UnitedHealthcare

Reimbursement Policy

Delivery of IMRT/SRS/SBRT

Policy Number	CMBT06222011RP	Approved By	UnitedHealthcare Medicare Reimbursement Policy Committee	Current Approval Date	06/25/2014

IMPORTANT NOTE ABOUT THIS REIMBURSEMENT POLICY

This policy is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

You are responsible for submission of accurate claims. This reimbursement policy is intended to ensure that you are reimbursed based on the code or codes that correctly describe the health care services provided. UnitedHealthcare reimbursement policies use Current Procedural Terminology (CPT®*), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT or other sources are for definitional purposes only and do not imply any right to reimbursement.

This reimbursement policy applies to all health care services billed on CMS 1500 forms and, when specified, to those billed on UB04 forms (CMS 1450). Coding methodology, industry-standard reimbursement logic, regulatory requirements, benefits design and other factors are considered in developing reimbursement policy.

This information is intended to serve only as a general resource regarding UnitedHealthcare's reimbursement policy for the services described and is not intended to address every aspect of a reimbursement situation. Accordingly, UnitedHealthcare may use reasonable discretion in interpreting and applying this policy to health care services provided in a particular case. Further, the policy does not address all issues related to reimbursement for health care services provided to UnitedHealthcare enrollees. Other factors affecting reimbursement may supplement, modify or, in some cases, supersede this policy. These factors may include, but are not limited to: legislative mandates, the physician or other provider contracts, and/or the enrollee's benefit coverage documents. Finally, this policy may not be implemented exactly the same way on the different electronic claims processing systems used by UnitedHealthcare due to programming or other constraints; however, UnitedHealthcare strives to minimize these variations.

UnitedHealthcare may modify this reimbursement policy at any time by publishing a new version of the policy on this Website. However, the information presented in this policy is accurate and current as of the date of publication.

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Table of Contents

Application **2**
Summary **2**
Intensity Modulated Radiation Therapy (IMRT) 2
Stereotactic Radiosurgery (SRS) 3
Stereotactic Body Radiation Therapy (SBRT) 3
Indications for IMRT 3
Indications for SRS 4
Indications for SBRT 4
CPT / HCPCS Codes **5**
References Included (but not limited to): **6**
CMS LCD(s) 6
CMS Article(s) 6
CMS Claims Processing Manual 6
CMS Transmittals 6
UnitedHealthcare Medicare Advantage Coverage Summaries 6
UnitedHealthcare Reimbursement Policies 6
UnitedHealthcare Medical Policies 6
MLN Matters 7
History **7**

Delivery of IMRT/SRS/SBRT

Application

This reimbursement policy applies to services reported using the Health Insurance Claim Form CMS-1500 or its electronic equivalent or its successor form, and services reported using facility claim form CMS-1450 or its electronic equivalent or its successor form. This policy applies to all products, all network and non-network physicians, and other health care professionals.

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 0.care. It is not enough to link the procedure code to a correct, payable ICD-9-CM diagnosis code. The diagnosis must be present for the procedure to be paid. Compliance with the provisions in this policy is subject to monitoring by pre-payment review and/or post-payment data analysis and subsequent medical review. The effective date of changes/additions/deletions to this policy is the committee meeting date unless otherwise indicated. CPT codes and descriptions are copyright 2010 American Medical Association (or such other date of publication of CPT). All rights reserved. CPT is a registered trademark of the American Medical Association. Applicable FARS/DFARS restrictions apply to Government use. Fee schedules, relative value units, conversion factors, and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Current Dental Terminology (CDT), including procedure codes, nomenclature, descriptors, and other data contained therein, is copyright by the American Dental Association, 2002, 2004. All rights reserved. CDT is a registered trademark of the American Dental Association. Applicable FARS/DFARS apply.

Summary

Intensity Modulated Radiation Therapy (IMRT)

Intensity Modulated Radiation Therapy (IMRT) is a computer-based method of planning for, and delivery of generally narrow, patient specific, spatially and often temporally modulated beams of radiation to solid tumors within a patient. IMRT planning and delivery uses an approach for obtaining the highly conformal dose distributions needed to irradiate complex targets positioned near, or invaginated by, sensitive normal tissues, thus improving the therapeutic ratios. IMRT delivers a more precise radiation dose to the tumor while sparing the surrounding normal tissues by using non-uniform radiation beam intensities that are determined by various computer-based optimization techniques.

The computer based optimization process is referred to as "inverse planning." Inverse planning develops a dose distribution based on the input of specific dose constraints for the planned treatment volume (PTV) and nearby clinical structures and is the beginning of the IMRT treatment planning process. The gross tumor volume (GTV), the PTV and surrounding normal tissues must be identified by a contouring procedure and the optimization must sample the dose with a grid spacing of 1 centimeter or less.

IMRT uses non-uniform and customized fluence distributions in 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 treatment unit isocenter or the use of compensator-based beam modulation treatment using three or more high resolution compensator convergent beam modulated fields. A MLC may use a dynamic (DMLC) or segmented mode (SMLC) to create the 3-dimensional, intensity-modulated dose distribution. The average segments (or "steps") per gantry position required to meet IMRT delivery is five. The exact delivery method is not restricted as long as the particular technique chosen has the ability to model the highly modulated intensity patterns that result from the planning process described above (e.g. solid modulators or compensators may be an alternative to MLC). However, the use of a MLC just to produce simple one-dimensional ramp intensity distributions is excluded because the inverse planning process is not necessary to produce this simple intensity variation. Also, the use of a MLC does not, in itself, constitute or define IMRT (for example, it is possible to use a MLC for intermediate or complex, 3D conformal therapy).

Note also, traditional "field-in-field technique" which is neither MLC nor compensator-based is not considered IMRT but rather external beam therapy.

IMRT delivery imposes a more stringent requirement than conventional radiation therapy in terms of accounting for patient position and organ motion. Methods that account for organ motion include but are not limited to:

1. use of published studies on organ movement when developing the PTV
2. image guided adaptive radiotherapy (e.g., ultrasound guided or portal-image guided setup with implanted fiducial markers)
3. respiratory gating of diaphragm movement for thoracic and upper abdominal sites.

Compensator-based beam modulation therapy uses intensity modulated radiotherapy (IMRT) dose delivery and beam modulation using a physical absorber to modulate the radiation beam with placement of the compensator between the accelerator target and the patient. The category III CPT code was developed because multileaf collimation is not used and current CPT codes did not accurately describe this method of radiation delivery.

Stereotactic Radiosurgery (SRS)

Stereotactic Radiosurgery (SRS) requires computer-assisted, three-dimensional planning and delivery with stereotactic and convergent-beam technologies, including, but not limited to: multiple convergent cobalt sources (e.g. Gamma Knife®); protons; multiple, coplanar or non-coplanar photon arcs or angles (e.g. XKnife®); fixed photon arcs; or image-directed robotic devices (e.g. CyberKnife®) that meet the criteria. To assure quality of patient care, the procedure involves a multidisciplinary team consisting of a neurosurgeon, radiation oncologist, and medical physicist.

SRS is a distinct discipline that utilizes externally generated ionizing radiation in certain cases to inactivate or eradicate a defined target(s) in the head or spine without the need to make an incision. The target is defined by high-resolution stereotactic imaging. To assure quality of patient care the procedure involves a multidisciplinary team consisting of a neurosurgeon, radiation oncologist, and medical physicist.

SRS typically is performed in a single session, using a rigidly attached stereotactic guiding device, other immobilization technology and/or a stereotactic-guidance system, but can be performed in a limited number of sessions, up to a maximum of five.

Technologies that are used to perform SRS include linear accelerators, particle beam accelerators, and multisource Cobalt 60 units. In order to enhance precision, various devices may incorporate robotics and real time imaging.

Stereotactic Body Radiation Therapy (SBRT)

Stereotactic Body Radiation Therapy (SBRT) is an emerging treatment method that utilizes externally generated high dose ionizing radiation in certain cases to inactivate or eradicate (a) defined target (s) within the body. The target is defined by high-resolution stereotactic imaging. In addition to the radiation oncologist and/or neurosurgeon and physicist, the process may involve input from other surgical specialists. SBRT performed using immobilization technology and a stereotactic image-guidance system can be performed in a limited number of sessions, up to a maximum of five.

Stereotactic body radiation therapy (SBRT) is a treatment that couples a high degree of anatomic targeting accuracy and reproducibility with very high doses of extremely precise, externally generated, ionizing radiation, thereby maximizing the cell-killing effect on the target(s) while minimizing radiation-related injury in adjacent normal tissues.

The adjective "stereotactic" describes a procedure during which a target lesion is localized relative to a known three dimensional reference system that allows for a high degree of anatomic accuracy and precision. Examples of devices used in SBRT for stereotactic guidance may 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 CT-imaging-based systems used to confirm the location of a tumor immediately prior to treatment.

All 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 or other motion, some form of motion control or "gating" should be used.

SBRT may be fractionated (up to 5 fractions). Each fraction requires an identical degree of precision, localization and image guidance. Since the goal of SBRT is to intensify the potency of the radiotherapy by completing an entire course of treatment within an extremely accelerated time frame, any course of radiation treatment extending beyond five fractions is not considered SBRT and is not to be billed using these codes.

Indications for IMRT

The decision process for using IMRT requires an understanding of accepted practices that take into account the risks and benefits of such therapy compared to conventional treatment techniques. While IMRT technology may empirically offer advances over conventional or three dimensional (3-D) conformal radiation, a comprehensive understanding of all consequences is required before applying this technology.
IMRT is not a replacement therapy for conventional and 3-D conformal radiation therapy methods. IMRT is considered reasonable and necessary for patients who have primary brain tumors, brain metastasis, prostate cancer, lung cancer, pancreas cancer, and other upper abdominal sites, spinal cord tumors, head and neck

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cancer, adrenal tumors, pituitary tumors and the patient has at least one of the following conditions met:

1. Sparing the surrounding normal tissue is essential
2. Important dose limiting structures adjacent to, but outside the PTV, are sufficiently close and require IMRT to assure safety and morbidity reduction.
3. An immediately adjacent volume has been irradiated and abutting portals must be established with high precision.
4. Gross Tumor Volume (GTV) margins are concave or convex and in close proximity to critical structures that must be protected to avoid unacceptable morbidity.
5. Only IMRT techniques would decrease the probability of grade 2 or grade 3 radiation toxicity as compared to conventional radiation in greater than 15% of radiated similar cases.

IMRT is an evolving technology and, as such, this IMRT Policy will be reviewed and updated as often as necessary. Currently, IMRT is indicated for primary brain tumors, brain metastasis, prostate cancer, lung cancer (with special provision for organ motion), pancreas cancer and other upper abdominal sites (with special provision for organ motion), spinal cord tumors, head and neck cancer, adrenal tumors, pituitary tumors and situations in which extremely high precision is required. Indications will include some left breast tumors due to risk to immediately adjacent cardiac and pericardial structures, though it would only rarely if ever be medically necessary for tumors of the right breast.

IMRT may be necessary in *some* gynecologic tumors or in *some* genitourinary tumors where its high precision is especially necessary to avoid immediately adjacent structures such as bowel or where there is a special need to avoid marrow. It may also be necessary in some lymphomas, malignant lymph nodes or sarcomas where anatomic location gives rise to a need for special care to avoid adjacent structures. Since these are likely to be only a relatively small fraction of gynecologic tumors, genitourinary tumors, lymphomas, malignant nodes or sarcomas, in each case particular care is required to document the necessity for IMRT.

Indications for SRS

Intracranial lesions under the following conditions:

1. The lesion(s) has an image-distinct margin.
2. The Karnofsky Performance Scale is greater than 50% (range is 0 - 100% with 100% = maximum functional level) or the ECOG performance status should be 2 or less.
3. Specific indications will include:
   a. Neuromas of the cranial nerves including acoustic, trigeminal, etc.
   b. Intracranial unresectable meningioma and/or residual meningioma where the neurosurgeon determines the patient's medical condition precludes surgery; and where because of the location of the tumor, surgery would result in devastating neurodeficits.
   c. Coverage for treatment of metastatic brain lesions under the following conditions:
      i. Patients should have essentially otherwise stable disease.
      ii. The lesion(s) margins should be radiographically distinct.
      iii. The number of lesions treated should not exceed five.
   d. As a boost treatment for larger cranial lesions that have been treated initially with external beam radiation therapy or surgery: i.e., grade III and IV gliomas: pilocytic astrocytoma oligodendrogliomas; sarcomas; chordomas
   e. Trigeminal neuralgia refractory to medical treatment
   f. Essential tremor: coverage is limited to the patient who cannot be controlled with medication, has major systemic disease or coagulopathy, and who is unwilling or unsuited for open surgery. Coverage is further limited to unilateral thalamotomy. Gamma Knife pallidotomy remains non-covered and will be denied.
4. AV Malformations
5. Acoustic neuromas
6. Pituitary adenomas
7. Craniopharyngiomas
8. Globus Jugulare tumors

Indications for SBRT

When billing for SBRT 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 (for example, a stereotactic approach with IMRT). Only one delivery code is to be billed.

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Delivery of IMRT/SRS/SBRT

A. SBRT for lung, liver, kidney, and, or pancreas neoplasms:

SBRT is covered for primary and metastatic tumors of the lung, liver, kidney, or pancreas when and only when each of the following criteria are met, and each specifically documented in the medical record:

1. The patient's general medical condition (notably, the performance status) justifies aggressive treatment to a primary cancer or, for the case of metastatic disease, justifies aggressive local therapy to one or more discreet deposits of cancer within the context of efforts to achieve total clearance or clinically beneficial reduction in the patient's overall burden of systemic disease. Typically, such a patient would have also been a potential candidate for alternate forms of intense local therapy applied for the same purpose (e.g. surgical resection, radiofrequency ablation, cryotherapy, etc).
2. Other forms of radiotherapy, including but not limited to external beam and IMRT, cannot be as safely or effectively utilized, and
3. The tumor burden can be completely targeted with acceptable risk to critical normal structures
4. If the tumor histology is germ cell or lymphoma, effective chemotherapy regimens have been exhausted or are otherwise not feasible.
5. Other forms of focal therapy, including but not limited to radiofrequency ablation and cryotherapy, cannot be as safely or effectively utilized.

B. SBRT for Prostate Neoplasms

SBRT of the prostate is covered as monotherapy for patients with low risk and low/intermediate risk prostate cancer when:

1. The patient's general medical condition (notably, the performance status) justifies aggressive treatment to a primary cancer. Typically, such a patient would have also been a potential candidate for alternate forms of intense local therapy applied for the same purpose.
2. Other forms of radiotherapy, including but not limited to external beam and IMRT or seed implantation, cannot be as safely or effectively utilized, and
3. The tumor burden can be completely targeted with acceptable risk to critical normal structures

C. Other Neoplasms:

Lesions of bone, breast, uterus, ovary and other internal organs not listed above are not covered for primary definitive SBRT as literature does not support an outcome advantage over other conventional radiation modalities, but may be appropriate for SBRT in the setting of recurrence after conventional radiation modalities.

D. Other Indications for SBRT:

Except as above, any lesion with a documented necessity to treat using a high dose per fraction of radiation. When using high radiation doses per fraction, high precision is required to avoid surrounding normal tissue exposure.

Lesions which have received previous radiotherapy or are immediately adjacent to previously irradiated fields, where the additional precision of stereotactic radiotherapy is required to avoid unacceptable tissue radiation will be covered when other conditions of coverage are met (see Limitations below) and this necessity is documented in the medical record.

CPT / HCPCS Codes

Code	Description
0073T	Compensator-based beam modulation treatment delivery of inverse planned treatment using 3 or more high resolution (milled or cast) compensator convergent beam modulated fields, per treatment session
0197T	Intra-fraction localization and tracking of target or patient motion during delivery of radiation therapy (eg, 3d positional tracking, gating, 3d surface tracking), each fraction of treatment
C9728	Placement of interstitial device(s) for radiation therapy/surgery guidance (e.g., fiducial markers, dosimeter), for other than the following sites (any approach): abdomen, pelvis, prostate, retroperitoneum, thorax, single or multiple
G0173	Linear accelerator based stereotactic radiosurgery, complete course of therapy in one session

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Delivery of IMRT/SRS/SBRT

G0251	Linear accelerator based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, maximum 5 sessions per course of treatment
G0339	Image guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment
G0340	Image guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum 5 sessions per course of treatment
77293	Respiratory motion management simulation (List separately in addition to code for primary procedure) **(NEW CODE EFFECTIVE 01/01/2014)**
77301	Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications
77338	Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan
77371	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source Cobalt 60 based
77372	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based
77373	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions
77418	Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session
77421	Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy
77432	Stereotactic radiation treatment management of cranial lesion(s) (complete course of treatment consisting of 1 session)
77435	Stereotactic body radiation therapy, treatment management, per treatment course, to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions

References Included (but not limited to):

CMS LCD(s)

Numerous LCDs

CMS Article(s)

Numerous Articles

CMS Claims Processing Manual

Chapter 4; § 200.3 Billing Codes for Intensity Modulated Radiation Therapy (IMRT) and Stereotactic Radiosurgery (SRS), § 200.3.1 Billing for IMRT Planning and Delivery, §200.3.2 Additional Billing Instructions for IMRT Planning, §200.3.3 Billing for Stereotactic Radiosurgery (SRS) Planning and Delivery

CMS Transmittals

Transmittal 2845, Change Request 8572, Dated 12/27/2013 (January 2014 Update of the Hospital Outpatient Prospective Payment System (OPPS))

UnitedHealthcare Medicare Advantage Coverage Summaries

Radiologic Therapeutic Procedures

UnitedHealthcare Reimbursement Policies

Category III CPT Codes Reimbursement Policy

UnitedHealthcare Medical Policies

Intensity-Modulated Radiation Therapy

Proton Beam Radiation Therapy

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Delivery of IMRT/SRS/SBRT

MLN Matters

Article MM8572, January 2014 Update of the Hospital Outpatient Prospective Payment System (OPPS)

History

Date	Revisions
06/25/2014	Re-review presented to MRPC for approval
03/17/2014	• Policy title restructured per discussion • Policy does not include Planning services and is only to address the delivery • Decision also made to re-title the policy from "IMRT And Other Targeted Radiation Treatment Delivery" to now "Delivery of IMRT/SRS/SBRT"
03/12/2014	Announcement made to MRPC that policy is being revised to include additional codes
Feb 2014	Administrative updates
01/28/2014	Administrative updates
12/18/2013	Administrative updates
10/09/2013	• MRPC approved with the additions of CPT codes 77301, 77338 and 77418 • Decision also made to re-title the policy from "Compensator Based Beam Modulation Treatment Delivery Reimbursement Policy" to now "IMRT And Other Targeted Radiation Treatment Delivery"
06/12/2013	Re-review of policy presented to MRPC for approval
07/27/2012	Administrative updates
07/11/2012	MRP Committee reviewed and approved
06/06/2012	Administrative updates
06/22/2011	Policy developed and approved

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