Intensity Modulated Radiotherapy (IMRT) for Tumors in Close Proximity to Organs at Risk

Effective: January 1, 2024

Next Review: September 2024
Last Review: November 2023

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Intensity modulated radiotherapy (IMRT) is a form of radiation therapy that conforms closely to the targeted tumor shape and allows higher doses of radiation to be delivered while minimizing toxicity to surrounding healthy tissues.

MEDICAL POLICY CRITERIA

I. Intensity modulated radiotherapy (IMRT) may be considered **medically necessary** for primary and metastatic tumors in close proximity to organs at risk, when comparative 3D versus IMRT dose/volume histograms are submitted in color AND the summary analysis (table preferred; with preauthorization request) is completed demonstrating that only through IMRT can published dose/volume constraints be met for organs at risk (quality assurance procedures are not required for preauthorization).

Example table (Click here for a template to use):

Summary Analysis of 3D vs IMRT Planning					
Organ(s) At Risk	**Dose Constraint**	**Source of Constraint**	**3D**	**IMRT**	**Can constraint *only* be met with IMRT?**
Example: Brachial plexus	Max < 66 Gy	RTOG	58 Gy	52 Gy	No (both meet constraint)
Example: Cauda equina	Max < 16 Gy	RTOG #0631	19 Gy	17 Gy	No (neither meets constraint)
Example: Brainstem	Max < 54 Gy	Quantec	62 Gy	52 Gy	Yes (only IMRT meets constraint)

II. Intensity-modulated radiotherapy (IMRT) is considered **not medically necessary** for the treatment of tumors not meeting the criteria above (NOTE*: Please use Medicine, Policy No. 164, 165, or 166 (see Cross References) for specific indications addressed in those policies*).

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

POLICY GUIDELINES

ORGANS AT RISK

Organs at risk are defined as normal tissues whose radiation sensitivity may significantly influence treatment planning and/or prescribed radiation dose.[1] These organs at risk may be particularly vulnerable to clinically important complications from radiation toxicity.

DOSE CONSTRAINT REFERENCES

The source of the adopted dose constraint may be from published compilations of Radiation Therapy Oncology Group (RTOG (see link below), Quantec (see link below), Southwest Oncology Group (SWOG) or other cooperative group protocol constraints, or institutional constraints as appropriate to the dose/fractionation scheme employed. Radiation Therapy Oncology Group (RTOG) Radiation Dose Constraints

Available from: https://en.wikibooks.org/wiki/Radiation_Oncology/Toxicity/RTOG

Quantitative Analyses of Normal Tissue Effects in the Clinic (QUANTEC)

Available from: https://en.wikibooks.org/wiki/Radiation_Oncology/Toxicity/QUANTEC

DOSE–VOLUME CONSTRAINTS FOR ORGANS AT RISK IN RADIOTHERAPY (CORSAIR)

Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9600677/[2]

LIST OF INFORMATION NEEDED FOR REVIEW

REQUIRED DOCUMENTATION:

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome. Quality assurance for 3D and IMRT submitted plans are not required with a preauthorization request.

- Clinical history
- Physical/chart notes
- Relevant imaging reports documenting that the policy criteria are met for medical necessity.
- Comparative 3D versus IMRT dose/volume histograms in color and the completed analysis as described in the criteria above. The submitted information must demonstrate the need for IMRT to meet dose constraints not achievable through 3D planning. The best way to ensure criteria are met is to submit the provided summary analysis table with all components completed prior to submission. The table must document:
  1. The organ at risk, and
  2. Dose constraint employed, and
  3. Source of constraint, and
  4. Dose achieved via 3D planning, and
  5. Dose achieved via IMRT, and
  6. Answer (yes or no) to question, “Can dose restraint only be met with IMRT?

If any of these items are not provided it could impact our review and decision outcome.

CROSS REFERENCES

1. Charged-Particle (Proton) Radiotherapy, Medicine, Policy No. 49
2. Intensity Modulated Radiotherapy (IMRT) of the Central Nervous System (CNS), Head, Neck, and Thyroid, Medicine, Policy No. 164
3. Intensity Modulated Radiotherapy (IMRT) of the Thorax, Abdomen, Pelvis, and Extremities, Medicine, Policy No. 165
4. Intensity Modulated Radiotherapy (IMRT) for Breast Cancer, Medicine, Policy No. 166
5. Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy for Intracranial, Skull Base, and Orbital Sites, Surgery, Policy No. 213
6. Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy for Tumors Outside of Intracranial, Skull Base, or Orbital Sites, Surgery, Policy No. 214

BACKGROUND

RADIATION TECHNIQUES

Conventional External Beam Radiotherapy

Over the past several decades, methods to plan and deliver RT have evolved in ways that permit more precise targeting of tumors with complex geometries. Most early trials used two-dimensional radiation therapy (2D-RT) treatment planning, based on flat images and radiation beams with cross-sections of uniform intensity that were sequentially aimed at the tumor along two or three intersecting axes. Collectively, these methods are termed conventional external beam radiation therapy (EBRT).

Three-Dimensional Conformal Radiation

Treatment planning evolved by using three dimensional images, usually from computed tomography (CT) scans, to delineate the boundaries of the tumor and discriminate tumor tissue from adjacent normal tissue and nearby organs at risk for radiation damage. Computer algorithms were developed to estimate cumulative radiation dose delivered to each volume of interest by summing the contribution from each shaped beam. Methods also were developed to position the patient and the radiation portal reproducibly for each fraction and immobilize the

patient, thus maintaining consistent beam axes across treatment sessions. Collectively, these methods are termed three-dimensional conformal radiation therapy (3D-CRT).

Intensity-Modulated Radiotherapy

IMRT, which uses computer software, CT images, and magnetic resonance imaging (MRI), offers better conformality than 3D-CRT, as it is able 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 “inverse” 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 adjoining organs at risk (OAR). 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 underdosing within the tumor and may decrease toxicity by avoiding overdosing. Alternatively, IMRT provides the opportunity to construct heterogenous dose deposition within the target volume thus tailoring differential dose in keeping with physician assessment of differential cancer cell density, etc. This may diminish local failure within the overall target volume.

Because most tumors move as patients breathe, dosimetry with stationary targets may not accurately reflect doses delivered within target volumes and adjacent tissues in patients. Furthermore, treatment planning and delivery are more complex, time-consuming, and labor-intensive for IMRT than for 3D-CRT. Thus, clinical studies must test whether IMRT improves tumor control or reduces acute and late toxicities when compared with 3D-CRT.

EVIDENCE SUMMARY

Multiple-dose planning studies generate three-dimensional conformal radiation (3D-CRT) and intensity-modulated radiotherapy (IMRT) treatment plans from the same scans, and then compare predicted dose distributions within the target area and adjacent organs. Results of such planning studies have shown that IMRT is better than 3D-CRT with respect to conformality to, and dose homogeneity within, the target. Results have also demonstrated that IMRT delivers less radiation to nontarget areas. Dosimetry studies using stationary targets generally confirm these predictions. However, because patients move during treatment, dosimetry with stationary targets only approximate actual radiation doses received. Based on these dosimetry studies, radiation oncologists expect IMRT to improve treatment outcomes compared with those of 3D-CRT.

Comparative studies of radiation-induced adverse effects from IMRT versus alternative radiation delivery would constitute definitive evidence in establishing the benefit of IMRT. Single-arm series of IMRT can give some insights into the potential for benefit, particularly if an adverse effect that is expected to occur at high rates is shown to decrease by a large amount. Studies of treatment benefit are also important to establish that IMRT is at least as good as

other types of delivery, but, absent such comparative trials, it is likely that benefit from IMRT is at least as good as with other types of delivery.

In general, when the indication for IMRT is to avoid radiation to sensitive areas, dosimetry studies have been considered sufficient evidence to demonstrate that harm would be avoided by using IMRT. Organ-specific dose/volume outcome data has been published indicating the radiation limits for sensitive organs.[2, 3]

PRACTICE GUIDELINE SUMMARY

National Comprehensive Cancer Network

The National Comprehensive Cancer Network (NCCN) guidelines for multiple indications state that IMRT may be considered to decrease the respect the dose constraints of nearby organs at risk.[4]

SUMMARY

There is enough research to show that intensity modulated radiotherapy (IMRT) may improve health outcomes when it reduces radiation to vital structures below recommended thresholds compared to alternative radiation therapy techniques. Therefore, IMRT may be considered medically necessary to reduce the risk of toxicity to organs at risk (e.g., heart, spinal cord, esophagus) when policy criteria are met.

When intensity-modulated radiotherapy (IMRT) does not reduce radiation below recommended thresholds to vital structures compared to alternative radiation therapy techniques, it has not been shown to improve net health outcomes compared to other treatment modalities. Therefore, intensity modulated radiotherapy (IMRT) of tumors that do not meet the policy criteria are considered not medically necessary.

REFERENCES

1. International Commission on Radiation Units & Measurements. Prescribing, Recording, and Reporting Photon Beam Therapy (Report 50). [cited 10/31/2023]. 'Available from:' https://www.icru.org/report/prescribing-recording-and-reporting-photon-beam-therapy-report-50/#:~:text=This%20Report%20seeks%20to%20promote,29%20(published%20in%201978).
2. Bisello S, Cilla S, Benini A, et al. Dose-Volume Constraints fOr oRganS At risk In Radiotherapy (CORSAIR): An "All-in-One" Multicenter-Multidisciplinary Practical Summary. *Curr Oncol.* 2022;29(10):7021-50. PMID: 36290829
3. Marks LB, Yorke ED, Jackson A, et al. Use of normal tissue complication probability models in the clinic. *Int J Radiat Oncol Biol Phys.* 2010;76(3 Suppl):S10-S19. PMID: 20171502
4. National Comprehensive Cancer Network (NCCN). NCCN Guidelines for Treatment of Cancer by Site. [cited 10/31/2023]. 'Available from:' https://www.nccn.org/professionals/physician_gls/default.aspx.

CODES

NOTE: The correct code to use for image fusion performed to provide enhanced delineation of target and normal critical structures is CPT code 77399 (Unlisted procedure, medical radiation physics, dosimetry and treatment devices, and special services); however, it is considered part of the treatment planning.

Codes	Number	Description
CPT	77301	Intensity modulated radiotherapy plan, including dose volume histograms for target and critical structure partial tolerance specification
	77338	Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan
	77385	Intensity modulated radiation treatment deliver (IMRT), includes guidance and tracking, when performed; simple
	77386	;complex
HCPCS	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

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