Medical Coverage Policy | Intensity-Modulated Radiotherapy: Cancer of the Head, Neck or Thyroid

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OVERVIEW

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

MEDICAL CRITERIA

BlueCHiP for Medicare and Commercial Products

Intensity-modulated radiotherapy may be considered **medically necessary** for the treatment of head and neck cancers when the criteria below is met:

- Tumor is in close proximity to organs at risk (esophagus, salivary glands, and spinal cord), when these organs may be particularly vulnerable to complications from radiation toxicity, and;
- When 3-dimensional conformal radiation therapy (3D-CRT) planning is not able to meet dose volume constraints for normal tissue tolerance.

Intensity-modulated radiotherapy may be considered **medically necessary** for the treatment of thyroid cancers when the criteria below is met**:**

- For anaplastic thyroid carcinoma, or for
- Thyroid tumors that are located near critical structures such as the salivary glands or spinal cord, similar to the situation for head and neck cancers.

PRIOR AUTHORIZATION

Prior authorization is recommended and obtained via the online tool for participating providers.

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Products

Intensity-modulated radiotherapy may be considered **medically necessary** for the treatment of head and neck cancers, for the treatment of thyroid cancers when the criteria above is met.

Intensity-modulated radiotherapy is **not medically necessary** for the treatment of thyroid cancers not noted above as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable radiology benefit/coverage.

BACKGROUND

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. The table below outlines radiation doses that are generally considered tolerance thresholds for these normal structures in the area of the thyroid.

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 2D treatment planning based on flat images and radiation beams with cross-sections of uniform intensity that were sequentially aimed at the tumor along 2 or 3 intersecting axes. Collectively, these methods are termed conventional external beam radiotherapy (EBRT).

Three-Dimensional Conformal Radiation

Treatment planning evolved by using 3D 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 3D-CRT.

Intensity-Modulated Radiotherapy

IMRT, which uses computer software and CT 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 multiplyshaped treatment fields. It uses a device (a multileaf collimator) 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.

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.

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

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. EBRT 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

IMRT may be considered medically necessary for the treatment of thyroid cancers in close proximity to organs at risk such as the esophagus, salivary glands and the spinal cord.

In general, the evidence to assess the role of IMRT in the treatment of cancers of the head and neck suggests that tumor control rates achieved with IMRT are at minimum similar to those achieved with other non-IMRT techniques. In addition, although results are not uniform across all studies, most of the studies show a marked improvement in the rate of late xerostomia, a clinically significant complication of RT that leads to decreased quality of life for patients. Thus, published evidence on the use of IMRT in the treatment of head and neck cancers supports a conclusion that it improves the net health benefit compared with non-IMRT methods. Clinical input also was uniform in stating that IMRT is appropriate for the treatment of head and neck cancers.

Limited evidence exists on use of IMRT for thyroid cancer. The published literature consists of small case series. Due to the limitations in this evidence, clinical input was obtained. There was near-uniform consensus that the use of IMRT for thyroid tumors may be appropriate in some circumstances such as for anaplastic thyroid carcinoma or for thyroid tumors that are located near critical structures such as the salivary glands or spinal cord. When possible adverse events could result if nearby critical structures receive toxic radiation doses, the ability to improve dosimetry with IMRT should be accepted as meaningful evidence for its benefit. The results of the vetting, together with a strong indirect chain of evidence and the potential to reduce harms, led to the conclusion that IMRT may be considered for the treatment of thyroid cancers located in close proximity to organs at risk (esophagus, salivary glands, spinal cord) and 3D-CRT planning is not able to meet dose volume constraints for normal tissue tolerance.

Practice Guidelines and Position Statements

National Comprehensive Cancer Network

The National Comprehensive Cancer Network (NCCN) guidelines on head and neck cancers comment that, to minimize dose to critical structures, either IMRT or 3D-CRT is recommended for cancers of the oropharynx, nasopharynx, and paranasal sinus. The guidelines also indicate: "[t]he application of IMRT to other sites (eg, oral cavity, larynx, hypopharynx, salivary glands) is evolving and may be used at the discretion of treating physicians."20 NCCN guidelines for thyroid cancer state that when considering EBRT for the treatment of anaplastic thyroid cancer, IMRT may be useful to reduce toxicity.21

American College of Radiology and American Society for Therapeutic Radiation and Oncology

The American College of Radiology and the American Society for Therapeutic Radiation and Oncology note that IMRT is a widely used treatment option for many indications including head and neck tumors.22 This guideline was last amended in 2014.

National Cancer Institute

The National Cancer Institute (NCI) indicates IMRT may be appropriate for head and neck cancers in several instances. For radiation of cervical lymph nodes (for primary cancer of unknown origin) and untreated primary occult metastatic squamous neck cancer, IMRT may have less short- and long-term toxicity than conventional radiotherapy in terms of xerostomia, acute dysphagia, and skin fibrosis.23,24 For nasopharyngeal cancer, NCI indicates IMRT results in a lower incidence of xerostomia and may provide a better quality of life than conventional 3- or 2-dimensional radiotherapy.25 IMRT may also be appropriate in select cases of recurrent nasopharyngeal cancer per NCI.25 Finally, to prevent or reduce the extent of salivary gland hypofunction and xerostomia, NCI indicates parotid-sparing IMRT is recommended as a standard approach in head and neck cancers, if oncologically feasible.26

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

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

CODING

BlueCHiP for Medicare and Commercial Products

A4648 Tissue marker, implantable, any type, each (Note: This code is not separately reimbursed for institutional providers.)

Note: To ensure correct pricing of HCPC code **A4648** for the Calypso 4D localization system, the procedure/clinical notes and the invoice must be submitted.

The following codes are covered for BlueCHiP for Medicare and commercial products when the criteria above is met:

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 delivery (IMRT), includes guidance and tracking, when performed; simple; (Institutional Providers)

77386: Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex; (Institutional Providers)

G6015 Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session; (Professional Providers)

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; (Professional Providers)

RELATED POLICIES

Preauthorization via Web-Based Tool for Procedures

PUBLISHED

Provider Update, February 2016
Provider Update, October 2015

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