Intensity-Modulated Radiotherapy: Cancer of the Thyroid

Description

Radiotherapy (RT) 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 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. 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 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 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 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>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>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Portion of Organ Involved</td>
<td>Portion of Organ Involved</td>
</tr>
<tr>
<td>Site</td>
<td>1/3</td>
<td>2/3</td>
</tr>
<tr>
<td>Esophagus</td>
<td>60</td>
<td>58</td>
</tr>
<tr>
<td>Salivary glands</td>
<td>32</td>
<td>32</td>
</tr>
<tr>
<td>Spinal cord</td>
<td>50 (5-10 cm) NP 47 (20 cm)</td>
<td>70 (5-10 cm) 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).

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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 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) 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.

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 case series data. Relevant outcomes include overall survival (OS), functional outcomes, quality-of-life, and treatment-related morbidity. High-quality studies that differentiate the superiority of any type of external-beam radiation therapy (RT) 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.2.2019) guideline for thyroid cancer states, "External-beam radiotherapy (EBRT) 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. 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.

U.S. Preventive Services Task Force Recommendations

Not applicable.

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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


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></td>
</tr>
<tr>
<td>September 2013</td>
<td>Replace policy</td>
<td>Policy updated with literature review, no change to policy statements.</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>
<tr>
<td>September 2020</td>
<td>Replace policy</td>
<td>Policy updated with literature review through May 20, 2020; references added. Policy statements unchanged.</td>
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