Molina Clinical Policy
Intensity Modulated Radiation Therapy (IMRT): Policy No. 225

Last Approval: 10/13/2021
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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. 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 (e.g., 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 are any exclusion(s) 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 CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members.[1] References included were accurate at the time of policy approval and publication.

OVERVIEW

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 multi-leaf 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.[4-10]

COVERAGE POLICY [1-3,11]

Intensity Modulated Radiation Therapy (IMRT) **may be considered medically necessary** and may be authorized when **ALL** of the following criteria is met:

1. Sparing the surrounding normal tissue is essential; **AND**
2. One of the following conditions is present:
    a. 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**
    b. An immediately adjacent volume has been irradiated and abutting portals must be established with high precision; **OR**
    c. 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**
    d. 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.

AND

3. 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:
    a. 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:[12-17]
        - Brain including cranial nerves and meninges; **OR**

- Spinal cord including spinal meninges.

OR

b. Esophageal Cancer [18-22]

OR

c. Head and Neck Cancer including, but not limited to, **ANY** of the following: [3,23,24,25,58,60]
   - Hypopharynx; **OR**
   - Laryngeal (advanced); **OR**
   - Nasopharynx; **OR**
   - Oral cavity; **OR**
   - Oropharynx; **OR**
   - Orbits; **OR**
   - Paranasal sinuses and nasal cavity; **OR**
   - Salivary glands; **OR**
   - Tracheal Cancer.

OR

d. Prostate Tumors including, but not limited to, **ANY** of the following:[27,28,29,30,31]
   - Primary prostate carcinoma with an intact prostate and non-metastatic prostate cancer; **OR**
   - After radical prostatectomy as adjuvant/salvage therapy & 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.

OR

e. Thoracic Malignancies, including **ONE** of the following:
   - 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;[32-37] **OR**
   - Left breast tumors when **ONE** of the following criteria is met:[22,38-42]
     i. When there is documented risk to immediately adjacent cardiac and pericardial structures; **OR**
     ii. When 3D conformal produces focal regions with dose variation greater than 10% of target and for patients with target tissues that include the far medial chest wall, internal mammary nodal area or sternum (post-mastectomy or post lumpectomy).
   - Mediastinal tumors when radiation is indicated.[43]

OR

f. Cervical or Uterine Cancer in patients who have had a hysterectomy with intact cervix when the para-aortic lymph nodes require treatment;[22,44,45,55] **OR**

g. Rectal or Anal Cancer in unique clinical situations such as re-irradiation of previously treated recurrent disease or unique anatomical situations;[22,46-51] **OR**

h. Other Abdominal and Pelvic Tumors on a case by case basis only when medical necessity documentation is submitted to indicate that conventional or 3-dimensional treatment planning and delivery cannot be safely performed; **OR**

i. Soft Tissue Sarcoma when an R1 or R2 resection is anticipated to increase the therapeutic ratio;[22] **OR**

j. Repeat irradiation of a field that has received prior irradiation when the above criteria has been met.[22]

Limitations and 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.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

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 other thoracic tumors, abdominal tumors, esophageal and tracheal tumors, gynecologic tumors such as cervical cancer, anal cancer and in other genitourinary tumors where its high precision is especially necessary to avoid immediately adjacent structures such as heart, bowel or where there is a special need to avoid marrow. There is an increasing body of evidence in the peer reviewed medical literature that is demonstrating a positive impact of IMRT on patient health outcomes for these conditions.

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.[38-42]

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.[12-17]

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 conformality relative to tumor coverage and exposure to normal tissue, and had a lower risk of late moderate rectal bleeding.[26-31]

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 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.[3,23-25,60]

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.[32-37]

Cervical Cancer. Published literature from a Phase III randomized study (Chopra et al 2015), of three dimensional conformal radiation (3DCRT) vs. image guided radiation therapy (IGIMRT) was initiated in with a primary aim to demonstrate reduction in grade ≥ 2 late bowel toxicity in patients undergoing adjuvant chemoradiation for cervical cancer. A total of 120 patients completed a median follow up of 20 months (2–46). For cervical cancer patients undergoing postsurgical radiation therapy, image-guided intensity-modulated radiation therapy (IMRT) resulted in a 14% reduction in moderate-to-severe bowel side effects when compared to conventional three-dimensional conformal radiation therapy (3D CRT).[44,45,55]

Mediastinal Tumors. Koeck (2011) conducted a comparative treatment planning analysis according to the guidelines of the German Hodgkin Study Group. This study analyzed the impact of target volume reduction with involved node (IN) RT vs. involved field (IF) RT and 3D-CRT vs. IMRT in 20 subjects with early unfavorable mediastinal Hodgkin's lymphoma (HL) for achievable plan quality, treatment efficiency and degree of sparing of organs at risk for radiation exposure. Dose-volume histograms (DVH) were evaluated for planning target volumes (PTV) and organs at risk (OAR). Results showed almost identical mean dose to the PTV for all radiation plans. For the IF and IN PTVs, target conformity was better with IMRT but homogeneity was better with 3D-CRT. The authors concluded that the findings demonstrated a pronounced benefit with IMRT for irradiation of lymph nodes anterior to the heart. Reduction of target volumes to IN-PTV most effectively improved OAR sparing regardless of the RT technique.[43]

National and Specialty Organizations

The **American College of Radiology (ACR)** and the **American Radium Society (ARS)** published the *Practice Guideline for Intensity Modulated Radiation Therapy (IMRT).* In summary, IMRT is a widely used and has enabled radiation oncologists to deliver higher doses of radiation to target structures while reducing doses to adjacent normal critical tissues, thereby improving therapeutic outcomes in many clinical areas. Successful IMRT programs involve integration of many processes: patient selection, patient positioning/immobilization, target definition, treatment plan development, and accurate treatment delivery. Appropriate QA procedures, including patient-specific QA measures, are essential for maintaining the quality of an IMRT program and ensuring patient safety.[56]

The **ACR** and **American Society for Radiation Oncology (ASTRO)** published the *Model Policy: Intensity Modulated Radiation Therapy (IMRT)* which addresses indications and limitations of coverage; treatment planning and delivery; documentation requirements; coding information; and treatment devices.[57]

The **American College of Radiology (ACR)** also published *Appropriateness Criteria Anal Cancer* which includes information regarding radiation dosing and techniques.[58]

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
77301	Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications
77338	Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy
77385	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple
77386	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex
77387	Guidance for localization of target volume for delivery of radiation treatment delivery, includes intrafraction tracking, when performed

HCPCS Codes

HCPCS	Description
G6015	Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session
G6016	Compensator-based beam modulation treatment delivery of inverse planned treatment using 3 or more high resolution (milled or cast) compensator, convergent beam modulated fields, per treatment session

APPROVAL HISTORY

10/13/2021 Policy reviewed, no changes to criteria; updated the Summary of Medical Evidence section, references.
9/18/2019, 9/16/2020 Policy reviewed, no changes.
3/18/2018 Policy reviewed, added medical necessity criteria for indications of: orbits and tracheal cancer; esophageal cancer; mediastinal tumors; cervical or uterine cancer in patients who have had a hysterectomy with intact cervix when the para-aortic lymph nodes require treatment; left breast cancer when 3D conformal produces focal regions with dose variation greater than 10% of target; and for target tissues (e.g., far medial chest wall, internal mammary nodal area or sternum [post-mastectomy or post lumpectomy]); rectal/anal cancer in unique clinical situations such as re-irradiation of previously treated recurrent disease or unique anatomical situations; soft tissue sarcoma when an R1 or R2 resection is anticipated to increase the therapeutic ratio; and repeat irradiation of a field that has received prior irradiation.
12/16/2015, 9/15/2016, 6/22/2017 Policy reviewed, no changes.
6/24/2015 Policy reviewed, revised to incorporate two new clinical indications for IMRT (rectal/anal cancer, abdominal and pelvic tumors).
3/25/2015 New policy.

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Government Agencies

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Other Resources

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Peer Reviewed Publications

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APPENDIX

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