



HPHC Radiation Oncology Medical Policies

1. Image Guided Radiation Therapy (IGRT) Medical Policy
2. Intensity Modulated Radiation Therapy (IMRT) Medical Policy
3. Stereotactic Radiosurgery (SRS) Medical Policy
4. Stereotactic Body Radiation Therapy (SBRT) Medical Policy
5. High Dose Rate Electronic Brachytherapy Medical Policy
6. ⁹⁰Y Microsphere Radioembolization Medical Policy
7. Proton Beam Therapy (PBT) Medical Policy
8. Radiation Oncology Medical Policy for HPHC
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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

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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 taken into account 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.

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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 report⁵ 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.

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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
	New 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 dose.
- 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.

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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 ($V_{25} > 10$ 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:
 - A. Enlarged internal mammary nodes based on imaging
 - B. Pathologically involved internal mammary lymph node(s) based on tissue biopsy
 - C. 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 ($V_{25} > 10$ 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

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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 a MLC does not, by itself, constitute IMRT. For example, it is possible to use a 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

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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.

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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 multiloop 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

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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.

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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.

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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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Anus

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Gynecologic

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Vulva

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POLICY HISTORY:

Date	Action
	New policy

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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 a cancer that is not germ cell tumor, small cell carcinoma or lymphoma, **and**

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- 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

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***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=gAAAAACAAAA&>

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.

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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

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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

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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
	New policy

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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:

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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 completely 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, small cell carcinoma, 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

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

Kidney or Adrenal Gland Cancer

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

- Primary tumor ≤ 5 cm in kidneys or adrenal glands not amenable to resection by surgery, **or**
- Oligometastatic (≤ 5 lesions) disease where the lesions are all ≤ 5 cm with no active disease elsewhere in the body, **and**

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- 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 in patients who are not surgical candidates, **or**
- One to 5 liver metastases ≤ 5 cm requiring palliation that 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.

SBRT should not be used in a patient with Child-Pugh Class C chronic liver disease.

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 with no active disease elsewhere in the body.

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.

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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)

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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

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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=gAAAACAAAA&>

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

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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.

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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 (77472-77432).

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General

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POLICY HISTORY:

Date	Action
	New policy

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

PRIOR AUTHORIZATION: **Required**

POLICY:

According to the American Brachytherapy Society²⁶ and the National Comprehensive Cancer Network, high dose rate electronic brachytherapy remains experimental, investigational and unproven.

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

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Esteya®, Intrabeam®, SRT-100™ or Xofigo® 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

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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
	New 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.

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- 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 ⁹⁰Y 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 ⁹⁰Y 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)

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

5 Dead (Karnofsky 0)

EXCLUSIONS:

⁹⁰Y 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}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 ⁹⁰Y 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 ⁹⁰Y. The

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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 Devic 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

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Excellence (NICE) states that current evidence on the efficacy and safety of ⁹⁰Y 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 ⁹⁰Y 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 ⁹⁰Y 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).

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Unresectable Liver Metastases from Primary Colorectal Cancer

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Unresectable Liver Metastases from Neuroendocrine Tumors

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Unresectable Primary Hepatocellular Carcinoma

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Unresectable Intrahepatic Cholangiocarcinoma

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POLICY HISTORY:

Date	Action
	New policy

SERVICE: Proton Beam Therapy (PBT)

PRIOR AUTHORIZATION: Required

POLICY:

PBT is reasonable and medically necessary when documentation confirms that **both** of the following indications are met:

1. There is an unresectable target where standard radiotherapy techniques, including IMRT, SBRT or 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 when the tumor is no wider than 24 mm or taller than 14 mm and shows no extra-scleral extension or metastases
 - 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 intensity-modulated radiation therapy (IMRT), stereotactic body radiation therapy (SBRT) or ⁹⁰Y microsphere radioembolization
 - 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
 - Primary or benign solid tumors in patients younger than 21 years in age when treatment is performed with curative intent

Also, 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.

EXCLUSIONS:

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PBT is unproven and not medically necessary due to insufficient evidence of efficacy for treating **all** other indications not listed above as proven, including but not limited to:

- Adrenal cancer
- Age-related macular degeneration (AMD)
- Anal cancer
- Bladder cancer
- Breast cancer
- Cervical cancer
- Choroidal hemangioma or neovascularization
- Esophageal cancer
- Gynecologic cancers
- Lung cancer
- Lymphomas, including those with mediastinal involvement
- Non-T4 and resectable head and neck cancers including thymomas and thymic carcinomas
- Pancreatic cancer
- Prostate cancer
- PBT in conjunction with IMRT
- Rectal cancer
- Skin cancer
- Unresectable malignant lesions of the biliary tract

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

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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.

Though there is encouraging data that PBT can provide a dosimetric advantage compared with IMRT, there is a lack of quality studies in the published literature that demonstrate meaningful clinical benefits to PBT over IMRT in the treatment of most tumors outside of the brain, skull base and head and neck region in adults.

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.

c. Breast Cancer

The use of PBT for breast cancer is unproven. Currently, field-in-field 3DCRT-based or IMRT-based WBI and postmastectomy 3DCRT or IMRT to the chest wall with or without a boost are supported by a higher level of evidence and longer follow up than PBT.³⁵⁻⁴⁰ The current ASTRO Clinical Practice Statement on radiation therapy for the whole breast states that the preferred radiotherapeutic approach for initial treatment planning is “field-in-field” 3DCRT.³⁹ The current NCCN Guidelines on breast cancer state that: “radiation to the breast/chest wall and nodal regions is generally delivered with photons ± electrons. Greater target dose homogeneity and sparing of normal tissues can be accomplished using compensators such as wedges, forward planning using segments, and IMRT. Respiratory control techniques including deep inspiration breath-hold and prone positioning may be used to try to further reduce dose to adjacent normal tissues, in particular heart and lung. Boost treatment in the setting of breast conservation can be delivered using en face electrons, photons, or brachytherapy. Chest wall scar boost when indicated is typically treated with electrons or photons.”

d. Non-Small Cell Lung Cancer

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It remains unclear whether PBT is clinically superior to, equal to, or worse than 3DCRT, IMRT or SBRT for non-small cell lung cancer (Verma, 2016). Similarly, Liao and Simone have suggested that available evidence, which typically consists of retrospective studies with short follow up, does not clearly demonstrate that PBT is more effective than 3DCRT, IMRT or SBRT.⁴¹ Dosimetric advantages do not always translate into clinically meaningful advantages (Verma, 2016). PBT can result in financial toxicity (Palmer et al.). Research involving common cancers like non-small cell lung cancer should emphasize clinical trials over registries (Bekelman and Hahn; Mishra et al.). There is only one, open phase III clinical trial comparing proton with photon chemoradiation for inoperable stage II-III non-small cell cancer (NCT01993810). NCT01993810 will help to define the role of PBT in the treatment of non-small cell lung cancer.

e. Prostate Cancer

Published reports of prospective studies comparing PBT alone to conventional radiation therapy involving brachytherapy or IMRT are lacking. Several studies have found that external beam radiotherapy with a brachytherapy boost is more effective than external beam radiotherapy alone for intermediate-risk and high-risk prostate cancer patients (Xiang and Nguyen; Shen et al.; Morris et al.; Glaser et al.). Some of the largest studies have suggested that PBT results in more long-term gastrointestinal toxicity than IMRT (Kim et al.; Pan et al.; Sheets et al.). Based on studies that have been published since 2001, it remains unclear whether PBT is superior to, equal to, or worse than IMRT for prostate cancer (Moon et al.; Schroeck et al.). The National Comprehensive Cancer Network (NCCN) Guidelines state that the toxicity of effectiveness of PBT for prostate cancer cannot be drawn due to limitations with retrospective and observational studies. Also, according to Chan et al. and the NCCN Guidelines, dosimetric advantages such as a reduction in radiation doses delivered to the rectum, penile bulb and bladder with PBT have not always translated into clinically-meaningful advantages. In addition, PBT can result in financial toxicity (Palmer et al.). Research involving common cancers like prostate cancer should emphasize clinical trials over patient registries (Bekelman and Hahn; Mishra et al.). There is only one, open phase III clinical trial comparing PBT with IMRT for prostate cancer (NCT01617161). This study is currently being conducted at 10 centers around the US. It will help to determine the role of PBT in the treatment of prostate cancer (Schiller et al.).

MEDICARE ADVANTAGE:

There are no NCDs for PBT. There is “Local Coverage Determination (LCD): PROTON Beam Therapy (L35075)” for MA, CT, NH and ME:

<https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35075&ver=34&CoverageSelection=Local&ArticleType=All&PolicyType=Final&s=Main&Keyword=proton&KeywordLookup=Title&KeywordSearchType=And&bc=gAAAAACAAAA&>

The above Medicare LCD on PBT will also apply to Medicare Advantage.

BILLING CODES AND DESCRIPTIONS:

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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
	New policy

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SERVICE: Radiation Oncology

POLICY:

Harvard Pilgrim Health Care (HPHC) reimburses radiation oncology services provided by contracted providers in the outpatient setting or rendered in a Harvard Pilgrim-contracted facility.

Prerequisite(s):

Applicable Harvard Pilgrim referral, notification and authorization policies and procedures apply. Refer to “Referral, Notification and Authorization” for more information.

HMO/POS/PPO

- A referral is required for HMO and in-network POS members.
- An authorization is required for out-of-network HMO/POS services.
- A physician order is required for services.
- Notification by the ordering physician to NIA is required for non-emergency, outpatient advanced imaging services. (Refer to Outpatient Advanced Imaging Services Notification for specific requirements.)

Open Access HMO and POS

For Open Access HMO and Open Access POS products, no referral is required to see a contracted specialist.

Harvard Pilgrim Reimburses¹

HMO/POS/PPO

Professional-Only Services

- Tumor mapping and clinical treatment planning (simple, intermediate or complex) one time unless a new area of disease requires treatment.
- Treatment management which includes review of port films, review of dosimetry, dose delivery and treatment parameters, review of treatment set up, and examination of patient for medical evaluation and management.
- Weekly treatment management (simple, intermediate or complex) once every five treatment sessions, regardless of actual time period during which the sessions were furnished. (Sessions need not be on consecutive days.)
- Two treatment management sessions furnished on the same day if there is a break in therapy sessions and the sessions would usually be furnished on different days.
- Stereotactic radiation treatment management of cerebral lesions.

Technical-Only Services

- Proton beam therapy

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- Radiation physics consultations
- Treatment delivery

Professional, Technical or Global Services

- Therapeutic radiology simulated-aided field setting once per simulation, but a provider may be reimbursed additional simulations when fields are added or changed during a course of therapy, e.g., because the member experienced significant weight loss while undergoing radiotherapy.
- Special dosimetry for each field monitored.
- Brachytherapy, including prostate brachytherapy using permanently implanted palladium/iodine/cesium seeds.
- Basic radiation and dosimetry including intensity modulated radiotherapy plans, radiation dosage point calculations, simple, intermediate or complex teletherapy dose planning.
 - Complex teletherapy dose planning includes custom blocking resulting in off-axis isodose calculations and irregular field dosimetry; wedges compensators and other field attenuating devices; electrons combined with photon fields; rotational and arc plans; tangential ports; five or more ports converging on a single area; and use of CT or MRI images.
- Treatment devices.
- Hyperthermia.
- Intensity modulated radiation therapy planning.
- MRI and/or CT-guided planning.
- Stereotactic radiosurgery.

Harvard Pilgrim Does Not Reimburse

HMO/POS/PPO

- Professional services for port images.
- Services provided at an outpatient imaging/radiation therapy facility to a member during an inpatient admission. These are inclusive of the admitting hospital's inpatient rate and should be billed to the admitting hospital.
- Treatment device design and construction which is derived from an intensity modulated radiation therapy plan.

Member Cost-Sharing

Services subject to applicable member out-of-pocket cost (e.g., copayment, coinsurance and/or deductible).

OVERVIEW:

Radiation oncology is a specialty of medicine that utilizes high-energy ionizing radiation in the treatment of cancers and certain non-malignant conditions. It uses many types of radiotherapy techniques, including image guided radiation therapy, intensity modulated radiation therapy, low dose rate or high dose rate brachytherapy, proton beam therapy, stereotactic body radiation therapy, stereotactic radiosurgery, three-dimensional conformal radiation therapy and ⁹⁰Y microsphere radioembolization.

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MEDICARE ADVANTAGE:

There is a Medicare national coverage determination on hyperthermia in combination with radiotherapy entitled “National Coverage Determination (NCD) for HYPERTHERMIA for Treatment of Cancer (110.1)”: <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=66&ncdver=1&CoverageSelection=National&Keyword=hyperthermia&KeywordLookupUp=Title&KeywordSearchType=And&bc=gAAAACAAAA&>

Also, there are Medicare local coverage determinations (LCDs) involving radiotherapy techniques, including LCDs for stereotactic radiosurgery, stereotactic body radiation therapy and proton beam therapy, for MA, CT, NH and ME. Any applicable Medicare NCD or LCD for the radiotherapy technique in question will apply to Medicare Advantage.

REQUIRED CLINICAL DOCUMENTATION FOR RADIATION ONCOLOGY BILLING CODES:²

Billing codes and their descriptions are listed in the table 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.

Billing Code(s)	Description	Required Clinical Documentation
77014 (TC)	Ct scan for therapy guide	As of 2014, CPT code 77014 for CT acquisition is included in 3D simulation codes 77280, 77285, 77290. CPT code 77014 and IMRT plan code 77301 and should not be separately reported when a CT scan is obtained for simulation. 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.
77014, 77387, G6001, G6002, G6017	Image-guided radiation therapy (IGRT)	Physician’s note detailing the type and frequency of IGRT along with why IGRT will be medically necessary.
77261, 77262 and 77263	Radiation therapy planning	Physician’s signed/dated clinical treatment plan specifying the prescribed course of radiotherapy.
		Physician’s 3D simulation note for date of service. No more than one 3D simulation should be reported on any given day. The maximum quantity for code 77280 is 2 and the maximum quantity for codes 77285 and 77290 is 3 where the number of units refers to the number of phases of treatment.

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77280, 77285 and 77290	Set radiation therapy field	<p>As of 2017, if IMRT will be delivered, simulation codes 77280, 77285 and 77290 should not be reported in addition to 77301.</p> <p>A clinical simulation performed for skin lesions that will be treated with superficial or orthovoltage radiation therapy is considered a simple simulation (77280) regardless of the number of treatment areas or the use of custom shielding.</p>
77295	3D radiotherapy plan	3D physics plan, including DVH, and physician's note detailing medical necessity of the 3D plan. Code 77295 should not be reported with 77301.
77300	Radiation therapy dose plan	Basic dose calculation, Isodose plan or dose verification such as RadCalc, IMSure, etc for date of service in question. If more than 10 units were requested, then documentation must be provided Explaining why additional units are needed. Code 77300 should not be separately reported with codes 0394T, 0395T, 77306, 77307, 77316, 77317, 77318, 77321, 77767, 77768, 77770, 77771, 77772 or 77778.
77301	Radiotherapy dose plan IMRT	Physician's note detailing medical necessity of IMRT. A request for 2 units of an IMRT dose plan (77301) would require that an additional CT scan was performed for planning purposes and that a medical necessity statement is provided by the requesting physician. The new CT data set must demonstrate a significant change in patient size or tumor volume to necessitate use of a new data for planning.
77306 - 77307	Teletherapy plan	Physics photon plan for date of service in question. Do not report 77307 with 77295 for the same volume. Contiguous volumes such as breast tangential ports and a supraclavicular nodal field are considered one volume. Only one teletherapy isodose plan, e.g., 77295, is allowed per volume.
77321	Special teletherapy port plan	Electron physics plan for date of service in question. Code 77321 may be reported in cases such as an electron boost in a breast cancer patient. In contrast, electron beam therapy for small skin cancers does not justify code 77321. Code 77300 should be used instead.
77316-77318	Brachytherapy isodose plan	Brachytherapy physics plan for date of service in question. In medically necessary situations where each application of

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		brachytherapy requires a new image set, a new brachytherapy isodose plan may be billed for each application. Additional brachytherapy isodose plans within the same course of therapy may be approved if the requesting physician provides a rationale that explains why the previous brachytherapy isodose plan cannot be used and that supports the medical necessity of creating a new isodose plan. Do not report code 77300 with 77317.
77331	Special radiation dosimetry (diode)	Physician's order for diodes, diode reading for date of service in question and physician's note detailing why diodes were medically necessary. Code 77331 should not be reported with 77301.
77332 - 77334	Radiation treatment aid(s)	Documentation of immobilization device and /or each treatment device reported for date of service in question. If a quantity more than 10 is requested, then documentation to support why a quantity greater than 10 is required.
77336	Radiation physics consult	Documentation of physics' weekly chart check for date of service in question.
77370	Radiation physics consult	Physician's request and physicist's report for date of service in question. Code 77370 may be reported in situations such as the patient has a pacemaker near the planned treatment area, the planned treatment area is close to a previously irradiated area, the dose needs to be calculated to the fetus in a pregnant patient or mixed radiotherapy techniques are planned. Code 77370 should not be reported with 77301. Also, code 77370 should not be reported for treatment planning summaries. However, code 77370 may be used if a radiation physics consult was requested by the physician to evaluate a clinical scenario separate from development of the IMRT treatment plan.
77385	Ntsty modul rad tx dlvr smpl	Code 77385 is for the delivery of simple IMRT in a hospital setting. It 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 code 77385, then you cannot request CPT code 77371, 77372 or 77373. In addition, if you are requesting code 77385 for

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		compensator-based IMRT to any site in the body, then you cannot request code 77338.
77386	Ntsty modul rad tx dlvr cplx	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 code 77386, then you cannot request code 77371, 77372 or 77373.
77399	External radiation dosimetry	Documentation/report for date of service in question.
77417	Radiology port image(s)	Do not report CPT code 77417 for electron beam therapy.
77427	Radiation treatment management x5	Physician’s weekly progress note or On Treatment Visit note for date of service in question.
77470	Special radiation treatment	There is no situation in which code 77470 should be routinely used. CPT code 77470 may be requested under certain circumstances. Examples of where code 77470 may be requested include: 1) patient is very difficult to set up (not every patient is a difficult 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 code 77470 to be approved.

Other Information

- Bill each treatment delivery on a separate line with a separate date of service—not a date range.
- Bill one unit for treatment delivery for each session/fraction given regardless of the time period over which the treatment took place.
 - Use the start date of the first fraction of therapy as the date of service.
 - If there are three or four sessions beyond a multiple of five at the end of a course of treatment, bill CPT 77427 with a count of one. (It is not appropriate to bill for one or two fractions beyond a multiple of five at the end of a course of treatment.)
 - If the entire course of treatment consists of one or two sessions, use CPT code 77431 for radiation therapy management with a count of one for 77431.

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Related Policies

- Clinical Trials Payment Policy
- High Dose Rate Electronic Brachytherapy Medical Policy
- Hyperthermia Medical Policy
- Image-Guided Radiation Therapy (IGRT) Medical Policy
- Intensity-Modulated Radiation Therapy (IMRT) Medical Policy
- Notification Policy
- Outpatient Advanced Imaging Services Notification
- Positron emission Tomography Scan Payment Policy
- Proton Beam Therapy (PBT) Medical Policy
- Radiology Payment Policy
- Stereotactic Body Radiation Therapy (SBRT) Medical Policy
- Stereotactic Radiosurgery (SRS) Medical Policy
- ⁹⁰Y Microsphere Radioembolization Medical Policy

POLICY HISTORY:

Date	Action
	New policy

¹This 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.

²The table does not include all possible CPT and HCPCS codes related to radiation oncology.

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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, i.e., melanomas, squamous or basal cell carcinomas, adenocarcinomas or sarcomas, that are progressive or recurrent despite conventional therapy. 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

When hyperthermia is indicated, no more than 10 hyperthermia treatments delivered twice weekly at 72-hour intervals should be utilized.

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 is 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

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use of hyperthermia be limited to treatment centers with appropriate training, expertise and equipment...”.

Coding for hyperthermia is recognized and published. 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). This is currently the only device approved for reimbursement. 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 have documented the benefit of hyperthermia given 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

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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) for 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
	New policy

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