DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Intensity-modulated radiation therapy (IMRT) is a specialized form of external beam radiation treatment that involves modulation of radiation beam intensities within treatment fields to obtain more conformal dose delivery around the target(s) of irradiation. IMRT uses computer software, CT images, and magnetic resonance imaging (MRI) to modulate the intensity of the overlapping radiation beams projected on the target and to use multiple-shaped treatment fields. It uses a device (a multileaf collimator, MLC) which, coupled to a computer algorithm, allows for treatment planning. The radiation oncologist delineates the target on each slice of a CT scan and specifies the target’s prescribed radiation dose, acceptable limits of dose heterogeneity within the target volume, adjacent normal tissue volumes to avoid, and acceptable dose limits within the normal tissues. Based on these parameters and a digitally reconstructed radiographic image of the tumor and surrounding tissues and organs at risk, computer software optimizes the location, shape, and intensities of the beams ports, to achieve the treatment plan’s goals. Increased conformality may permit escalated tumor doses without increasing normal tissue toxicity and thus may improve local tumor control, with decreased exposure to surrounding normal tissues, potentially reducing acute and late radiation toxicities. Better dose homogeneity within the target may also improve local tumor control by avoiding under dosing within the tumor and may decrease toxicity by avoiding overdosing. The benefits of IMRT are the greatest for patients with tumor targets that are concave, and where normal tissues around it are clinically important.

RECOMMENDATION 13-3843-47

1. Intensity Modulated Radiation Therapy (IMRT) may be considered medically necessary and may be authorized when sparing the surrounding normal tissue is essential and one of the following conditions is present: [ONE]
   - Important dose limiting structures adjacent to, but outside the planned treatment volume (PTV), are sufficiently close and require IMRT to assure safety and morbidity reduction; or
   - An immediately adjacent volume has been irradiated and abutting portals must be established with high precision; or
   - Gross Tumor Volume (GTV) margins are concave or convex and in close proximity to critical structures that must be protected to avoid unacceptable morbidity; or
   - Only IMRT techniques would decrease the probability of grade 2 or grade 3 radiation toxicity as compared to conventional radiation in greater than 15% of radiated similar cases
2. Documentation is submitted by the treating physician that outlines the medical necessity for IMRT instead of using conventional or 3-dimensional treatment planning and delivery for any of the following conditions: [ONE]

- Central nervous system (CNS) tumors (primary or metastatic lesions) with close proximity to the optic nerve, lens, retina, optic chiasm, cochlea, or brain stem including any of the following: \(^{21-25,38,45}\) [ONE]
  - Brain including cranial nerves and meninges,
  - Spinal cord including spinal meninges

- Head and neck cancer including but not limited to any of the following: \(^{4,15-20,32,43,48}\) [ONE]
  - Hypopharynx; or
  - Larynx; or
  - Nasopharynx; or
  - Oral cavity; or
  - Oropharynx; or
  - Paranasal sinuses and nasal cavity; or
  - Salivary glands

- Prostate Tumors: \(^{310-14,37,47,49}\) [ONE]
  - Primary prostate carcinoma in individuals with an intact prostate and non-metastatic prostate cancer; or
  - After radical prostatectomy as adjuvant/salvage therapy and no evidence of disseminated disease; or
  - For symptomatic, metastatic prostate cancer when the target disease is within, or immediately adjacent to, previously irradiated tissue, and in selected solitary metastatic lesions

- Thoracic malignancies, including: [ONE]
  - Lung tumors when a critical anatomical structure (such as cardiac or spine) is located in the radiation field and there is documented significantly impaired or limited pulmonary function; or \(^{26-31,46}\)
  - Left breast tumors when there is documented risk to immediately adjacent cardiac and pericardial structures \(^{5-9,44}\)

3. Exclusions: Other uses of IMRT are considered experimental, investigational and unproven due to insufficient peer reviewed medical literature for the treatment of any other condition not outlined above.
The peer reviewed medical evidence from randomized controlled trials, prospective and retrospective studies is sufficient to determine the safety and efficacy of IMRT as a treatment for primary brain tumors, brain metastasis, prostate cancer, lung cancer, spinal cord tumors, head and neck cancer, adrenal tumors, and pituitary tumors where extremely high radiation precision is required. Other indications for IMRT include some left breast tumors due to risk to immediately adjacent cardiac and pericardial structures. There is a large body of literature therefore only a summary of the most relevant studies is provided below.

IMRT is an emerging technology and is being studied in abdominal tumors, gynecologic tumors, anal cancer and in other genitourinary tumors where its high precision is especially necessary to avoid immediately adjacent structures, however there is insufficient evidence in the peer reviewed medical literature to demonstrate the impact of IMRT on patient health outcomes for these conditions. The quality of evidence is low and no conclusions can be drawn regarding the relative efficacy and safety of IMRT because no studies directly compare the different treatments such as conventional radiation therapy to IMRT.

**Breast Cancer**

The published literature on IMRT for the treatment of breast cancer suggests that whole breast irradiation (WBI) by intensity-modulated radiation therapy (IMRT) using standard fractionation schedules has lower rates of acute toxicity than standard two-dimensional (2D) radiation therapy in patients with early-stage breast cancer. Randomized controlled trials with sample sizes from 306 to 815 participants and follow-up times ranged from 6 weeks to 6.3 years show that WBI using IMRT delivered on a standard fractionation schedule for treatment of patients with early-stage breast cancer who have undergone breast-conserving surgery may be appropriate specifically in patients with left breast tumors when sparing surrounding tissue due to risk of immediately adjacent cardiac and pericardial structures.

**Central Nervous System (CNS)**

The published evidence on IMRT for the treatment of CNS tumors consistently report better sparing of healthy tissues and reduced toxicity in IMRT-treated patients and suggest that IMRT provides tumor control and survival outcomes comparable to existing radiotherapy techniques. Retrospective and prospective trials with sample sizes from 25-200 participants and follow-up times up to 2 years show that in most IMRT series excellent compliance and low rates of toxicity were recorded. Hypofractionated regimens in association with chemotherapy showed results that are even superior to the standard treatment.

**Prostate Cancer**

The published literature on IMRT for the treatment of prostate cancer reports that IMRT may permit the delivery of higher doses of radiation to the prostate with relatively little toxicity to surrounding tissues and that higher radiation doses resulted in improved local tumor control, biochemical outcomes, and biopsy findings. IMRT is also associated with a significant reduction in acute GI/GU toxicity. Randomized controlled trials with sample sizes from 100 to 12,976 participants and follow-up times up to 5 years show that high-dose IMRT was feasible and safe, improved dose conformity relative to tumor coverage and exposure to normal tissue, and had a lower risk of late moderate rectal bleeding.
Head and Neck Cancer

The published literature on IMRT for the treatment of head and neck cancers (oral cavity and lip, larynx, hypopharynx, oropharynx, nasopharynx, paranasal sinuses and nasal cavity, salivary glands, and occult primaries in the head and neck region) reports that IMRT provides tumor control rates comparable to existing radiotherapy techniques. Randomized controlled trials, prospective and retrospective studies with sample sizes from 50 to 250 participants and follow-up times from 2 - 5 years show that IMRT may reduce the risk of exposure to radiation in critical nearby structures, such as spinal cord, salivary glands, and esophagus, thus decreasing risks of adverse effects such as xerostomia and esophageal stricture. The 5-year local control, overall survival, disease-specific survival, disease-free survival, and freedom from distant metastasis rate was 70.7%, 58.5%, 67%, 59.3%, and 82.2%, respectively. 16

Lung Cancer

The published literature on IMRT for the treatment of lung cancer suggests that IMRT should be considered for lung cancer patients where the tumor is in close proximity to an organ at risk, where the target volume includes a large volume of an organ at risk, or in scenarios where dose escalation would be potentially beneficial while minimizing normal tissue toxicity. Evidence from systematic reviews, retrospective and prospective studies with sample sizes from 50 to 400 participants and follow-up times from 2 - 3 years report significant reduction in toxicity and improvement in survival. Median overall survival time was 1.8 years; the 2-year and 3-year overall survival rates were 46% and 30%, respectively. 28

**Coding Information**

The codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is covered or non-covered. Coverage is determined by the benefit document. This list of codes may not be all inclusive.

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
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<tr>
<td>77301</td>
<td>Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications</td>
</tr>
<tr>
<td>77338</td>
<td>Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy</td>
</tr>
<tr>
<td>77385</td>
<td>Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple</td>
</tr>
<tr>
<td>77386</td>
<td>Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex</td>
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<th>HCPCS</th>
<th>Description</th>
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<tr>
<td>G6015</td>
<td>Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session</td>
</tr>
<tr>
<td>G6016</td>
<td>Compensator-based beam modulation treatment delivery of inverse planned treatment using 3 or more high resolution (milled or cast) compensator, convergent beam modulated fields, per treatment session</td>
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| ICD-9   | Description                                                                 |

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140.0 - 239.9 | Neoplasms code range

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<td>C00-D49</td>
<td>Neoplasms code range</td>
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</tbody>
</table>

**REFERENCES**

**Government Agencies**


**Peer Reviewed Publications**


Hayes


Professional Organizations


42. Catton C, Rumble RB, Warde P, IMRT Indications Expert Panel. The role of IMRT in soft-tissue sarcomas. Toronto (ON): Cancer Care Ontario (CCO); 2010 Oct 29. (Evidence-based series; no. 21-3-6).


Other Resources

48. UpToDate: Song S. General principles of radiation therapy for head and neck cancer. 2015.
49. UpToDate: Dibase S, Roach M. External beam radiation therapy for localized prostate cancer. 2015.
50. Advanced Medical Review: Policy reviewed by a practicing physician board certified in Radiation Oncology. 1/16/2015.

DISCLAIMER

This Medical Guidance is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there is any exclusion or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the following website: http://www.cms.hhs.gov/center/coverage.asp

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina medical coverage guidance (MCG) document and provide the directive for all Medicare members.

CMS does not have a National Coverage Determination (NCD) for Intensity Modulated Radiation Therapy (IMRT). Local Coverage Determinations (LCDs) are available.