FEP Medical Policy Manual

FEP 8.01.46 Intensity-Modulated Radiotherapy of the Lung

Effective Policy Date: October 1, 2020

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 cancers. 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 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

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The 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.

Investigators are exploring an active breathing control device combined with moderately deep inspiration breath-holding techniques to improve conformity 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. The impact of these techniques on the outcomes of 3D-CRT or IMRT for breast cancer is unknown. However, it appears likely that respiratory motion alters the dose distributions actually delivered while treating patients from those predicted by plans based on static CT scans or measured by dosimetry using stationary (nonbreathing) targets.

**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.

**POLICY GUIDELINES**

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**

<table>
<thead>
<tr>
<th>Site</th>
<th>TD 5/5, Gray</th>
<th>TD 50/5, Gray</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>60</td>
<td>45</td>
<td>70</td>
</tr>
<tr>
<td>Lung</td>
<td>45</td>
<td>30</td>
<td>47 (20 cm)</td>
</tr>
<tr>
<td>Spinal cord</td>
<td>50 (5 cm)</td>
<td>50 (10 cm)</td>
<td>70 (5 cm)</td>
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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 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. Relevant outcomes are overall survival (OS), locoregional control, 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

National Comprehensive Cancer Network

Lung Cancer

Current NCCN guidelines (v.5.2020) for non-small-cell lung cancer indicate that "More advanced technologies are appropriate when needed to deliver curative RT safely. These technologies include (but are not limited to) ... IMRT/VMAT [volumetric modulated arc

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therapy]. Nonrandomized comparisons of using advanced technologies versus older techniques demonstrate reduced toxicity and improved survival.*13

Current NCCN guidelines (v.3.2020) for small-cell lung cancer indicate that "Use of more advanced technologies is appropriate when needed to deliver adequate tumor doses while respecting normal tissue dose constraints." IMRT is included in the technologies listed. The guidelines also states that "IMRT is preferred over 3D conformal external-beam RT on the basis of reduced toxicity in the setting of concurrent chemotherapy/RT."

American Society for Radiation Oncology

Lung Cancer

In 2018, the American Society for Radiation Oncology has also published evidence-based guidelines on RT 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.15

American Society of Clinical Oncology/American Society for Radiation Oncology/Society of Surgical Oncology

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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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>
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<th>Description</th>
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<tbody>
<tr>
<td>September 2012</td>
<td>New policy</td>
<td>Policy updated with literature search. References added; practice guidelines updated. No change to policy statements.</td>
</tr>
<tr>
<td>June 2013</td>
<td>Replace policy</td>
<td>Policy updated with literature search. References 16-17 added; reference 19 updated. Policy statement added stating other indications not meeting the criteria for medical necessity are considered not medically necessary.</td>
</tr>
<tr>
<td>June 2014</td>
<td>Replace policy</td>
<td>Policy updated with literature review. Reference 27 added. Title changed from “radiation therapy”. No change to policy statements.</td>
</tr>
<tr>
<td>June 2015</td>
<td>Replace policy</td>
<td>Policy updated with literature review through May 10, 2018; references added; some references removed. Policy statements unchanged.</td>
</tr>
<tr>
<td>September 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through May 6, 2019; references added. Policy statements unchanged.</td>
</tr>
<tr>
<td>September 2019</td>
<td>Replace policy</td>
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