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Medical Policy Manual

Topic: Intensity Modulated Radiation Therapy (IMRT) for Head and Neck Cancers and Thyroid Cancer

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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 radiation therapy (IMRT), which uses computer software, CT, and magnetic resonance imaging (MRI) images, 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 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 underdosing within the tumor and may decrease toxicity by avoiding overdosing.

Since 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.

Head and Neck Tumors

Head and neck cancers account for approximately 3% to 5% of cancer cases in the United States. The generally accepted definition of head and neck cancers includes cancers arising from the oral cavity and lip, larynx, hypopharynx, oropharynx, nasopharynx, paranasal sinuses and nasal cavity, salivary glands, and occult primaries in the head and neck region. Cancers generally not considered as head and neck cancers include uveal and choroidal melanoma, cutaneous tumors of the head and neck, esophageal cancer, and tracheal cancer. Thyroid cancers are also addressed in this policy. External-beam radiation therapy is uncommonly used in the treatment of thyroid cancers but may be considered in patients with anaplastic thyroid cancer and for locoregional control in patients with incompletely resected high-risk or recurrent differentiated (papillary, follicular, or mixed papillary-follicular) thyroid cancer.

POLICY/CRITERIA

I. Intensity-modulated radiation therapy may be considered **medically necessary** for the treatment of head and neck cancers.

II. Intensity-modulated radiation therapy may be considered **medically necessary** for the treatment of thyroid cancer.

SCIENTIFIC EVIDENCE

Background

Multiple-dose planning studies have generated 3D-CRT and IMRT treatment plans from the same scans, then compared predicted dose distributions within the target and in adjacent organs at risk. Results of such planning studies show that IMRT improves on 3D-CRT with respect to conformality to, and dose homogeneity within, the target. Dosimetry using stationary targets generally confirms these predictions. Thus, radiation oncologists hypothesized that IMRT may improve treatment outcomes compared with those of 3D-CRT. However, these types of studies offer indirect evidence on treatment benefit from IMRT and it is difficult to relate results of dosing studies to actual effects on health outcomes.

Comparative studies of radiation-induced side effects from IMRT versus alternative radiation delivery are probably the most important type of evidence in establishing the benefit of IMRT. Such studies would answer the question of whether the theoretical benefit of IMRT in sparing normal tissue translates into real health outcomes. 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.

Head and Neck Cancers

Comparative Effectiveness and Systematic Reviews

- A comparative effectiveness review was published on radiotherapy treatment for head and neck cancers by Samson and colleagues from BCBSA's Technology Evaluation Center under contract with the Agency for Healthcare Research and Quality (AHRQ).[1] This report noted that based on moderate evidence, IMRT reduces late xerostomia and improves quality of life domains related to xerostomia compared with 3D-CRT. The report also noted that no conclusions on tumor control or survival could be drawn from the evidence comparing IMRT with 3D-CRT.
- A systematic review published in 2008 summarized evidence on the use of IMRT for a number of cancers, including head and neck, prostate, gynecologic, breast, lung, and gastrointestinal.[2] This review mentioned that the ability of IMRT to generate concave dose distributions and tight dose gradients around targets may be especially suitable to avoid organs at risk such as the spinal cord or optic structures in head and neck cancer.

    - Twenty studies (1 randomized controlled trial [RCT] and 19 case series) were identified for IMRT in treatment of head and neck cancers. However, the RCT was for two-dimensional (2D) radiation therapy compared to IMRT. Four studies (including the RCT) were for treatment of nasopharyngeal carcinoma, 3 for sinonasal cancer, and 13 were for cancer involving the oropharynx, hypopharynx, larynx, and oral cavity. The majority of the studies reviewed showed a decrease in xerostomia with use of IMRT. However, there was variability in measurement, e.g., flow rate versus symptoms. The case series of sinonasal cancers showed less ocular toxicity (e.g., blindness) after use of IMRT.
    - The authors of this review recognized the limitations and biases of the studies used in their analysis. With these limitations, they supported the finding of decreased xerostomia (as well as improved salivary–gland function) with use of IMRT in head and neck cancers involving the oral cavity, larynx, oropharynx, and hypopharyngeal area.

- Other reviews also came to the conclusion that, when compared with other radiation techniques for treatment of head and neck cancers, treatment with IMRT resulted in reduced rates of acute and/or late xerostomia.[3-5]

Primary Literature

- de Arruda and colleagues reported on their experience treating 50 patients with oropharyngeal cancer (78% stage IV) with IMRT between 1998 and 2004.[6] Eighty-six percent also received chemotherapy. The authors noted this represents the largest single-institution report for use of IMRT in this tumor. This study found 2-year progression-free survival of 98% and regional progression-free survival of 88%, results similar to the 85% to 90% rates for locoregional control reported in other published studies. The rate for grade 2 xerostomia was 60% for acute and 33% for chronic (after 9 months or more of follow-up); these rates are lower than the 60% to 75% generally reported with radiation therapy.
- Hoppe reported on experience treating 37 patients with cancer of the paranasal sinuses, nasal cavity, and lacrimal glands with postoperative IMRT between 2000 and 2007.[7] In this report with 28-month median follow-up, there was no early or late grade 3 or 4 radiation–induced ophthalmologic toxicity. Two-year local progression-free survival was 75%, and overall survival was 80%.
- Braam reported on a phase II study that compared IMRT to conventional radiation therapy (RT) in oropharyngeal cancer.[8] This study appeared to use 2D radiation therapy. The mean dose to the parotid glands was 48 Gy for RT and 34 Gy for IMRT. Both stimulated parotid flow rate and parotid

complication (more than 25% decrease in flow rate) were greater in the RT group. At 6 months after treatment, 56% of IMRT patients and 81% of RT patients were found to have parotid complications.

- Rusthoven and colleagues compared outcomes with use of IMRT and -CRT in patients with oropharyngeal cancer.[9] In this study, in which 32 patients were treated with IMRT and 23 with 3D-CRT, late xerostomia occurred in 15% of the IMRT patients and 94% of the 3D-CRT patients. There was also a trend toward improved locoregional control of the tumor with IMRT.
- Hodge and colleagues compared outcomes for patients with oropharyngeal cancer in the pre-IMRT era to those obtained in the IMRT era.[10] In this study of 52 patients treated by IMRT, the late xerostomia rate was 56% in the IMRT patients, compared to 63% in those that did not receive IMRT. The authors noted that outcomes in these patients improved at their institution since the introduction of IMRT but that multiple factors may have contributed to this change. They also noted that even in the IMRT-era, the parotid-sparing benefit of IMRT cannot always be used; for example, in patients with bulky primary tumors and/or bilateral upper cervical disease.
- Rades reported on 148 patients with oropharyngeal cancer treated with radiation therapy.[11] In this study, late xerostomia was noted in 17% of those treated with IMRT compared with 73% of those who received 3D-CRT and 63% of those who received standard radiation therapy.
- Vergeer published a report that compared IMRT with 3D-CRT for patient-rated acute and late xerostomia, and health-related quality of life (HRQoL) among patients with head and neck squamous cell carcinoma (HNSCC).[12] The study included 241 patients with HNSCC (cancers arising from the oral cavity, oropharynx, hypopharynx, nasopharynx, or larynx and those with neck node metastases from squamous cell cancer of unknown primary) treated with bilateral irradiation with or without chemotherapy. All patients were included in a program that prospectively assessed acute and late morbidity and HRQoL at regular intervals. Before October 2004, all patients were treated with 3D-CRT (n = 150), starting in October 2004, 91 patients received IMRT. The use of IMRT resulted in a significant reduction of the mean dose to the parotid glands (27 Gy vs. 43 Gy; $p < 0.001$). During radiation, Grade 3 or higher xerostomia at 6 weeks was significantly less with IMRT (about 20%) than with 3D-CRT (about 45%). At 6 months, the prevalence of Grade 2 or higher xerostomia was significantly lower after IMRT (32%) versus 3D-CRT (56%). Treatment with IMRT also had a positive effect on several general and head and neck cancer-specific HRQoL dimensions. The authors concluded that IMRT resulted in a significant reduction of xerostomia, as well as other head and neck symptoms, compared with standard 3D-CRT in patients with HNSCC.
- A randomized trial that compared conventional radiotherapy with parotid-sparing IMRT in patients with pharyngeal squamous-cell carcinoma reported that sparing the parotid glands significantly reduces the incidence of xerostomia and leads to recovery of saliva secretion and improvements in associated quality of life.[13] The trial was very small (47 patients per treatment arm) and had significant loss to follow-up.
- Additional publications of IMRT for head and neck cancers consist of a number of small case series and non-randomized comparisons that generally report favorable outcomes of this treatment.[14-35]

Clinical Practice Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for treatment of head and neck cancers state that either IMRT or 3D-CRT is recommended for cancers of the oropharynx in order to minimize radiation dose to critical structures.[36] However, IMRT is preferred over 3D-CRT for nasopharynx, maxillary sinus, and paranasal/ethmoid sinus tumors to minimize dose to critical structures. In addition, the guidelines state that:

- "IMRT is now widely used in head and neck cancers and is the predominant technique used at NCCN centers.

- "IMRT has been shown to be useful in reducing long-term toxicity in oropharyngeal, paranasal sinus, and nasopharyngeal cancers by reducing the dose to salivary glands, temporal lobes, auditory structures (including cochlea), and optic structures. The application of IMRT to other sites (eg, oral cavity, larynx, salivary glands) is evolving and may be used at the discretion of treating physicians."
- The guidelines note that phase II studies of IMRT consistently show a decrease in acute and late toxicities without compromising tumor control. This was confirmed in one phase III randomized trial (discussed in primary literature above).

The American College of Radiology and the American Society for Therapeutic Radiation and Oncology note IMRT is a widely used treatment option for many indications including head and neck tumors.[37]

Thyroid Cancer

In thyroid cancer, radiation therapy is generally used for 2 indications. The first indication is the treatment of anaplastic thyroid cancer and the second indication is the potential use for locoregional control in patients with incompletely resected high-risk or recurrent differentiated (papillary, follicular, or mixed papillary-follicular) thyroid cancer.

Historical outcomes in anaplastic thyroid carcinoma (ATC) are poor, with a median survival of only 5 months and <20% of patients surviving 1 year from diagnosis.[38]

Primary Literature

The published literature consists of small case series with limited comparisons among the techniques for delivering radiation therapy.

- The largest study comparing IMRT to 3D-CRT was published by Bhatia and colleagues.[39] This study reviewed institutional outcomes for anaplastic thyroid cancer treated with 3D-CRT or IMRT for 53 consecutive patients. Thirty-one (58%) patients were irradiated with curative intent. Median radiation dose was 55 Gray (Gy; range, 4-70 Gy). Thirteen (25%) patients received IMRT to a median 60 Gy (range, 39.9-69.0 Gy). The Kaplan-Meier estimate of overall survival (OS) at one year for definitively irradiated patients was 29%. Patients without distant metastases receiving 50 Gy or higher had superior survival outcomes; in this series, use of IMRT versus 3D-CRT did not influence toxicity. The authors concluded that outcomes for anaplastic thyroid cancer treated with 3D-CRT or IMRT remain equivalent to historical results, and that healthy patients with localized disease who tolerate full-dose irradiation can potentially enjoy prolonged survival.
- Schwartz and colleagues reviewed institutional outcomes for patients treated for differentiated thyroid cancer with postoperative conformal external beam radiotherapy.[40] This was a single-institution retrospective review of 131 consecutive patients with differentiated thyroid cancer who underwent RT between January 1996 and December 2005. Histologic diagnoses included 104 papillary, 21 follicular, and 6 mixed papillary-follicular types. Thirty-four patients (26%) had high-risk histologic types and 76 (58%) had recurrent disease. Extraglandular disease spread was seen in 126 patients (96%); microscopically positive surgical margins were seen in 62 patients (47%); and gross residual disease was seen in 15 patients (11%). Median RT dose was 60 Gy (range, 38-72 Gy). Fifty-seven patients (44%) were treated with IMRT to a median dose of 60 Gy (range, 56-66 Gy). Median follow-up was 38 months (range, 0-134 months). Kaplan-Meier estimates of locoregional relapse-free survival, disease-specific survival, and overall survival at 4 years were 79%, 76%, and 73%, respectively. On multivariate analysis, high-risk histologic features, M1 (metastatic) disease, and gross residual disease predicted for inferior disease-specific and overall survival. IMRT did not

impact survival outcomes but was associated with less frequent severe late morbidity (12% vs. 2%), primarily esophageal stricture. The authors concluded that conformal external beam radiotherapy provides durable locoregional disease control for patients with high-risk differentiated thyroid cancer if disease is reduced to microscopic burden and that IMRT may reduce chronic radiation morbidity, but additional study is required.

- A small case series (n=10) reported the outcomes of the 10 anaplastic thyroid carcinoma (ACT) patients treated with an aggressive treatment combining IMRT, radiosensitizing, and adjuvant chemotherapy. The study found improved outcomes, including survival in stages IVA and IVB regionally confined ATC. Benefit in patients with stage IVC (metastatic) disease as well as the optimal chemotherapy regimen to use in conjunction with IMRT remains uncertain.[38]

Clinical Practice Guidelines

The National Comprehensive Cancer Network (NCCN)[41] guidelines for thyroid cancer state that when considering external-beam radiation therapy for the treatment of anaplastic thyroid cancer, "IMRT may be useful to reduce toxicity. However, the addition of larger doses of other chemotherapeutic drugs has not been associated with improved control of distant disease or with improved survival."

Summary

Head and Neck Cancers

In general, the evidence to assess the role of intensity-modulated radiation therapy (IMRT) in the treatment of cancers of the head and neck suggests that IMRT provides tumor control rates comparable to existing radiotherapy techniques. In addition, while results are not uniform across all studies, the majority of the studies showed a marked improvement in the rate of late xerostomia, a clinically significant complication of radiation therapy and a complication that leads to decreased quality of life for patients. Therefore, IMRT may be considered medically necessary for the treatment of head and neck cancers.

Thyroid Cancers

The available evidence on the use of intensity-modulated radiation therapy (IMRT) for the treatment of thyroid cancer consists of a limited number of small case series. This evidence does not permit conclusions about the impact of IMRT on health outcomes in patients with thyroid cancer. However, 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. Given the possible adverse effects that could result if nearby critical structures receive toxic radiation doses, IMRT dosimetric improvements may be accepted as meaningful evidence for its benefit. Therefore, IMRT may be considered medically necessary for treatment of thyroid cancer.

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CROSS REFERENCES

Intensity Modulated Radiation Therapy (IMRT) of the Thorax, Medicine, Policy No. 136

Intensity Modulated Radiation Therapy (IMRT) of the Prostate, Medicine, Policy No. 137

Intensity-Modulated Radiation Therapy (IMRT) of the Abdomen and Pelvis, Medicine, Policy No. 139

Intensity-Modulated Radiation Therapy (IMRT): Central Nervous System (CNS) and Vertebral Tumors, Medicine, Policy No. 147

CODES	NUMBER	DESCRIPTION
CPT	77301	Intensity modulated radiotherapy plan, including dose volume histograms for target and critical structure partial tolerance specification

CODES	NUMBER	DESCRIPTION
	77338	Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan (new code 1/1/10)
	77418	Intensity modulated treatment deliver, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary dynamic MLC, per treatment session
	0073T	Compensator-based beam modulation treatment delivery of inverse planned treatment using three or more high resolution compensator convergent beam modulated fields, per treatment session
HCPCS	None	