FEP 8.01.46 Intensity-Modulated Radiotherapy of the Lung

Effective Policy Date: October 1, 2019

Original Policy Date: September 2012

Related Policies:
- 8.01.48 - Intensity-Modulated Radiotherapy: Cancer of the Thyroid
- 8.01.49 - Intensity-Modulated Radiotherapy: Abdomen and Pelvis
- 8.01.59 - Intensity-Modulated Radiotherapy: Central Nervous System Tumors

Intensity-Modulated Radiotherapy of the Lung

Description

Radiotherapy (RT) is an integral component of the treatment of lung cancer. Intensity-modulated radiotherapy (IMRT) has been proposed as a method of RT that allows adequate radiation to the tumor while 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 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.

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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 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.

Investigators are exploring an active breathing control device combined with moderately deep inspiration breath-holding techniques to improve conformality and dose distributions during IMRT for breast cancer. Techniques presently being studied with other tumors (eg, lung cancer) either gate beam delivery to the patient's respiratory movement or continuously monitor tumor (by in-room imaging) or marker (internal or surface) positions to aim radiation more accurately at the target.

**OBJECTIVE**

The objective of this evidence review is to determine whether intensity-modulated radiotherapy improves the net health outcome in patients with lung cancer.

**POLICY STATEMENT**

IMRT may be considered **medically necessary** as a technique to deliver radiotherapy in patients with lung cancer when all of the following conditions are met:

- Radiotherapy is being given with curative intent,
- Three-dimensional conformal radiotherapy will expose >35% of normal lung tissue to more than a 20-Gy dose-volume (V20), and
- IMRT dosimetry demonstrates a reduction in the V20 to at least 10% below the V20 that is achieved with the 3-dimensional plan (eg, from 40% down to 30% or lower).

IMRT is considered **not medically necessary** as a technique to deliver radiotherapy in patients receiving palliative treatment for lung cancer.

IMRT is **not medically necessary** for the treatment of lung cancer for all indications not meeting the criteria above.
Table PG1 outlines radiation doses generally considered tolerance thresholds for these normal structures for the chest and abdomen. Dosimetry plans may be used to demonstrate that radiation by 3-dimensional conformal radiotherapy (3D-CRT) would exceed tolerance doses to structures at risk.

Table PG1. Radiation Tolerance Doses for Normal Tissues of the Chest and Abdomen

<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>
<th>Complication End Point</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Portion of Organ Involved</td>
<td>Portion of Organ Involved</td>
<td></td>
</tr>
<tr>
<td>Heart</td>
<td>1/3, 2/3, 3/3</td>
<td>1/3, 2/3, 3/3</td>
<td>Pericarditis</td>
</tr>
<tr>
<td>Lung</td>
<td>1/3, 2/3, 3/3</td>
<td>1/3, 2/3, 3/3</td>
<td>Pneumonitis</td>
</tr>
<tr>
<td>Spinal cord</td>
<td>1/3, 2/3, 3/3</td>
<td>1/3, 2/3, 3/3</td>
<td>Myelitis, necrosis</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) cleared in 2006.
and the decimal tissue compensator (Southeastern Radiation Products), cleared in 2004. FDA product code: IXI. Intensity modulators may be added to standard linear accelerators to deliver IMRT when used with proper treatment planning systems.

RT 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) in 2008. FDA product code: MUJ.

Fully integrated IMRT systems are also 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 lung cancer who receive Intensity-modulated radiotherapy (IMRT), the evidence includes nonrandomized, retrospective, comparative studies. The relevant outcomes are overall survival (OS), disease-specific survival, quality of life (QOL), and treatment-related morbidity. Dosimetry studies have shown that IMRT can reduce radiation exposure to critical surrounding structures, especially in large lung tumors. Based on nonrandomized comparative studies, IMRT appears to produce survival outcomes comparable to those of 3-dimensional conformal radiotherapy (3D-CRT) and reduce toxicity. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Clinical vetting also provided strong support for IMRT when alternative radiotherapy (RT) dosimetry exceeds a threshold of V20 to at least 35% of normal lung tissue. Based on available evidence, clinical vetting, a strong chain of evidence, and the potential to reduce harms, IMRT may be considered medically necessary for lung cancer when(1) RT is given with curative intent, (2) alternative RT dosimetry demonstrates radiation dose exceeding V20 for at least 35% of normal lung tissue, and (3) IMRT reduces the V20 of radiation to the lung at least 10% below the V20 of 3D-CRT (eg, 40% reduced to 30%).

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

National Comprehensive Cancer Network

Lung Cancer

Current NCCN guidelines (v.4.2019) for non-small-cell lung cancer indicate that "More advanced technologies are appropriate when needed to deliver curative RT [radiotherapy] safely. These technologies include (but are not limited to) ... IMRT/VMAT [volumetric modulated arc therapy].... Nonrandomized comparisons of using advanced technologies versus older techniques demonstrate reduced toxicity and improved survival."24.

Current NCCN guidelines (v.1.2019) for small-cell lung cancer indicate that "Use of more advanced technologies is appropriate when needed to deliver adequate tumor dose while respecting normal tissue dose constraints."25. IMRT is included in the technologies listed.

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The American Society for Radiation Oncology (2018) has published evidence-based guidelines on radiotherapy for lung cancer. The guidelines recommended "moderately hypofractionated palliative thoracic radiation therapy" with chemotherapy as palliative care for stage III and IV incurable non-small-cell lung cancer. In 2017, the Society updated its guidelines on stage I to IIIA resectable non-small-cell lung cancer. Adjuvant radiotherapy was not recommended.

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.

Some local Medicare Part B carriers have indicated that IMRT for the lung is considered medically necessary. These documents do not detail the rationale for this conclusion.

REFERENCES


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