Protocol

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

(80148)

Medical Benefit		**Effective Date**: 07/01/15	**Next Review Date**: 03/21
Preauthorization	No	**Review Dates**: 09/09, 09/10, 03/11, 03/12, 09/12, 09/13, 03/14, 03/15, 03/16, 03/17, 03/18, 03/19, 03/20	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With head and neck cancer	Interventions of interest are: • Intensity-modulated radiotherapy	Comparators of interest are: • Three-dimensional conformal radiotherapy • Two-dimensional radiotherapy	Relevant outcomes include: • Overall survival • Functional outcomes • Quality of life • Treatment-related morbidity
Individuals: • With thyroid cancer in close proximity to organs at risk	Interventions of interest are: • Intensity-modulated radiotherapy	Comparators of interest are: • Three-dimensional conformal radiotherapy • Two-dimensional radiotherapy	Relevant outcomes include: • Overall survival • Functional outcomes • Quality of life • Treatment-related morbidity

DESCRIPTION

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

SUMMARY OF EVIDENCE

For individuals who have head and neck cancer who receive IMRT, the evidence includes comparative studies, systematic reviews, randomized controlled trials, and nonrandomized studies. Relevant outcomes are overall survival, functional outcomes, quality of life, and treatment-related morbidity. The single randomized controlled trial that compared IMRT with three-dimensional conformal radiotherapy found a significant benefit of IMRT on xerostomia that persisted through five years. Oncologic outcomes did not differ significantly between treatments. Nonrandomized cohort studies have supported the findings that both short- and long-term xerostomia are reduced with IMRT. Overall, the 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 three-dimensional conformal radiotherapy. The evidence is sufficient to determine that the technology results in a meaningful 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 nonrandomized, retrospective studies. Relevant outcomes include overall survival, 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 (e.g., 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 a meaningful improvement in the net health outcome.

Clinical input obtained in 2012 provided a uniform consensus that IMRT is appropriate for the treatment of head and neck cancers. There was a near-uniform consensus that IMRT is appropriate in select patients with thyroid cancer. Respondents noted that IMRT for the head, neck, and thyroid tumors may reduce the risk of exposure to radiation in critical nearby structures (e.g., spinal cord, salivary glands), thus decreasing the risks of adverse events (e.g., xerostomia, esophageal stricture).

POLICY

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, and spinal cord) and three-dimensional conformal radiotherapy planning is not able to meet dose volume constraints for normal tissue tolerance (see Policy Guidelines).

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 protocol, head and neck cancers are those 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.

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 following table 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 three-dimensional conformal radiotherapy without intensity-modulated radiotherapy would exceed tolerance doses to structures at risk.

Radiation Tolerance Doses for Normal Tissues

Site	TD 5/5 Gray[a]			TD 50/5 Gray[b]			Complication End Point
	Portion of organ involved			Portion of organ involved			
	1/3	2/3	3/3	1/3	2/3	3/3	
Brain stem	60	53	50	NP	NP	65	Necrosis, infarct
Spinal cord, cm	50 (five-10)	NP	47 (20)	70 (five-10)	NP	NP	Myelitis, necrosis
Optic nerve and chiasm	50	50	50	65	65	65	Blindness

Site	TD 5/5 Gray[a]			TD 50/5 Gray[b]			Complication End Point
	Portion of organ involved			Portion of organ involved			
	1/3	2/3	3/3	1/3	2/3	3/3	
Retina	45	45	45	65	65	65	Blindness
Eye lens	10	10	10	18	18	18	Cataract requiring intervention

Compiled from the following two sources:

Morgan MA (2011). Radiation Oncology. In DeVita, Lawrence and Rosenberg, Cancer (p.308). Philadelphia: Lippincott Williams and Wilkins.

Kehwar TS, Sharma SC. Use of normal tissue tolerance doses into linear quadratic equation to estimate normal tissue complication probability. Available online at: http://www.rooj.com/Radiation%20Tissue%20Tolerance.htm

NP: not provided; TD: tolerance dose cm: centimeters

[a]TD 5/5, the average dose that results in a 5% complication risk within five years

[b]TD 50/5, the average dose that results in a 50% complication risk within five years

BACKGROUND

HEAD AND NECK CANCERS

This evidence review focuses on cancers affecting 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.

RADIOTHERAPY TECHNIQUES

Conventional External-Beam Radiotherapy

Methods to plan and deliver radiotherapy (RT) have evolved in ways that permit more precise targeting of tumors with complex geometries. Most early trials used two-dimensional 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 radiotherapy.

Three-Dimensional Conformal Radiotherapy

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 were also 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, CT and magnetic resonance imaging images, offers better conformality than 3D-CRT because it modulates the intensity of the overlapping radiation beams projected on the target and uses multiple shaped treatment fields. Treatment planning and delivery are more complex, time-consuming, and labor-intensive for IMRT than for 3D-CRT. The technique uses a multileaf collimator [MLC]), which, when coupled with 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, 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 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.

Technologic developments have produced advanced techniques that may further improve RT treatment by improving dose distribution. These techniques are considered variations of IMRT. Volumetric modulated arc therapy delivers radiation from a continuously rotating 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 deliver RT to the target volume more precisely.

IMRT methods to plan and deliver RT are not uniform. IMRT may use beams that remain on as MLCs move around the patient (dynamic MLC), or that are off during movement and turn on once the MLC reaches prespecified positions ("step and shoot" technique). A third alternative uses a very narrow, single beam that moves spirally around the patient (tomotherapy). Each method uses different computer algorithms to plan treatment and yields somewhat different dose distributions in and outside the target. Patient position can alter target shape and thus affect treatment plans. Treatment plans are usually based on a single imaging scan, a static 3D-CT image. Current methods seek to reduce positional uncertainty for tumors and adjacent normal tissues by various techniques. Patient immobilization cradles and skin or bony markers are used to minimize day-to-day variability in patient positioning. In addition, many tumors have irregular edges that preclude drawing tight margins on CT scan slices when radiation oncologists contour the tumor volume. It is unknown whether omitting some tumor cells or including some normal cells in the resulting target affects outcomes of IMRT.

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. 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) in 2003, TiGRT (LinaTech) in 2009, and the Ray Dose (RaySearch Laboratories). 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.

RELATED PROTOCOL

Stereotactic Radiosurgery and Stereotactic Body Radiotherapy

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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