ASTRO Model Policies

INTENSITY MODULATED RADIATION THERAPY (IMRT)

This Model Policy[1] addresses coverage for Intensity Modulated Radiation Therapy (IMRT).

DESCRIPTION

Intensity Modulated Radiation Therapy (IMRT) is a technology for delivering highly conformal external beam radiation to a well-defined treatment volume with radiation beams whose intensity varies across the beam. IMRT is particularly useful for delivering a highly conformal radiation dose to targets positioned near sensitive normal tissues.

TREATMENT

IMRT Treatment Planning

IMRT treatment plans are tailored to the target volumes and are geometrically more accurate than conventional or three-dimensional conformal radiation therapy plans. IMRT planning defines the necessary field sizes, gantry angles and other beam characteristics needed to achieve the desired radiation dose distribution.

IMRT treatment planning (i.e., inverse treatment planning) is a multi-step process:

1. **Imaging:** Three-dimensional image acquisition of the target region by simulation employing CT, MR, PET scanners or similar image fusion technology is an essential prerequisite to IMRT treatment planning. If respiratory or other normal organ motion is expected to produce significant movement of the target region during radiotherapy delivery, the radiation oncologist may additionally elect to order multi-phasic treatment planning image sets to account for motion when rendering target volumes.

2. **Contouring:** Defining the target and avoidance structures is in itself a multi-step process:

    a. The radiation oncologist reviews the three-dimensional images and outlines the treatment target on each slice of the image set. The summation of these contours defines the Gross Tumor Volume (GTV). For multiple image sets, the physician may outline separate GTVs on each image set to account for the effect of normal organ motion upon target location and shape. Some patients may not have GTVs if they have had previous treatment with surgery or chemotherapy, in which case treatment planning will be based on CTVs as described below.

    b. The radiation oncologist draws a margin around the GTV to generate a Clinical Target Volume (CTV) which encompasses the areas at risk for microscopic disease (i.e., not visible on imaging studies). Other CTVs may be created based on the estimated volume of residual disease. For multiple image sets, the physician may draw this margin around an aggregate volume containing all image set GTVs to generate an organ-motion CTV, or Internal Target Volume (ITV).

    c. To account for potential daily patient set-up variation and/or organ and patient motion, a final margin is then added to create a Planning Target Volume (PTV).

[1] ASTRO model policies were developed as a means to efficiently communicate what ASTRO believes to be correct coverage policies for radiation oncology services. The ASTRO Model Policies do not serve as clinical guidelines and they are subject to periodic review and revision without notice. The ASTRO Model Policies may be reproduced and distributed, without modification, for noncommercial purposes.

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d. Any combination of the GTV, CTV, ITV or PTV may be contoured depending on the clinical situation and the intent of treatment.

e. Nearby normal structures that could potentially be harmed by radiation (i.e., "organs at risk", or OARs) are also contoured.

3. **Radiation Dose Prescribing:** The radiation oncologist assigns specific dose requirements for the PTV which typically includes a prescribed dose that must be given to at least 90-95% of the PTV. This is often accompanied by a minimum acceptable point dose within the PTV and a constraint describing an acceptable range of dose homogeneity. Additionally, PTV dose requirements routinely include dose constraints for the OARs (e.g., upper limit of mean dose, maximum allowable point dose, and/or a critical volume of the OAR that must not receive a dose above a specified limit). A treatment plan that satisfies these requirements and constraints should maximize the potential for disease control and minimize the risk of radiation injury to normal tissue.

4. **Dosimetric Planning and Calculations:** The medical physicist or a supervised dosimetrist calculates a multiple static beam and/or modulated arc treatment plan to deliver the prescribed radiation dose to the PTV and simultaneously satisfy the normal tissue dose constraints by delivering significantly lower doses to nearby organs. Dose-volume-histograms are prepared for the PTV and OARs. Here, an arc is defined as a discrete complete or partial rotation of the linear accelerator gantry during which there is continuous motion of the multi-leaf collimator to deliver an optimized radiation dose distribution within the patient. The essential feature of an IMRT plan is that it describes the means to deliver treatment utilizing non-uniform beam intensities. Each radiation beam or arc is, in effect, a collection of numerous "beamlets," each with a different level of radiation intensity; the summation of these "beamlets" delivers the characteristic highly conformal IMRT dose distribution. The physicist and dosimetrist perform basic dose calculations on each of the modulated beams or arcs. These patient specific monitor unit computations verify through an independent second dose calculation method the accuracy of the calculations.

5. **Patient Specific Dose Verification:** The calculated beams or arcs are then delivered either to a phantom or a dosimetry measuring device to confirm that the intended dose distribution for the patient is physically verifiable and that the intensity modulated beams or arcs are technically feasible. Additional information can be found in the ASTRO QA White Paper (General Reference #13), which critically evaluates guidance and literature on the safe delivery of IMRT, with a primary focus on recommendations to prevent human error and methods to reduce or eliminate mistakes or machine malfunctions that can lead to catastrophic failures.

Documentation of all aspects of the treatment planning process is essential.

IMRT Treatment Delivery

The basic requirement for all forms of IMRT treatment delivery is that the technology must accurately produce the calculated dose distribution described by the IMRT plan. IMRT treatment delivery may be accomplished via various combinations of gantry motion, table motion, slice-by-slice treatment (tomotherapy) and multi-leaf collimator (MLC) or solid compensators to modulate the intensity of the radiation beams or arcs.

The highly conformal dose distribution produced by IMRT results in sharper spatial dose gradients than conventional or three-dimensional conformal radiation therapy. Consequently, small changes in patient position or target position within the body can cause significant changes in the dose delivered to the PTV and to the organs at risk; thus reproducible patient immobilization is required for precision IMRT. Imaging techniques such as stereoscopic kilovoltage or megavoltage X-ray, ultrasound, or cone beam or megavoltage CT scan (collectively referred to as Image Guided Radiation Therapy or IGRT) may be utilized to account for daily motion of the PTV to accurately deliver the treatment.

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Documentation Requirements

Documentation in the patient's medical records must support:

1. The reasonable and necessary requirements as outlined under the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy.

2. The prescription which defines the goals and requirements of the treatment plan, including the specific dose constraints to the target and nearby critical structures.

3. A note of medical necessity for IMRT by the treating physician.

4. Signed IMRT inverse plan that meets prescribed dose constraints for the planning target volume (PTV) and surrounding normal tissue.

5. The target verification methodology must include the following:
   a. Documentation of the clinical treatment volume (CTV) and the planning target volume (PTV).
   b. Documentation of immobilization and patient positioning.

6. Independent basic dose calculations of monitor units have been performed for each beam before the patient's first treatment.

7. Documentation of fluence distributions (re-computed and measured in a phantom or dosimetry measuring device) is required.

8. Documentation supporting identification of structures that traverse high-and low-dose regions created by respiration is indicated when billing for respiratory motion management simulation.

INDICATIONS AND LIMITATIONS OF COVERAGE AND/OR MEDICAL NECESSITY

Indications For Coverage

As IMRT technology was introduced and the appropriate clinical applications were being established, earlier versions of this model policy identified specific disease sites for which IMRT was considered a standard option. The maturation and dissemination of IMRT capabilities with improved clinical outcomes has expanded to the point that a definitive list of "approved sites" driven solely by diagnosis codes (ICD-9 or ICD-10) is no longer sufficient. However, it is important to note that normal tissue dose volume histograms (DVHs) or dosimetry must be demonstrably improved with an IMRT plan to validate coverage. Therefore, coverage decisions must extend beyond ICD-9 and ICD-10 codes to incorporate additional considerations of clinical scenario and medical necessity with appropriate documentation. For some anatomical sites such as nasopharynx, oropharynx, hypopharynx, larynx (except for early true vocal cord cancer), prostate, anus and central nervous system, IMRT is commonly performed. In all cases, documentation of the medical necessity is required.

IMRT is considered reasonable and medically necessary in instances where sparing the surrounding normal tissue is of added clinical benefit to the patient. Common clinical indications that frequently support the use of IMRT include:

1. Primary, metastatic or benign tumors of the central nervous system.
2. Primary, metastatic tumors of the spine where spinal cord tolerance may be exceeded by conventional treatment.
3. Selected extracranial primary, metastatic or benign lesions.
4. Reirradiation that meets the requirements for medical necessity.

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IMRT offers advantages as well as added complexity over conventional or three-dimensional conformal radiation therapy. Before applying IMRT techniques, a comprehensive understanding of the benefits and consequences is required. In addition to satisfying at least one of the four selection criteria noted above, the radiation oncologist's decision to employ IMRT requires an informed assessment of benefits and risks including:

- Determination of patient suitability for IMRT allowing for reproducible treatment delivery.
- Adequate definition of the target volumes and organs at risk.
- Equipment capability, including ability to account for organ motion when a relevant factor.
- Physician and staff training.
- Adequate quality assurance procedures.

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, 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, but not limited to those involving:
    - Orbits,
    - Sinuses,
    - Skull base,
    - Aero-digestive tract, and
    - Salivary glands.
- Thoracic malignancies.
- Abdominal malignancies when dose constraints to small bowel or other normal tissue are exceeded and prevent administration of a therapeutic dose.
- Pelvic malignancies, including prostatic, gynecologic and anal carcinomas.
- Other pelvic or retroperitoneal malignancies.

The final determination of the appropriateness and medical necessity for IMRT resides with the treating radiation oncologist who should document the justification for IMRT for each patient.

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ICD-10-CM Codes that may be Associated with Medical Necessity

Note: Diagnosis codes are based on the current ICD-10-CM codes that are effective at the time of the Model Policy publication. Any updates to ICD-10-CM codes will be reviewed by ASTRO, and coverage should not be presumed until the results of such review have been published/posted. These ICD codes may support medical necessity under this Model Policy.

System	Site	ICD-10-CM Codes
Head and Neck	Lip	C00.0 - C00.9
	Tongue	C01 - C02.9
	Major salivary glands	C07 - C08.9
	Gum	C03.0 - C03.9
	Floor of mouth	C04.0 - C04.9
	Other parts of the mouth	C05.0 - C06.9
	Oropharynx	C09.0 - C10.9
	Nasopharynx	C11.0 - C11.9
	Hypopharynx	C12 - C13.9
	Nasal cavities, middle ear and accessory sinuses	C30.0 - C31.9
	Larynx	C32.0 - C32.9
Digestive Organs and Peritoneum	Esophagus	C15.3 - C15.9
	Stomach	C16.0 - C16.9
	Small intestine	C17.0 - C17.9
	Colon	C18.0 - C18.9
	Rectum, rectosigmoid, anus	C19 - C21.8
	Liver, intrahepatic bile ducts	C22.0 - C22.9
	Gallbladder, extrahepatic bile ducts	C23 - C24.9
	Pancreas	C25.0 - C25.9
	Retroperitoneum, peritoneum	C45.1 C48.0 - C48.8
Respiratory and Intrathoracic Organs	Trachea, bronchus and lung	C33 - C34.92
	Pleura	C38.4 C45.0
	Thymus, heart and mediastinum	C37 - C38.8 C45.2

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System	Site	ICD-10 Codes
Bone, connective tissue and skin	Bone	C40.00 - C41.9
	Connective and other soft tissue	C47.0 - C49.9
	Skin	C43.0 - C44.99 D03.0 - D03.9
	Kaposi's sarcoma	C46.0- C46.9
	Merkel cell carcinoma	C4A.0 - C4A.9 D3A.00 - D3A.8 C7B.00 - C7B.1
Breast	Female breast	C50.011 - C50.019 C50.111 - C50.119 C50.211 - C50.219 C50.311 - C50.319 C50.411 - C50.419 C50.511 - C50.519 C50.611 - C50.619 C50.811 - C50.819 C50.911 - C50.919 D05.00 - D05.92
	Male breast	C50.021 - C50.029 C50.121 - C50.129 C50.221 - C50.229 C50.321 - C50.329 C50.421 - C50.429 C50.521 - C50.529 C50.621 - C50.629 C50.821 - C50.829 C50.921 - C50.929
Genitourinary organs	Cervix	C53.0 - C53.9
	Uterus	C55 C54.0 - C54.9
	Ovary and adnexa	C56.1 - C57.4
	Other female genital organs	C51.0 - C52 C57.7 - C57.9
	Prostate	C61
	Testis	C62.00 - C62.90
	Penis and other male genital organs	C60.0 - C60.9 C63.00 - C63.9
	Bladder	C67.0 - C67.9
	Kidney	C64.1 - C66.9 C68.0 - C68.9

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System	Site	ICD-10 Codes
Other sites	Eye	C69.00 - C69.92
	Brain, other parts of nervous system	C70.0 - C72.9
	Endocrine glands	C73 C74.00 - C75.9
	Benign neoplasms of brain, cranial nerves and meninges	D32.0 - D33.3
	Benign neoplasms of pituitary, pineal, aortic body and other paraganglia	D35.2 - D35.6
Malignant neoplasm of other and ill-defined sites	Various regions	C76.0 - C76.8 C45.7
Secondary and unspecified malignant neoplasm of lymph nodes	Lymph node metastases	C77.0 - C77.9
Secondary malignant neoplasm of respiratory, digestive and other specified sites	Metastatic disease other than lymph node metastases	C78.00 - C80.1 C45.9
Lymphatic and hematopoietic tissue	Non-Hodgkin's lymphoma	C82.00 - C86.6 C91.40 - C91.42 C96.A C96.0 - C96.9 C96.Z
	Hodgkin's lymphoma	C81.00 - C81.99
	Multiple myeloma	C90.00
Reirradiation	Various regions	T66.XXXA*

*ICD-10-CM T66.XXXA (Effects of Radiation, Unspecified) may only be used where prior radiation therapy to the site is the governing factor necessitating IMRT in lieu of other radiotherapy. An ICD diagnosis code for the anatomic diagnosis must also be used.

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Limitations of Coverage

IMRT is not considered reasonable and medically necessary unless at least one of the criteria listed in the "Indications of Coverage" section of this policy is present.

Clinical scenarios that would not typically support the use of IMRT include:

1. Where IMRT does not offer an advantage over conventional or three-dimensional conformal radiation therapy techniques that deliver good clinical outcomes and low toxicity.

2. Clinical urgency, such as spinal cord compression, superior vena cava syndrome or airway obstruction.

3. Palliative treatment of metastatic disease where the prescribed dose does not approach normal tissue tolerances.

4. Inability to accommodate for organ motion, such as for a mobile lung tumor.

5. Inability of the patient to cooperate and tolerate immobilization to permit accurate and reproducible dose delivery.

PHYSICIANS' CURRENT PROCEDURAL TERMINOLOGY (CPT®)/HCPCS

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CPT®/HCPCS codes

CPT Code for IMRT Treatment Planning

77301	Intensity Modulated Radiation Therapy (IMRT) plan, including dose-volume histograms for target and critical structure partial tolerance specifications. *This code is typically reported only once per course of IMRT.*
+77293	Respiratory motion management simulation (List separately in addition to code for primary procedure). *This is an add-on code and cannot be billed on its own. It should be billed with either CPT code 77295 or 77301.*

CPT Codes for IMRT Treatment Delivery

77385	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple *Use with any of the following: prostate, breast, and all sites using physical compensator based IMRT.*
77386	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex *Includes all other sites if not using physical compensator based IMRT.*
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.*

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Medical Radiation Physics, Dosimetry and Treatment Devices

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.

CPT® Code for IMRT Dosimetry

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.*

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 in order to guide the generation of the multi-leaf collimator (MLC) segments. CPT® code 77338 was established to report multileaf collimator (MLC) design and construction for IMRT. It captures the physician work associated with design and fabrication of the device, the practice expense associated with staff (physicists and dosimetrists) and the equipment used to design, analyze and fabricate the device. While 77334 was previously billed once for each gantry angle, 77338 is billed only once per IMRT plan. There is no separate accounting for gantry angles or other beam arrangements. CPT code 77334 may be used in the IMRT process of care to report the immobilization device constructed at time of the simulation. Additional IMRT plans during a course of care merit additional reporting of 77338.

CPT Codes for IMRT Treatment Devices

77332	Treatment devices, design and construction; simple *Simple treatment devices include simple multi-use shaped blocks, bolus and passive, multiuse devices.*
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.*
77334	Treatment devices, design and construction; complex *Complex treatment devices include custom-fabricated cast blocks, immobilization devices, wedges, compensators and eye shields.*
77338	Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan *Report once per IMRT plan.*

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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.

CPT® and HCPCS Codes for IGRT

77387	Guidance for localization of target volume for delivery of radiation treatment delivery, includes intrafraction tracking, when performed
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.*
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.*
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.*

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 the course of IMRT treatment (i.e. with CPT codes 77385 or 77386) if they are not performed in conjunction with the development of an IMRT plan.

CPT® Code	CPT Code Descriptor
77014	Computed tomography guidance for placement of radiation therapy fields
77280	Therapeutic radiology simulation-aided field setting; simple *Criteria for level: Single treatment area. 77280 may be performed and reported separately from the IMRT plan to report verification of the field after the planning process is complete and prior to the initial treatment.*
77285	Therapeutic radiology simulation-aided field setting; intermediate *Criteria for level: Two separate treatment areas.*
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.*
77295	3-dimensional radiotherapy plan, including dose-volume histograms *May be reported once per treatment course per treatment volume.*
77321	Special teletherapy port plan, particles, hemibody, total body *Use for particle beam isodose planning. Use for electrons, protons and neutron therapy; half body or total body therapy.*
77331	Special dosimetry (e.g., TLD, microdosimetry) (specify), only when prescribed by the treating physician *Explanation of medical necessity may be required.*
77370	Special medical radiation physics consultation *The radiation oncologist makes a direct request to the qualified medical physicist for a special consultative report or for specific physics services for an individual patient.*

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REFERENCES

The medical literature regarding Intensity Modulated Radiation Therapy is extensive. The following list comprises a compliation of selected peer reviewed publications from the last 10 years reporting clinical outcomes in patients treated with IMRT, organized by disease site.

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