous, any method, using yttrium-90 microspheres. Not covered by Medicare (for commercial plans only).

REFERENCES:

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2. Devcic Z, Rosenberg J, Braat AJ, et al. The efficacy of hepatic 90Y resin radioembolization for metastatic neuroendocrine tumors: a meta-analysis. J Nucl Med. 2014; 55(9):1404-10.

Unresectable Primary Hepatocellular Carcinoma

3. National Institute for Health and Care Excellence (NICE). MIB62. TheraSphere for treating operable and inoperable hepatocellular carcinoma. Medtech innovation briefing. Published: 30 March 2016.
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Unresectable Intrahepatic Cholangiocarcinoma

5. Al-Adra, D, Gill, R, Axford, S. Treatment of unresectable intrahepatic cholangiocarcinoma with yttrium-90 radioembolization: A systematic review and pooled analysis. Eur J Surg Oncol. 2015; 41(1): 120–127.

POLICY HISTORY:

Date	Action
January 3, 2020	Original policy
November 18, 2022	Updates and clarifications made regarding proton beam therapy