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FEP Medical Policy Manual

FEP 8.01.48 Intensity-Modulated Radiotherapy: Cancer of the Head and Neck or Thyroid

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Related Policies:

6.01.10 - Stereotactic Radiosurgery and Stereotactic Body Radiotherapy
8.01.49 - Intensity-Modulated Radiotherapy: Abdomen, Pelvis and Chest

Intensity-Modulated Radiotherapy: Cancer of the Head and Neck or Thyroid

Description

Radiotherapy is an integral component in the treatment of head and neck cancers. Intensity-modulated radiotherapy has been proposed as a method to allow adequate radiation to the tumor, minimizing the radiation dose to surrounding normal tissues and critical structures.

Intensity-modulated radiotherapy is the more recent development in external radiation. Treatment planning and delivery are more complex, time-consuming, and labor-intensive for IMRT than for 3D-CRT. Similar to 3D-CRT, the tumor and surrounding normal organs are outlined in 3D by a scan and multiple radiation beams are positioned around the patient for radiation delivery.[1,] In IMRT, radiation beams are divided into a grid-like pattern, separating a single beam into many smaller "beamlets". Specialized computer software 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, surrounding tissues, and organs at risk, computer software optimizes the location, shape, and intensities of the beam ports to achieve the treatment plan's goals.

Increased conformality may permit escalated tumor doses without increasing normal tissue toxicity and is proposed to 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.

Other advanced techniques may further improve RT treatment by improving dose distribution. These techniques are considered variations of IMRT. Volumetric modulated arc therapy delivers radiation from a continuous rotation of the radiation source. The principal advantage of volumetric modulated arc therapy is greater efficiency in treatment delivery time, reducing radiation exposure, and improving target radiation delivery due to less patient motion. Image-guided RT involves the incorporation of imaging before and/or during treatment to more precisely deliver RT to the target volume.

OBJECTIVE

The objective of this evidence review is to determine whether intensity-modulated radiotherapy improves the net health outcome when used to treat head and neck cancers or thyroid cancers.

POLICY STATEMENT

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

Intensity-modulated radiotherapy may be considered **medically necessary** for the treatment of thyroid cancers in close proximity to organs at risk (esophagus, salivary glands, spinal cord) and 3-dimensional conformal radiotherapy planning is not able to meet dose volume constraints for normal tissue tolerance (see Policy Guidelines section).

Intensity-modulated radiotherapy is **not medically necessary** for the treatment of thyroid cancers for all indications not meeting the criteria above.

POLICY GUIDELINES

For this policy, head and neck cancers are those 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.

Organs at risk are defined as normal tissues whose radiation sensitivity may significantly influence treatment planning and/or prescribed radiation dose. These organs at risk may be particularly vulnerable to clinically important complications from radiation toxicity. Table PG1 outlines radiation doses that are generally considered tolerance thresholds for these normal structures in the area of the thyroid. Clinical documentation based on dosimetry plans may be used to demonstrate that radiation by 3-dimensional conformal radiotherapy without intensity-modulated radiotherapy would exceed tolerance doses to structures at risk.

Table PG1. Radiation Tolerance Doses for Normal Tissues

	TD 5/5, Gray[a]			TD 50/5, Gray[b]			
	Portion of Organ Involved			**Portion of Organ Involved**			
Site	**1/3**	**2/3**	**3/3**	**1/3**	**2/3**	**3/3**	**Complication End Point**
Esophagus	60	58	55	72	70	68	Stricture, perforation
Salivary glands	32	32	32	46	46	46	Xerostomia
Spinal cord	50 (5-10 cm)	NP	47 (20 cm)	70 (5-10 cm)	NP	NP	Myelitis, necrosis

Compiled from 2 sources: (1) Morgan MA, Ten Taken RK, Lawrence TS. Essentials of Radiation Therapy. In: DeVita, Helman, and Rosenberg, *Cancer: Principles and Practice of Oncology.* Philadelphia: Lippincott Williams and Wilkins. 2019; and (2) Emami B, Lyman J, Brown A, et al. Tolerance of normal tissue to therapeutic irradiation. Int J Radiat Oncol Biol Phys. 1991;21(1):109-122.
NP: not provided; TD: tolerance dose.
[a] TD 5/5 is the average dose that results in a 5% complication risk within 5 years.
[b] TD 50/5 is the average dose that results in a 50% complication risk within 5 years.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

In general, IMRT systems include intensity modulators, which control, block, or filter the intensity of radiation, and RT planning systems, which plan the radiation dose to be delivered.

A number of intensity modulators have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Intensity modulators include the Innocure Intensity Modulating Radiation Therapy Compensators (Innocure) and Decimal Tissue Compensator (Southeastern Radiation Products), cleared in 2006 and 2004, respectively. FDA product code: IXI. Intensity modulators may be added to standard linear accelerators to deliver IMRT when used with proper treatment planning systems.

Radiotherapy treatment planning systems have also been cleared for marketing by the FDA through the 510(k) process. They include the Prowess Panther (Prowess) cleared in 2003, TiGRT (LinaTech) cleared in 2009, and the Ray Dose (RaySearch Laboratories) cleared in 2008. FDA product code: MUJ.

Fully integrated IMRT systems also are available. These devices are customizable and support all stages of IMRT delivery, including planning, treatment delivery, and health record management. One such device cleared for marketing by the FDA through the 510(k) process is the Varian IMRT system (Varian Medical Systems). FDA product code: IYE.

RATIONALE

Summary of Evidence

For individuals who have head and neck cancer who receive intensity-modulated radiotherapy (IMRT) , the evidence includes systematic reviews, randomized controlled trials (RCTs) , and nonrandomized comparative studies. Relevant outcomes are overall survival (OS) , functional outcomes, quality of life, and treatment-related morbidity. Recently published systematic reviews compared IMRT to 2-dimensional radiotherapy (2D-RT) and 3-dimensional conformal radiotherapy (3D-CRT) in patients with nasopharyngeal carcinoma. Results revealed a significant improvement in clinical oncologic outcomes (eg, OS, progression-free survival , locoregional control/survival) and toxicities such as xerostomia with IMRT in this patient population. A 2014 systematic review concluded that IMRT, when compared with 2D-RT or 3D-CRT, had no significant impact on OS or locoregional control in previously untreated patients with non-metastatic head and neck cancers; however, IMRT was associated with a significant improvement in xerostomia. A 2023 systematic review concluded that local and regional control are similar for patients with early stage glottic cancer treated with IMRT and 2D-RT or 3D-CRT.One RCT compared 2 fractionation schedules of IMRT for locally advanced head and neck cancer and found a survival benefit in using simultaneous modulated accelerated radiotherapy boost over simultaneous integrated boost-IMRT. Nonrandomized cohort studies have supported the findings that both short- and long-term xerostomia are reduced with IMRT. Overall, evidence has shown that IMRT significantly and consistently reduces both early and late xerostomia and improves quality of life domains related to xerostomia compared with 2D-RT or 3D-CRT. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have thyroid cancer in close proximity to organs at risk who receive IMRT, the evidence includes case series data. Relevant outcomes include OS, functional outcomes, quality of life, and treatment-related morbidity. High-quality studies that differentiate the superiority of any type of external beam radiotherapy to treat thyroid cancer are not available. However, the published evidence plus additional dosimetry considerations together suggest IMRT may be appropriate for thyroid tumors in some circumstances, such as for anaplastic thyroid carcinoma or thyroid tumors located near critical structures (eg, salivary glands, spinal cord), similar to the situation for head and neck cancers. Thus, when adverse events could result if nearby critical structures receive toxic radiation doses, the ability to improve dosimetry with IMRT might be accepted as meaningful evidence for its benefit. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

National Comprehensive Cancer Network

The National Comprehensive Cancer Network (NCCN; v1.2023) guideline on head and neck cancers notes that: "Advanced RT [radiation therapy] technologies such as IMRT, tomotherapy, VMAT [volumetric modulated arc therapy] , image-guided RT (IGRT), and PBT [proton beam therapy] may offer clinically relevant advantages in specific circumstances to spare important organs at risk (OARs)...and decrease the risk for late, normal tissue damage while still achieving the primary goal of local tumor control.[36,] The demonstration of clinically significant dose-sparing of these OARS reflects best clinical practice." The NCCN guideline also notes that "randomized studies to test [advanced radiation therapy technologies] are unlikely to be done since specific clinical scenarios represent complex combinations of multiple variables. In light of that, the modalities and techniques that are found best to reduce the doses to the clinically relevant OARs without compromising target coverage should be considered."

The NCCN (v1.2023) guideline for thyroid cancer states, "EBRT [external-beam radiotherapy] or IMRT can increase short-term survival in some patients with anaplastic thyroid carcinoma; EBRT or IMRT can also improve local control and can be used for palliation (eg, to prevent asphyxiation)." Additionally, the guideline notes, "IMRT may be useful to reduce toxicity" in these patients.[37,] The NCCN also states that the use of IMRT can be considered if an unresectable gross residual disease or locoregional recurrence threatens vital structures in the neck.

American Thyroid Association

The American Thyroid Association published guidelines for the management of patients with anaplastic thyroid cancer in 2021.[38,] These guidelines contained the following recommendations regarding use of IMRT:

- "Following R0 or R1 resection, we recommend that good performance status patients with no evidence of metastatic disease who wish an aggressive approach should be offered standard fractionation IMRT with concurrent systemic therapy.
  Strength of recommendation: strong; Quality of evidence: low.
- We recommend that patients who have undergone R2 resection or have unresectable but nonmetastatic disease with good performance status and who wish an aggressive approach be offered standard fractionation IMRT with systemic therapy.
  Strength of recommendation: strong; Quality of evidence: low.
- Among patients who are to receive radiotherapy for unresectable thyroid cancer or in the postoperative setting, IMRT is recommended.
  Strength of recommendation: strong; Quality of evidence: low."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
September 2012	New policy	
September 2013	Replace policy	Policy updated with literature review, no change to policy statements.
September 2014	Replace policy	Policy updated with literature review, added a not medically necessary policy statement for thyroid indications not included in the medically necessary statement.
September 2015	Replace policy	Policy updated with literature review. Policy statements unchanged.
September 2018	Replace policy	Policy updated with literature review through May 24, 2018; reference 3 updated. Policy statements unchanged.
September 2019	Replace policy	Policy updated with literature review through May 28, 2019; references added. Policy statements unchanged.
September 2020	Replace policy	Policy updated with literature review through May 20, 2020; references added. Policy statements unchanged.
September 2021	Replace policy	Policy updated with literature review through May 31, 2021; references added. Policy statements unchanged.
September 2022	Replace policy	Policy updated with literature review through June 5, 2022; references updated. Policy statements unchanged.
September 2023	Replace policy	Policy updated with literature review through May 10, 2023; reference added. Minor editorial refinements to policy statements; NMA to INV.