DELIVERY OF IMRT/SRS/SBRT

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INSTRUCTIONS FOR USE

This Policy Guideline is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates for health care services submitted on CMS 1500 forms and, when specified, to those billed on UB04 forms (CMS 1450), or their electronic comparative. The information presented in this Policy Guideline is believed to be accurate and current as of the date of publication.

This Policy Guideline provides assistance in administering health benefits. All reviewers must first identify member eligibility, any federal or state regulatory requirements, Centers for Medicare and Medicaid Services (CMS) policy, the member specific benefit plan coverage and individual provider contracts prior to use of this Policy Guideline. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document may differ greatly from the standard benefit plan upon which this Policy Guideline is based. In the event of a conflict, the member specific benefit plan document supersedes this Policy Guideline. Other Policies and Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

UnitedHealthcare follows Medicare coverage guidelines and regularly updates its Medicare Advantage Policy Guidelines to comply with changes in CMS policy. UnitedHealthcare encourages physicians and other healthcare professionals to keep current with any CMS policy changes and/or billing requirements by referring to the CMS or your local carrier website regularly. Physicians and other healthcare professionals can sign up for regular distributions for policy or regulatory changes directly from CMS and/or your local carrier. This Policy Guideline is provided for informational purposes. It does not constitute medical advice.

POLICY 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
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:

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

**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. If more than one session is required, the SBRT codes must be used.

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 in instances where sparing the surrounding normal tissue is essential for patients who have 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 the patient has at least one of the following conditions met:

- Important dose limiting structures adjacent to, but outside the PTV, are sufficiently close and require IMRT to assure safety and morbidity reduction.
- An immediately adjacent volume has been irradiated and abutting portals must be established with high precision.
- Gross Tumor Volume (GTV) margins are concave or convex and in close proximity to critical structures that must be protected to avoid unacceptable morbidity.
- 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. 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 particular care is required to document the necessity for IMRT.

**Indications for SRS**
Intracranial lesions would be considered medically reasonable and necessary for the following conditions:

- Primary central nervous system malignancies, generally under 5 cm and as a boost treatment for larger cranial, base of skull, or spinal lesions that have been treated initially with external beam radiation therapy or surgery (e.g. grade III and IV gliomas, oligodendrogliomas, sarcomas, chondrosarcomas, chordomas, and nasopharyngeal of paranasal sinus malignancies).
- Primary and secondary tumors involving the brain or spine parenchyma, meninges/dura, or immediately adjacent bony structures.
- Benign brain and spinal tumors such as cranial meningiomas, acoustic neuromas, other schwannomas, pituitary adenomas, pineal cystomas, craniopharyngiomas, gliomas tumors, and hemangioblastomas.
- Cranial arteriovenous malformations and hemangiomas.
- Trigeminal neuralgia not responsive to medical management.
- Metastatic brain lesions, generally limited in number, with stable systemic disease, Karnofsky Performance Status of 40 or greater or 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 or spinal field where the additional stereotactic precision is required to avoid unacceptable vital tissue radiation.
- 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.

**Indications for SBRT**

**SBRT for Lung, Liver, Kidney, Adrenal Gland, or Pancreas Neoplasms**
SBRT is covered for primary and metastatic tumors of the lung, liver, kidney, adrenal gland or pancreas when and only when each of the following criteria are met, and each specifically documented in the medical record:

- 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).
• Other forms of radiotherapy, including but not limited to external beam and 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.
• Other forms of focal therapy, including but not limited to radiofrequency ablation and cryotherapy, cannot be as safely or effectively utilized.

**SBRT for Prostate Neoplasms**

SBRT of the prostate is covered for patients with clinically localized low to intermediate risk prostate cancer on an individual case by case basis.

**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.

**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 and this necessity is documented in the medical record.

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.

**APPLICABLE CODES**

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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<tr>
<th>CPT Code</th>
<th>Description</th>
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<tr>
<td>77293</td>
<td>Respiratory motion management simulation (List separately in addition to code for primary procedure)</td>
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<tr>
<td>77301</td>
<td>Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications</td>
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<td>77338</td>
<td>Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan</td>
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<td>77371</td>
<td>Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source Cobalt 60 based</td>
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<tr>
<td>77372</td>
<td>Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based</td>
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<tr>
<td>77373</td>
<td>Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions</td>
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<tr>
<td>77385</td>
<td>Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple</td>
</tr>
<tr>
<td>77386</td>
<td>Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex</td>
</tr>
<tr>
<td>77387</td>
<td>Guidance for localization of target volume for delivery of radiation treatment delivery, includes intrafractio n tracking, when performed</td>
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<tr>
<td>77432</td>
<td>Stereotactic radiation treatment management of cranial lesion(s) (complete course of treatment consisting of 1 session)</td>
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</tbody>
</table>
CPT Code | Description
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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

HCPCS Code | Description
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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
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
G6002 | Stereoscopic x-ray guidance for localization of target volume for the delivery of radiation therapy
G6015 | Intensity modulated treatment delivery, single or multiple fields/arcas, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session
G6016 | 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
G6017 | Intra-fraction localization and tracking of target or patient motion during delivery of radiation therapy (e.g., 3D positional tracking, gating, 3D surface tracking), each fraction of treatment

ICD-10 Diagnosis Codes
There are numerous reasonable and necessary conditions that might warrant the use of these procedures but which are too many to list. However, an appropriate ICD-10 diagnosis must be submitted with each claim and failure to do so may result in denial or delay in claim processing. The highest level of specificity should be used to report the patient’s condition. The most current ICD-10 codebook should be used to ensure proper payment.

DEFINITIONS

DMLC: Dynamic Multi-leaf Collimator

Eastern Cooperative Oncology Group (ECOG) Performance Scale:
0 - Fully active, able to carry on all pre-disease performance without restriction.
1 - Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g. light house work, office work.
2 - Ambulatory and capable of all self-care but unable to carry out work activities. Up and about more than 50% of waking hours.
3 - Capable of only limited self-care, confined to bed or chair more than 50% of waking hours.
4 - Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.
5 - Dead

GTV: Gross Tumor Volume

IMRT: Intensity Modulated Radiation Therapy

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

**MLC**: Multi-leaf Collimator

**PTV**: Planned Treatment Volume

**SBRT**: Stereotactic Body Radiation Therapy

**SMLC**: Segmented Mode Multi-leaf Collimator

**SRS**: Stereotactic Radiosurgery

## REFERENCES

### CMS Local Coverage Determinations (LCDs)

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<th>LCD</th>
<th>Medicare Part A</th>
<th>Medicare Part B</th>
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**CMS Articles**

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**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))
- Transmittal 3425, Change Request 9486, Dated 12/18/2015 (January 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS))
- Transmittal 3471, Change Request 9549, Dated 02/26/2016 (April 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS))
- Transmittal 3523, Change Request 9658, Dated 05/13/2016 (July 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS))
- Transmittal 3531, Change Request 9668, Dated 05/27/2016 (July 2016 Update of the Ambulatory Surgical Center (ASC) Payment System)
- Transmittal 3685, Change Request 9930, Dated 12/22/2016 (January 2017 Update of the Hospital Outpatient Prospective Payment System (OPPS))

**MLN Matters**

- Article MM8572, January 2014 Update of the Hospital Outpatient Prospective Payment System (OPPS)
- Article MM9486, January 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS)
- Article MM9549, April 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS)
- Article MM9658, July 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS)
- Article MM9668, July 2016 Update of the Ambulatory Surgical Center (ASC) Payment System

**UnitedHealthcare Commercial Policies**

- Intensity-Modulated Radiation Therapy
- Proton Beam Radiation Therapy
## GUIDELINE HISTORY/REVISION INFORMATION

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<td>06/14/2017</td>
<td>• Annual review&lt;br&gt;• Removing CPT codes 77280, 77285, and 77290 from this policy, see&lt;br&gt;Reimbursement Policy <a href="#">Intensity Modulated Radiation Therapy (IMRT) Policy</a>.&lt;br&gt;• Administrative updates</td>
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