INTENSITY MODULATED RADIATION THERAPY (IMRT)

This Model Policy 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.
**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.
INTENSITY MODULATED RADIATION THERAPY (IMRT)

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.
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.

<table>
<thead>
<tr>
<th>System</th>
<th>Site</th>
<th>ICD-10-CM Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Head and Neck</td>
<td>Lip</td>
<td>C00.0 - C00.9</td>
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<td>Tongue</td>
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<td>Floor of mouth</td>
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<td>Other parts of the mouth</td>
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<td>Oropharynx</td>
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<td>Nasopharynx</td>
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<td>Hypopharynx</td>
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<td>Nasal cavities, middle ear and accessory sinuses</td>
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<td>Larynx</td>
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<td>Rectum, rectosigmoid, anus</td>
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<td>Liver, intrahepatic bile ducts</td>
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<td>Gallbladder, extrahepatic bile ducts</td>
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<td>Pleura</td>
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<td>Thymus, heart and mediastinum</td>
<td>C37 - C38.8 - C45.2</td>
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<td>System</td>
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<td>Bone, connective tissue and skin</td>
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<td>Connective and other soft tissue</td>
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<td>Merkel cell carcinoma</td>
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<td>C50.521 - C50.529</td>
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<td>Genitourinary organs</td>
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<td>Uterus</td>
<td>C55</td>
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<td>Ovary and adnexa</td>
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<td>Other female genital organs</td>
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<td>Prostate</td>
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<td>Testis</td>
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<td>Penis and other male genital organs</td>
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<td>Bladder</td>
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<td>Kidney</td>
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<tr>
<td>System</td>
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<tr>
<td>Other sites</td>
<td>Eye</td>
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<td>Brain, other parts of nervous system</td>
<td>C70.0 - C72.9</td>
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<td></td>
<td>Endocrine glands</td>
<td>C73, C74.00 - C75.9</td>
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<td></td>
<td>Benign neoplasms of brain, cranial nerves and meninges</td>
<td>D32.0 - D33.3</td>
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<tr>
<td></td>
<td>Benign neoplasms of pituitary, pineal, aortic body and other paranglia</td>
<td>D35.2 - D35.6</td>
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<tr>
<td>Malignant neoplasm of other and ill-defined sites</td>
<td>Various regions</td>
<td>C76.0 - C76.8, C45.7</td>
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<tr>
<td>Secondary and unspecified malignant neoplasm of lymph nodes</td>
<td>Lymph node metastases</td>
<td>C77.0 - C77.9</td>
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<tr>
<td>Secondary malignant neoplasm of respiratory, digestive and other specified sites</td>
<td>Metastatic disease other than lymph node metastases</td>
<td>C78.00 - C80.1, C45.9</td>
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<td>Lymphatic and hematopoietic tissue</td>
<td>Non-Hodgkin's lymphoma</td>
<td>C82.00 - C86.6, C91.40 - C91.42, C96.A, C96.0 - C96.9, C96.Z</td>
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<td>Hodgkin's lymphoma</td>
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<td>Multiple myeloma</td>
<td>C90.00</td>
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<tr>
<td>Reirradiation</td>
<td>Various regions</td>
<td>T66.XXXA*</td>
</tr>
</tbody>
</table>

*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.
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

Note: CPT is a trademark of the American Medical Association (AMA)

CPT®/HCPCS codes

CPT Code for IMRT Treatment Planning

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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</table>
| 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

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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</table>
| 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. |
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

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>77300</td>
<td>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.</td>
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</tbody>
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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

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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| 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. |
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

<table>
<thead>
<tr>
<th>CPT® Code</th>
<th>CPT Code Descriptor</th>
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<tbody>
<tr>
<td>77387</td>
<td>Guidance for localization of target volume for delivery of radiation treatment delivery, includes intrafraction tracking, when performed</td>
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<tr>
<td>G6001</td>
<td>Ultrasonic guidance for placement of radiation therapy fields</td>
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<tr>
<td>G6002</td>
<td>Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy</td>
</tr>
<tr>
<td>77014</td>
<td>Computed tomography guidance for placement of radiation therapy fields</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CPT® Code</th>
<th>CPT Code Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>77280</td>
<td>Therapeutic radiology simulation-aided field setting; simple</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td>77285</td>
<td>Therapeutic radiology simulation-aided field setting; intermediate</td>
</tr>
<tr>
<td></td>
<td>Criteria for level: Two separate treatment areas.</td>
</tr>
<tr>
<td>77290</td>
<td>Therapeutic radiology simulation-aided field setting; complex</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td>77295</td>
<td>3-dimensional radiotherapy plan, including dose-volume histograms</td>
</tr>
<tr>
<td></td>
<td>May be reported once per treatment course per treatment volume.</td>
</tr>
<tr>
<td>77321</td>
<td>Special teletherapy port plan, particles, hemibody, total body</td>
</tr>
<tr>
<td></td>
<td>Use for particle beam isodose planning. Use for electrons, protons and neutron therapy; half body or total body therapy.</td>
</tr>
<tr>
<td>77331</td>
<td>Special dosimetry (e.g., TLD, microdosimetry) (specify), only when prescribed by the treating physician</td>
</tr>
<tr>
<td></td>
<td>Explanation of medical necessity may be required.</td>
</tr>
<tr>
<td>77370</td>
<td>Special medical radiation physics consultation</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
</tbody>
</table>

ADDITIONAL INFORMATION
Per CMS, payment for the services identified by CPT codes 77014, 77280, 77285, 77290, 77295, 77306, 77307, 77321, and 77331, are included in the payment for CPT code 77301 (IMRT planning). These codes should not be reported in addition to CPT code 77301, when provided prior to, or as part of, the development of the IMRT plan. They may, however, be reported as needed during the course of IMRT treatment delivery (i.e., with CPT codes 77385, 77386, G6015 or G6016). Additionally, CPT codes 77280-77290 Simulation aided field settings should not be reported for verification of the treatment field during the course of IMRT.
REFERENCES

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

General


Anus


Breast


Breast


Central Nervous System


**Gynecologic**


**Head and Neck**


Liver


**Lung**


**Pancreas**


**Prostate**


**Vulva**
