“FOR CMS (MEDICARE) MEMBERS ONLY”

Coverage Indications, Limitations, and/or Medical Necessity

Radiation oncology is the specialty of medicine that utilizes high-energy ionizing radiation in the treatment of malignant neoplasms and certain non-malignant conditions. It uses several distinct therapeutic modalities: teletherapy, brachytherapy, hyperthermia, and stereotactic radiation. These may be directed at either malignant or benign lesions.

Indications

Radiation oncology services are considered medically reasonable and necessary when the following conditions are indicated and documented in the patient's medical records.

I. Conventional External Beam Teletherapy including 3-D Conformal Teletherapy
   A. Tumor Mapping and Clinical Treatment Planning

   Clinical treatment planning and tumor mapping are crucial to identifying the location, extent, and volume of tumor(s) to be treated and all critical structures surrounding them. The physician plans the appropriate course of radiation therapy, which will allow for maximum benefit while protecting surrounding tissues and structures. Clinical treatment planning may involve ordering and interpreting special tests such as lymphangiography, CT scan, nuclear medicine study, ultrasound, MR scan, and/or surgical exploration with biopsy and markers placed, for the purpose of treatment planning, and tumor localization, virtual reality-based 3-D simulation system or other dedicated diagnostic x-ray, ultrasound, or nuclear medicine equipment that has been modified to localize treatment volumes in order to define the area that requires treatment.

   Clinical treatment planning requires consideration of: treatment time/dose determination, choice of modalities, determination of number and size of treatment portals, planning of appropriate devices, sequencing and combination of modalities, and correlation of physical exam findings with imaging studies and special tests to
delineate precise clinical location of the tumor or area at risk.

Clinical treatment planning is a one-time charge per course of therapy. Billing for multiple treatment plans for a single course of treatment is not allowed. This is a professional service only and the physician is responsible for all of the technical aspects of the treatment planning process.

**CPT code 77261**

Report CPT code 77261 when the volume to be treated is clearly defined and easily encompasses the tumor while excluding normal tissue and structures. If a patient requires therapy to a new volume of interest a separate treatment plan may be allowed and appropriate documentation should be available upon request.

Simple planning requires no interpretation of special tests and involves no more than one critical structure or volume of interest.

**77261 Therapeutic radiology treatment planning: SIMPLE**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Level of Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Special tests</td>
<td>None</td>
</tr>
<tr>
<td>Modality</td>
<td>External photon beam as sole modality</td>
</tr>
<tr>
<td>Treatment time/dose</td>
<td>Standard fractionated (once per day) treatment. Normal tissues may be included, and normal tissue tolerance may be exceeded, if patient survival is presumed to be limited.</td>
</tr>
<tr>
<td>Devices</td>
<td>Single area of interest in a single port or simple parallel opposed ports</td>
</tr>
<tr>
<td></td>
<td>None, or single set of any type of pre-made devices. A &quot;set&quot; may include multiple loose blocks placed on a tray or fixed to the tray by connecting devices. Immobilization devices not designed or manufactured for a specific patient.</td>
</tr>
</tbody>
</table>

**CPT code 77262**

Report CPT code 77262 when there is an intermediate level of planning difficulty. Two separate volumes of interest (non-contiguous) are involved.

Critical or sensitive organs that need protection require special tests for localization of tumor volume. Not more than two critical structures are involved when planning the optimum course of treatment.
### 77262 Therapeutic radiology treatment planning: INTERMEDIATE

In order to bill this treatment planning code, at least two criteria must be met.

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Level of Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Special tests</td>
<td>Fluoroscopy (other than for simulation purposes), ultrasound,</td>
</tr>
<tr>
<td>interpreted necessary to define</td>
<td>which are necessary to define tumor volume for treatment purposes</td>
</tr>
<tr>
<td>tumor volume for treatment</td>
<td></td>
</tr>
<tr>
<td>purposes</td>
<td></td>
</tr>
<tr>
<td>Modality</td>
<td>External photon beam as sole modality</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment time/dose considerations</td>
<td>Standard fractionated (once per day) or special time-dose considerations (e.g. hyperfractionated) treatment. The number of critical/sensitive organs, will not determine complexity, per se, unless tolerance levels of these organs is reached or exceeded, and unless survival into a period of risk is reasonably anticipated. Treatment should be calculated to dose within a volume.</td>
</tr>
<tr>
<td>Ports</td>
<td>Three or more converging ports, two separate treatment volumes</td>
</tr>
<tr>
<td>Devices</td>
<td>Multiple sets of pre-made or manufactured generic treatment devices</td>
</tr>
</tbody>
</table>

### CPT code 77263

Report CPT code 77263 when complex treatment planning is involved. Three or more volumes of interest may require treatment. Planning includes interpreting complex tests such as MR and/or CT localization of tumor(s). The cancer is generally complex in its distribution regardless of whether the patient is in early or advanced stages of cancer. Multiple critical areas generally require planning of special protection. Combined therapy may be required for optimum benefit such as brachytherapy, surgery, and chemotherapy. Use of electrons, tangents, wedges, customized blocks, and immobilized devices qualify for complex planning.

### 77263 Therapeutic radiology treatment planning: COMPLEX

In order to bill this treatment planning code, at least two criteria must be met.

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Level of Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Special tests interpreted</td>
<td>CT, MRI, angiography, PET scan, molecular imaging</td>
</tr>
</tbody>
</table>
for determination of tumor volume for treatment purposes

<table>
<thead>
<tr>
<th>Modality</th>
<th>External beam as primary modality (with or without electron boost*) or in conjunction with another modality (e.g. brachytherapy, hyperthermia, concurrent chemotherapy). Special or concurrent mixed beam considerations.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment time/dose considerations</td>
<td>Standard or non-standard fractionation. The number of critical/sensitive organs, will not, per se, determine complexity, but dose levels should not reach or exceed normal tissue tolerance with survival reasonably anticipated into a period of risk. Calculated doses must be to a volume.</td>
</tr>
<tr>
<td>Ports</td>
<td>Three or more separate treatment volumes and/or rotational arcs. Tangential* and/or oblique.</td>
</tr>
<tr>
<td>Devices</td>
<td>Blocks/immobilization devices must be customized, and, when used, must be required for appropriate clinical management. Custom blocks fabricated for palliative ports only with supporting written justification and clinical appropriateness.</td>
</tr>
</tbody>
</table>

*Electrons, wedges and tangents qualify for complex

B. Therapeutic Radiology Simulation - Aided Field Setting (CPT codes 77280-77295)

Radiation oncology simulation is defined as the process of determining and establishing the radiation therapy treatment portals to a specific treatment volume. Ordering and interpreting special tests may be required to assist in the field settings.

Simulation procedures 77280-77290 may be performed if medically necessary to prepare the patient for treatment planning and to ensure accurate treatment.

Following treatment planning, simulation is used to actually direct the treatment beams to the specific volumes of interest. Simulation may be carried out on a dedicated conventional simulator or CT scanner, radiation therapy treatment unit (e.g., linear accelerator), or using diagnostic imaging equipment (e.g., fluoroscopy, Pet scan, CT, MR, ultrasound or virtual reality-based 3-D simulation system).

The complexity of simulation is based on the number of ports, volumes of interest,
and the inclusion and type of treatment devices. However the number of films taken per treatment, the modality from which images for simulation are obtained, and the use of fluoroscopy are not determinants of complexity. Portal changes based on unsatisfactory initial simulation(s) are not reported as additional simulations. Additional simulations may be necessary during treatment in order to account for changes in port size, boost dose, or tumor volume.

However, minor changes in port size without changes in beam or without clinical justification do not warrant an additional charge or a higher level of complexity. The inclusion of treatment devices in the simulation process typically increases the complexity. Simulation without the inclusion of devices or with any pre-made devices (e.g., blocks, immobilization) is considered simple. Custom devices elevate complexity when clinically appropriate. Documentation of simulation requires a written record of the procedure and hard copy of a x-ray film or electronic images and evidence of image review by physicians including signature or initials and data review.

The typical course of radiation therapy will require from one to three simulations. However, no more than one simulation may be reported on any given day. Frequency in excess of three simulations should be supported by documentation in the medical record and be made available upon request.

1. **CPT code 77280**
   Set radiation therapy field
   Single volume of interest with either a simple port or parallel opposed ports
   Simple or no blocking
   Block verification simulation
   Re-simulation at a later date to verify the accuracy of custom blocks, prior to beginning a treatment is considered a simple simulation.

2. **CPT code 77285**
   Set radiation therapy field
   Simulation of three or more converging ports, or two separate volumes of interest.
   Multiple blocks are covered when clinically necessary.

3. **CPT code 77290**
   Set radiation therapy field
   Three or more volumes of interest, or when one or more of the following conditions exists:
   - Rotation or arc therapy
   - Complex blocking or custom made shielding blocks or compensators, or custom immobilization devices, when clinically necessary.
- Any use of contrast media (e.g. body cavity, GI tract, or intravascular), when clinically necessary to define anatomic structures and volumes of interest.
- Tangential ports with/or without multiple devices.

4. **CPT code 77295**
   
   Set radiation therapy field
   
   This procedure involves three dimensional computer-generated reconstruction of tumor volume and surrounding critical normal tissue structures from direct CT scan and/or MRI data in preparation for non-coplanar or coplanar therapy. The simulation uses documented 3-D beam's eye view volume-dose displays of multiple or moving beams. Code 77295 includes those simulation procedures done on the same day in preparation for use of coplanar therapy beams and an additional simulation charge (CPT codes 77280, 77285, and 77290) is not separately payable on the same date. CPT code 77295 also includes the work done for a teletherapy isodose plan.
   
   Code 77295 may be billed once per treatment course per treatment volume. Documentation in the medical record of 3-D volume reconstruction of target and critical structures and dose distribution is required.

   Three dimensional simulation and treatment is clinically warranted when one or more of the following conditions exists:
   
   a. The volume of interest is irregular and in close apposition to normal structures that must be protected.
   b. The volume of interest is in such a location that its parameters can only be defined by MRI or CT.
   c. The final boost volume of interest must be constructed to the exact tumor volume with its irregular configuration.
   d. Multiple conformed portals are necessary to cover the volumes of interest with close margins and protect immediately adjacent normal structures.
   e. "Beams eye view" of multiple portals must be established for conformal treatment delivery.
   f. Volume of interest bordering a previously irradiated area
   g. 3-D reconstruction of tumor volume and critical structure volume in brachytherapy cases to develop a DVH.

   Additional simulations may be required when they are done to verify plan parameters before starting new portals or boosts. In those uncommon circumstances, where there is a substantial change in either patient anatomy or tumor conformation and where a second CT dataset is required to produce an accurate, efficacious and safe "cone-down" plan, a second 77295 charge may be appropriate. When the physician deems this to be the case, the medical necessity for the second 77295 simulation must be documented.
C. Dosimetry

1. Basic Radiation Dosimetry Calculation (CPT 77300)

   This service is considered to be medically necessary for each treatment port and if a patient has off-axis calculations, calculations for different depth doses, different volumes of interest, secondary film dosimetry, abutting volumes of interest, or any other situation requiring individual point calculations of radiation dosage.

   Changes in a patient's weight or girth during the course of radiation treatment may necessitate dosimetry recalculation. This procedure need not be routinely performed each time the patient is treated.

   Basic dosimetry calculations may be reported as many times as the calculations are performed. The typical course of radiation therapy will require from one to six dosimetry calculations, depending on the complexity of the patient's problem. However, radiation treatments to the head/neck, prostate and Hodgkin's disease may require eight or more calculations.

   Medicare would expect to see ongoing documentation that would include any changes in dosimetry calculations and change in radiation treatment and frequency. Documentation requires that the calculation(s) be reviewed, signed and dated by a physician.

2. Teletherapy Isodose Plan (CPT codes 77306, 77307)

   This service is considered medically necessary for a given course of radiation therapy to a specific volume of interest.

   The physician's documentation must be specific to the number of volumes of interest. The specific location of tumor(s) to be treated must be documented as well as the specific number of ports involved with each volume of interest treated. All isodose plans must be checked and signed by the medical radiological physicist and approved and signed by the radiation oncologist.

3. Special Teletherapy Port Plan (CPT code 77321)

   This service is considered medically necessary only when a plan for a special beam consideration is required for the treatment of a neoplasm, such as the use of electrons for total skin irradiation, photons for hemibody irradiation or heavy particles. Only one plan should be billed per volume of interest. A teletherapy isodose plan may be involved with a special teletherapy port plan.

   The radiation oncologist must document his/her involvement in the planning and selection of the special beam parameters and must make the final selection and initiation of the treatment process.
4. Special Dosimetry (CPT code 77331)
This service is considered medically necessary once per port when the physician determines that it is necessary to have a measurement of the amount of radiation that a patient has actually received at a given point with the final results being utilized to accept or modify the current treatment plan. The treating physician must prescribe this service.

This procedure is not to be routinely performed each time the patient is treated. It would be expected that the utilization of this procedure would correspond with the level of complexity of the clinical treatment planning services provided for the patient. The monitoring devices utilized for measuring and monitoring can include thermoluminescent dosimeters (TLD), solid state diode probes, special dosimetry probes, or film dosimetry.

The physician must specify the type of special dosimetry. When special dosimetry is employed, the usual frequency will vary from one to six, consistent with the number of dose calculations. Frequency in excess of the upper end of this range will require appropriate documentation in the medical record. This code (CPT 77331) may be used more than once per day per treatment course.

5. Treatment Devices, Designs, and Construction (CPT codes 77332-77334)
Multiple treatment devices may be billed during a course of therapy if documentation in the medical record substantiates multiple volumes of interest/portals, the use of custom-made devices, and/or the necessity of replacement devices.

Simple treatment devices (CPT code 77332) include any of the following:
- simple port blocks which include one or two hand positioned pre-made blocks
- simple prefabricated bolus that is capable of being shaped for an individual patient
- independent jaw motion or asymmetric collimation.

Intermediate treatment devices (CPT code 77333) include any of the following:
- multiple port blocks which include three or more pre-made blocks such as corner pelvis blocks, beam splitter blocks, or midline spinal cord blocks,
- stents
- bite blocks, or
- fabricated single patient use special bolus

Complex treatment devices (CPT code 77334) include any of the following:
- customized blocks (low temperature alloy),
- customized compensators,
- wedges, molds or casts,
- multi-leaf collimator,
- intensity modulated therapy,
- custom immobilization device (thermal plastic devices, solidifying polymers or vacuum devices),
- eye shields

Providers should bill for devices at the beginning of the treatment course and then may bill again later in the course of treatment when additional or new devices are required. Payment for one set of treatment devices may be allowed per separate port when radiation therapy is started. However, a pair of mirror imaged opposing ports, ports that direct parallel beams such as anterior-posterior or left lateral-right lateral pairs are considered, for billing purposes, to be one port. This is true regardless of the level of complexity of the devices used to create the ports. However, if these devices are significantly different from each other, then the contractor may allow payment for each of the pair of devices. It is the responsibility of the provider to determine the CPT code that most accurately describes the devices employed. At all levels of complexity, the physician must be directly involved in the design, selection, and placement of any of the devices.

It should be noted that when more than one volume of interest is being treated, it may be appropriate to bill for devices for each volume of interest. The level of complexity of these devices will be independent of each other. Custom-made immobilization devices must be billed at a complex level (CPT code 77334). These would include restraining and immobilization devices such as aquaplast and alpha cradle and vac-locs. The use of passive restraints such as straps, pillows, sandbags, etc. are not billable.

When the patient has a combination of a wedge, a compensator, a bolus, or a port block covering the same treatment portal, this would be billed as a single complex treatment device charge rather than a separate charge rendered for each of the individual items. If devices of two separate levels of complexity are utilized for the same treatment portal only the one of highest complexity will be billable.

The typical course of radiation therapy will justify from one to five charges for devices.

Treatment for prostate, head & neck and other complex therapy may require eight or more treatment devices. Frequency in excess of the upper limit must be supported by documentation in the medical record. These codes (CPT 77332-77334) may be used more than once per day per treatment course.

Code(s) 77332-77334 may be quantity billed on the same line of the 1500 claim form if a global service is billed. When billing these codes with a 26 or a TC modifier each service has to be broken out and billed per line.
D. Medical Radiation Physics Consultation (CPT codes 77336, 77370)

**CPT code 77336** - Continuing medical physics consultation: This service ensures that the treatment administered conforms to the specifications of the prescribing physician. This service includes a documented review of the patient’s treatment chart and record to verify that the patient received the prescribed radiation dosage, appropriate positioning and beam orientation and radiation safety. This procedure is reported once for every five consecutive treatments delivered.

This is a weekly code and is reported once for each week of external beam radiation treatments in which at least 3 fractions have been given, or once for each 5 treatments when treatment is given more than once per day. For radiation therapy treatment that is not administered in 5 weekly fractions (such as brachytherapy or stereotactic radiosurgery) or for a course of radiation therapy consisting of one or two fractions, code 77336 may be reported.

**CPT code 77370** must be used for consultative purposes when a problem or special situation arises during radiation therapy. This code requires a detailed written report describing the problem to be given to the requesting physician.

*CPT codes 77336, 77370 are technical services only, and are payable by Medicare Part B only in settings in which the technical component is payable, i.e., in the freestanding radiation oncology center that employs its own radiation physicist.*

Examples of problems that might justify use of this code include:
- the complex interrelationships of electron and photon ports and complex dosimetric considerations in brachytherapy, including high dose rate remote afterloader applications, intravascular brachytherapy treatments, and interstitial radioactive seed implantation;
- analysis of customized beam modification devices and special blocking procedures (and their dosimetric evaluation) to protect critical organs during treatment; or analysis of the effects of previous radiation therapy with assessment of cumulative radiation dose to critical organs.

Computation of dose to the fetus of a pregnant patient undergoing radiation therapy may be reported using this code. Special brachytherapy equipment developed by the qualified medical physicist to treat a particular patient can also be reported with this code. The qualified medical physicist will spend a considerable amount of time and effort on behalf of a specific patient and will render a customized written report (which will form part of the patient’s chart) to the radiation oncologist in reference to the problem or service being addressed. Documentation of the physician’s request and the physics report, as well as the physician review of that report, in the medical record is necessary. Special physics consultations should not be charged when a
qualified medical physicist verifies the calculations performed by others or performs the duties of other members of the treatment team (e.g. dosimetrists).

E. Radiation Treatment Delivery (CPT/HCPCS codes 77401, G6003 – G6014)

These codes recognize the technical component and the various energy levels administered. It is important to code according to the level of service and the energy used.

When more than one treatment is performed on the same day, e.g., hyperfractionation, each treatment should be billed on a separate detail line. *Multiple treatment sessions on the same day are payable as long as there has been a distinct break in therapy services and the individual sessions are of the character usually furnished on different days. When billing for multiple treatments on the same day, the claim must document that there has been a distinct break between therapy. Statements such as "A.M. and P.M. treatments" suffice.*

Radiation treatment delivery can be billed using a date range if the treatments are performed on consecutive days and the energy and level of service are the same, the total number being indicated in the CMS 1500 days or units field. If the dates of service are not consecutive or the energy or level of service is not the same, each date of service must be billed in a separate detail line.

The physician's documentation within the patient's medical record must support complexity of treatment and the specific energy levels reported to Medicare.

Two factors determine which treatment delivery code to choose:
- the energy level used in treatment, in megavolts (MV); and
- the complexity of treatment (defined as number of treatment sites, ports and devices).

These two selection criteria allow for the following matrix for determining which code to use:

<table>
<thead>
<tr>
<th>Tier</th>
<th>Kilovoltage</th>
<th>≤ 5 MV</th>
<th>6-10 MV</th>
<th>11-19 MV</th>
<th>≥20 MV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simple</td>
<td>77401</td>
<td>G6003</td>
<td>G6004</td>
<td>G6005</td>
<td>G6006</td>
</tr>
<tr>
<td>Intermediate</td>
<td>77401</td>
<td>G6007</td>
<td>G6008</td>
<td>G6009</td>
<td>G6010</td>
</tr>
<tr>
<td>Complex</td>
<td>77401</td>
<td>G6011</td>
<td>G6012</td>
<td>G6013</td>
<td>G6014</td>
</tr>
</tbody>
</table>
Intensity Modulated Radiation Treatment (IMRT) **CPT/HCPCS code G6015**

*Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session. For intensity modulated treatment planning, use 77301.*

Code(s) 77401 and G6015 may be quantity billed on the same line of the 1500 claim form.

**F. Portal Verification Film(s) (**CPT code 77417**)**

Use CPT code 77417 to report port verification films or electronically generated portal images. These images should agree with the original simulation films and dosimetry. Port film verification is a technical component only procedure and does not carry a professional physician component. No modifier is required for these services. The review and interpretation of port films by the physician, is considered part of the weekly clinical treatment management. Although radiographs may be used in brachytherapy simulation, these images should not be reported as port-films.

*Portal verification films should be reported as 1 charge per 5 fractions of therapy, per portal, one charge per port per week, with additional charges as needed as the patient's clinical status warrants. If at the end of a treatment course, three or four fractions remain, then one unit of portal verification will be reimbursed. If only one or two fractions remain, then no reimbursement will be made. This code (CPT 77417) may be used more than once per day per treatment course.*

**G. Stereoscopic x-ray guidance for localization of target volume for the delivery of radiation therapy. (**CPT/HCPCS code: G6002**)**

Image Guided Radiation Therapy (IGRT) uses various imaging technologies to account for changes in the position of the intended target before or during treatment delivery. IGRT is used where patients have tumors located near or within critical structures and/or in tissue with inherent setup variation. Thus, although IGRT is a distinct service, it may be used and documented along with conformal treatment delivery (CPT/HCPCS G6003-G6014) or IMRT treatment delivery (G6015). Several different imaging modalities are used for IGRT. These include the use of kV and mV imaging via stereoscopic X-ray guidance, 2-D or 3-D ultrasound guidance, 3-D cone beam CT guidance, and 4-D localization and tracking of electromagnetic transponders. Some image guidance modalities require the implantation of fiducial markers; other image guidance modalities use external markers, the organ itself, or adjacent anatomic structures to reference location of the target.

**H. Radiation Treatment Management (**CPT codes 77427, 77431**)**

CPT code 77427 - Radiation treatment management, x5 treatments
The regulation reads:

**Weekly Radiation Therapy Management (CPT 77427).** Pay for a physician's weekly treatment management services under code 77427. Instruct billing entities to indicate on each claim the number of fractions for which payment is sought.

A weekly unit of treatment management is equal to five fractions or treatment sessions. A week for the purpose of making payments under these codes is comprised of five fractions regardless of the actual time period in which the services are furnished. It is not necessary that the radiation therapist personally examine the patient during each fraction for the weekly treatment management code to be payable.

Multiple fractions representing two or more treatment sessions furnished on the same day may be counted as long as there has been a distinct break in therapy sessions, and the fractions are of the character usually furnished on different days. Code 77427 is also reported if there are three or four fractions beyond a multiple of five at the end of a course of treatment: one or two fractions beyond a multiple of five at the end of a course of treatment are not reported separately. The professional services furnished during treatment management typically consist of:

- review of port films;
- review of dosimetry, dose delivery, and treatment parameters;
- review of patient treatment set-ups;
- examination of patient for medical evaluation and management, (e.g., assessment of the patient's response to treatment, coordination of care and treatment, review of imaging and/or lab test results).

**EXAMPLE:**

- 18 fractions = 4 weekly services
- 62 fractions = 12 weekly services
- 8 fractions = 2 weekly services
- 6 fractions = 1 weekly service

If billings have occurred which indicate that the treatment course has ended (and, therefore, the number of residual fractions has been determined), but treatments resume, adjust your payments for the additional services consistent with the above policy.

**EXAMPLE:**

- 8 fractions = payment for 2 weeks
- 2 additional fractions are furnished by the same physician. No additional Medicare payment is made for the 2 additional fractions.
I. Radiation Therapy Management (CPT code 77431)
This CPT code is to be used only if a patient's entire treatment course consists of only one or two fractions. This code should not be used to bill for the remaining treatments at the end of a long course of therapy. The quantity billed should be one whether one or two fractions are used.

J. Special Treatment Procedures (CPT code 77470)
CPT code 77470 (Special radiation treatment) covers the additional physician effort and work required for the special procedures of:
- hyperfractionation
- total body irradiation
- brachytherapy
- hyperthermia
- planned combination with chemotherapy; or
- other combined modality therapy
- stereotactic radiosurgery
- intra-operative radiation therapy, and
- hemibody irradiation
- intracavitary cone use
- radiation response modifiers
- heavy particles (e.g. protons/neutrons)
- 3-D CRT
- IMRT
- any other special time consuming treatment plan.

This code is not intended for use when a patient has another ongoing medical diagnosis such as diabetes, C.O.P.D or hypertension.

It is considered an acceptable standard of practice for this code to be reported only once during a treatment course and may be billed with the weekly management codes.

For the remaining treatment course, a physician should use the appropriate weekly radiation therapy management codes (CPT codes 77427 and 77431) for the management of the patient.

If the treatment course is modified for any reason, the physician should use the appropriate CPT code for the simulation field setting and dosimetry. CPT code 77470 should not be used for this reason.

II. Intensity Modulated Radiation Therapy (IMRT)

Description:
Intensity Modulated Radiation Therapy (IMRT) is a new technology in radiation oncology that delivers radiation more precisely to the tumor while relatively sparing the surrounding
normal tissues. It is an advanced form of three-dimensional conformal radiation therapy (3-D CRT) that allows for varying intensities of radiation to produce dose distribution that are more conformal than those possible with standard 3-D CRT.

IMRT is a computer-based method of planning for, and delivery of, narrow, patient specific, spatially and temporally modulated beams of radiation to solid tumors within a patient. IMRT planning and delivery uses a new 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.

A. Treatment Planning
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 treatment plans are geometrically more accurate and tailored to the target volumes than are conventional or three-dimensional radiation plans. The IMRT planning computer algorithm describes the necessary field sizes, gantry angles, and other beam characteristics needed to achieve the desired dose distribution. The essential feature of an IMRT plan is that it describes the means to deliver treatment utilizing non-uniform beam intensities.

Three-dimensional image acquisition by simulation (e.g., CT, MRI, PET or similar image fusion technology) is a prerequisite to IMRT treatment planning. The physician then outlines (contours) the visible abnormality seen on each slice of the image set. The three-dimensional summation of these contours defines the Gross Tumor Volume (GTV). The physician draws a margin around the GTV to generate a Clinical Target Volume (CTV) which encompasses the volume of tissue at risk for microscopic disease (not visible on imaging studies). To account for potential patient set-up variation or organ and patient motion, a final margin is then added to create what is termed the Planning Target Volume (PTV). The physician also contours nearby normal structures that potentially could be damaged by radiation (“organs at risk”).

The physician must assign specific dose requirements for the PTV (minimum dose and dose homogeneity) and dose constraints for the organs at risk (maximum allowable doses). 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.

Finally, the radiation physicist or a supervised dosimetrist calculates a complex multi-beam treatment plan that will deliver the prescription dose to the PTV and satisfy the normal tissue dose constraints. The radiation beam is, in effect, a collection of
"beamlets," each with a different level of radiation intensity. The summation of these "beamlets" delivers the characteristic, highly conformal IMRT dose distribution. The PTV, therefore, receives a high dose of radiation while nearby organs receive significantly lower doses.

Prior to treatment delivery the physicist performs basic dose calculations on each of the modulated beams. These patient specific monitor unit computations verify through a second (independent of treatment planning) dose calculation method that the computer has correctly performed the treatment planning calculations. The calculated beams are then delivered either to a phantom or a dosimetry measuring device to confirm that the point dose and dose distribution are physically verifiable and that the intensity modulated beams are technically feasible.

Documentation of all aspects of the planning process is essential.

B. Treatment Delivery

IMRT treatment delivery can be accomplished through a variety of technologies. The most common approach utilizes a multi-leaf collimator (MLC) to modulate the intensity of the beam. Various forms of MLC technology include fixed gantry types such as static MLC (step and shoot) where the leaves do not move when the beam is on and dynamic MLC (sliding window) where they move during treatment. There are also moving gantry technologies including fan-beam therapy that uses a binary collimator to deliver slice-by-slice treatment and intensity modulated arc therapy, in which the gantry rotates while moving MLCs create non-uniform dose to the planning target volume during individual arc segments. A different technical solution for IMRT is to use a solid compensator with varying thickness filters to modulate the beam. 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 uses non-uniform and customized fluence distributions in treatment delivery. Delivery and planning of IMRT may require the use of a multi-leaf collimator (MLC) with leaves that project to a nominal 1cm or less at the treatment unit isocenter. The MLC may be in a dynamic (DMLC) or segmented mode (SMLC) (mean segments per gantry position or 'steps' required to meet IMRT delivery is 5) to create the 3-dimensional, intensity-modulated dose distribution. These processes maybe called segmental, binary or step and shoot.

The use of a MLC to produce simple one-dimensional ramp intensity distributions is excluded because the inverse planning process is not expected to produce these intensity patterns.

Other planning and delivery methods include:
- Conformal Arc
- Intensity Modulated Arc
- Electronic forward planned compensator
- Inverse planned IMRT Solid Compensators

**Note:** There are also so called normal tissue compensators that do not produce IMRT. These devices are called wedges, compensators, etc. and do not modulate a beam into small "beamlets" as do IMRT. Do not bill for IMRT when it is not performed.

C. The exact planning and 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 and the planning/delivery method is FDA approved.

D. Patient immobilization is required for precision IMRT. A number of imaging techniques (e.g., ultrasound, kilovoltage or megavoltage cone beam CT scan, stereoscopic X-ray) may also be utilized to account for the daily motion of the PTV and more accurately deliver the treatment (Image Guided Radiation Therapy or IGRT). Changes in the location of the target within the body during a single fraction can arise from respiratory motion or other physiologic variances. To accommodate such changes the PTV may be drawn based upon published studies of organ motion or on dynamic imaging studies, or treatment delivery may be actively modulated by direct measures of motion during treatment.

IMRT delivery imposes a more stringent requirement than conventional radiation therapy in terms of accounting for patient position and organ motion.

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 used in conjunction with IMRT in patients whose tumors are located near or within critical structures and/or in tissue with inherent setup variation. Thus, although IGRT is a distinct service, it may be used and documented along with IMRT treatment delivery when necessary.

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 fiducially markers, or 4-D localization and tracking of electromagnetic transponders); and
3. respiratory gating of diaphragm movement for thoracic and upper abdominal sites.
(CPT/HCPCS codes: 77014, G6001, G6002, G3017)
**Indications and Limitations of Coverage:**

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 3-Dimensional 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 of added benefit and at least one of the following conditions is met:
- The target volume is in close proximity to critical structures that must be protected.
- The volume of interest must be covered with narrow margins to adequately protect immediately adjacent structures.
- An immediately adjacent area has been previously irradiated and abutting portals must be established with high precision.
- The target volume is concave or convex, and critical normal tissues are within or around that convexity or concavity.
- Dose escalation is planned to deliver radiation doses in excess of those commonly utilized for similar tumors with conventional treatment.

**Indications**

IMRT is indicated as a standard treatment option for:

1. Primary, metastatic or benign tumors of the central nervous system including the brain, brain stem and spinal cord;
2. Primary, metastatic tumors of the spine where the spinal cord tolerance may be exceeded with conventional treatment
3. Primary, metastatic, or benign lesions to the head and neck area including: Orbits, Sinuses, Skull base, Aero-digestive tract, Salivary glands;
4. Carcinoma of the prostate;
5. Selected cases of thoracic and abdominal malignancies;
6. Selected cases (i.e. not routine) of breast cancers with close proximity to critical structures;
7. Other pelvic and retroperitoneal tumors that meet the requirements for medical necessity; and
8. Reirradiation that meets the requirements for medical necessity.

Although IMRT is not indicated as the routine management for other cancers, IMRT is often reasonable and necessary treatment for other sites. There is no definitive list of "approved sites" nor is it possible to preclude some cancers solely on the basis of primary site of origin. The radiation oncologist must consider the five criteria detailed above (proximity to critical structures, narrow margins, previous radiation, target shape, and dose escalation requirement) and then determine if IMRT is indicated. For example, IMRT may
be indicated in the treatment of lung cancers and intra-abdominal and pelvic malignancies where the effect of organ motion must be considered. In the case of breast cancer, while not routine, IMRT may be indicated when the tumor is in proximity to the heart. For all instances, the physician should document the indications for IMRT. It may be used as the primary/sole modality or as a boost to conventional therapy.

**Bill Type Codes:**
Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

999x Not Applicable

**Revenue Codes:**
Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

**CPT/HCPCS Codes**

**Group 1 Paragraph: Radiation Therapy**

**Group 1 Codes:**

- 77014  Ct scan for therapy guide
- 77261  Radiation therapy planning
- 77262  Radiation therapy planning
- 77263  Radiation therapy planning
- 77280  Set radiation therapy field
- 77285  Set radiation therapy field
- 77290  Set radiation therapy field
- 77293  Respirator motion mgmt simul
- 77295  3-D radiotherapy plan
- 77300  Radiation therapy dose plan
- 77306  Teleshx isodose plan simple
Group 2 Paragraph: **Radiation Therapy:** additional codes for use in OPPS, see attached Billing and Coding Guideline for additional information.

**Group 2 Codes:**

- 77307  Telexh isodose plan cplx
- 77321  Special teletx port plan
- 77331  Special radiation dosimetry
- 77332  Radiation treatment aid(s)
- 77333  Radiation treatment aid(s)
- 77334  Radiation treatment aid(s)
- 77336  Radiation physics consult
- 77370  Radiation physics consult
- 77401  Radiation treatment delivery
- 77417  Radiology port film(s)
- 77427  Radiation tx management x5
- 77431  Radiation therapy management
- 77470  Special radiation treatment
- G6002  Stereoscopic x-ray guidance
- G6003  Radiation treatment delivery
- G6004  Radiation treatment delivery
- G6005  Radiation treatment delivery
- G6006  Radiation treatment delivery
- G6007  Radiation treatment delivery
- G6008  Radiation treatment delivery
- G6009  Radiation treatment delivery
- G6010  Radiation treatment delivery
- G6011  Radiation treatment delivery
- G6012  Radiation treatment delivery
- G6013  Radiation treatment delivery
- G6014  Radiation treatment delivery

- 77387  Guidance for radiaj tx dlvr
- 77402  Radiation treatment delivery
77407 Radiation treatment delivery
77412 Radiation treatment delivery

**Group 3 Paragraph: IMRT**

**Group 3 Codes:**

77301 Radiotherapy dose plan imrt
77338 Design mlc device for imrt
G6015 Radiation tx delivery imrt
G6016 Delivery comp imrt
G6017 Intrafraction track motion

**Group 4 Paragraph:** Code for use in OPPS for IMRT See attached Billing and Coding Guidelines for additional information.

**Group 4 Codes:**

77385 Ntsty modul rad tx dlvr smpl
77386 Ntsty modul rad tx dlvr cplx

*Please refer to the CMS website for the ICD-10 Codes that Support Medical Necessity.*

**Documentation required with the claim:**

1. For Radiation Dosimetry Calculations (CPT code 77300) when over six dosimetry calculations are reported, the documentation on the claim must support the medical necessity.

2. For Complex Daily Radiation Treatment Delivery (CPT/HCPCS codes 77401, G6003 - G6014) and Weekly Radiation Therapy Management (CPT codes 77427) when billing for multiple treatments on the same day, the. The claim must document that there has been a distinct break between therapy. Statements such as "A.M. and P.M. treatments" suffice. The required information must be indicated in the appropriate documentation record for claims submitted electronically.
   If paper claims are submitted, the required documentation must be on an attachment to the CMS - 1500 claim form. Claims submitted without this information will be denied as not medically necessary.

**Documentation required in the patient’s medical record:** (Documentation must be available to Medicare upon request).
1. The patient’s medical record must indicate the medical necessity of services for each date of service submitted on a claim, and documentation must be available to Medicare upon request.

2. Documentation in the medical record must include the planned course of therapy, type and delivery of treatment, level of clinical management involved and ongoing documentation of any changes in course of treatment.

3. A patient referral with diagnostic information and request for consultation for radiation oncology must be maintained in the patient’s record and available to Medicare upon request.

For Treatment Devices, Designs, and Construction (CPT codes 77332-77334).

Additional sets may be allowed only when documentation explains why new or additional devices are necessary. If such documentation is not present, or if the information simply describes the function of the devices, the service will be denied as not medically necessary. Examples of acceptable reasons for additional sets of devices are listed below:

- The size of the lesion changes.
- The patient is repositioned.
- A different volume of interest is treated. (Identify each volume of interest).
- A boost, change in size of the volume of interest, or coned down beam is used.

Documentation for IMRT in the medical record

1. The reasonable and necessary requirements as outlined under the coverage and limitations sections of this policy and must be available to the Contractor for review upon request.

2. The prescription must define the goals and requirements of the treatment plan, including the specific dose constraints for the target(s) and nearby critical structures.

3. A statement by the treating physician documenting the special need for performing IMRT on the patient in question, rather than performing conventional or 3-dimensional treatment planning and delivery.

4. A signed IMRT inverse plan that meets prescribed dose constraints for the planning target volume (PTV) and surrounding normal tissue using either dynamic multi-leaf collimator (DMLC) or segmented multi-leaf collimator (SMLC) (average number of ‘steps’ required to meet IMRT delivery is 5 or more), or inverse planned IMRT solid compensators to achieve intensity modulation radiation delivery.

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.
   c. Means of dose verification and secondary means of verification.
d. Independent basic dose calculations of monitor units have been performed for each beam before the patient’s first treatment.

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

7. Identification of structures that traverse high- and low-dose regions created by respiration is indicated. Voluntary breath-holding alone is not a satisfactory solution for accounting for organ motion.

Utilization Guidelines
Limitation of liability and refund requirements apply to denials for frequency and/or medical necessity. When the advance notice is given, the service(s) must be submitted with HCPCS modifier GA (advance notice has been given to the beneficiary). Refer to the body of the policy for further utilization information.

Definitions:

Bite block - A restraining device generally used in the oral cavity often attached to an outside source for patient stability.

Block - A device fabricated of an energy-absorbing material such as lead or Cerrobend (Wood’s metal) to shape or delineate the treatment portal to match the configuration of the desired area and to shield or protect normal structures.

Bolus - A tissue equivalent material used to change the surface deposition of a radiation beam.

Compensator - An irregularly shaped beam-modifying device utilized to reconfigure the beam intensity to match irregular tissue contours.

Collimator - A beam shaping device attached to the head of the treatment machine to define the initial configuration (the length and width) of the treatment portal.

Dosimetry - The calculation of the radiation dose distribution within an area of clinical interest.

Hyperfractionation - Radiation therapy delivered more than once per day.

Isodose - A plotting of lines or a series of lines following paths of the same dosage distribution within a treatment beam.

Mold - A patient restraining device usually constructed of plaster or thermosetting plastic that fits to the contour of the patient and restricts the motion of the patient during treatment.
Port, Portal - These words are synonymous and refer to the site, on the skin, where the radiation beam enters the body.

Portal Verification - Any means of verifying the placement and configuration of the treatment portal.

Simulation - The use of simulator, or other means, to determine the various treatment portal outlines and orientation to be used in the course of radiation therapy.

Simulator - A radiation generator operating in the diagnostic x-ray range. A simulator has the mechanical capability to orient a radiation beam toward a patient with parameters imitating that, which is proposed for therapy while affording direct x-ray fluoroscopic visualization and roentgenographic images of the area. This machine is not capable of delivering radiation therapy.

Stent - A splint-restraining device generally used in the oral cavity. The device is usually constructed of acrylic or some other dental material but may incorporate lead or other energy absorbing material to protect some portion of the cavity from direct dose deposition.

Stereotactic - A 3-dimensional technique of intersecting multiple portals creating complex interaction of the treatment beams and resulting isodose plans.

Teletherapy or External Beam Radiation - The delivery of a beam of electromagnetic energy from a treatment machine at some distance from the treatment area. External beam radiation is commonly delivered by a linear accelerator which can deliver photons (x-rays) or electrons to the targeted area.