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 (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.

IMRT, which uses computer software along with CT and magnetic resonance images, offers better conformity 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 conformity 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 under-dosing 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 continuous rotation of the radiation source. The principal advantage of volumetric modulated therapy is its 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.

**OBJECTIVE**

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

**POLICY STATEMENT**

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**

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

<table>
<thead>
<tr>
<th>Site</th>
<th>Portion of Organ Involved</th>
<th>TD 5/5, Gray&lt;sup&gt;a&lt;/sup&gt;</th>
<th>TD 50/5, Gray&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Portion of Organ Involved</th>
<th>Complication End Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>Esophagus</td>
<td>1/3</td>
<td>60</td>
<td>72</td>
<td>2/3</td>
<td>58</td>
</tr>
<tr>
<td>Salivary glands</td>
<td>32</td>
<td>32</td>
<td>46</td>
<td>3/3</td>
<td>32</td>
</tr>
<tr>
<td>Spinal cord</td>
<td>50 (5-10 cm)</td>
<td>NP</td>
<td>47 (20 cm)</td>
<td>3/3</td>
<td>NP</td>
</tr>
</tbody>
</table>


NP: not provided; TD: tolerance dose.

<sup>a</sup> TD 5/5 is the average dose that results in a 5% complication risk within 5 years.

<sup>b</sup> 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. 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.

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RATIONALE

Summary of Evidence

For individuals who have thyroid cancer in close proximity to organs at risk who receive intensity-modulated radiotherapy (IMRT), the evidence includes nonrandomized, retrospective studies. The relevant outcomes include overall survival (OS), functional outcomes, quality of life (QOL), 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 a meaningful improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

National Comprehensive Cancer Network

The NCCN (v.1.2019) guidelines for thyroid cancer state, "IMRT is useful for thyroid cancers because of its ability to spare the larynx, brachial plexus, and esophagus." The NCCN supports the use of intensity-modulated radiotherapy if an unresectable, gross residual disease or locoregional recurrence threatens vital structures in the neck.

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.

REFERENCES


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

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 2012</td>
<td>New policy</td>
<td>Policy updated with literature review, no change to policy statements.</td>
</tr>
<tr>
<td>September 2013</td>
<td>Replace policy</td>
<td>Policy updated with literature review.</td>
</tr>
<tr>
<td>September 2014</td>
<td>Replace policy</td>
<td>Policy updated with literature review, added a not medically necessary policy statement for thyroid indications not included in the medically necessary statement.</td>
</tr>
<tr>
<td>September 2015</td>
<td>Replace policy</td>
<td>Policy updated with literature review. Policy statements unchanged.</td>
</tr>
<tr>
<td>September 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through May 24, 2018; reference 3 updated. Policy statements unchanged.</td>
</tr>
<tr>
<td>September 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through May 28, 2019; references added. Policy statements unchanged.</td>
</tr>
</tbody>
</table>

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