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FEP Medical Policy Manual

FEP 8.01.46 Intensity-Modulated Radiotherapy of the Breast and Lung

Effective Policy Date: October 1, 2023

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Related Policies:

8.01.48 - Intensity-Modulated Radiotherapy: Cancer of the Head and Neck or Thyroid
8.01.49 - Intensity-Modulated Radiotherapy: Abdomen, Pelvis and Chest
8.01.59 - Intensity-Modulated Radiotherapy: Central Nervous System Tumors

Intensity-Modulated Radiotherapy of the Breast and Lung

Description

Description

Radiotherapy (RT) is an integral component of the treatment of breast and 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.

Intensity-modulated radiotherapy 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.[3,] 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 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.

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.[4,] Techniques presently being studied with other tumors (eg, lung cancer)[5,] 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 breast or lung cancer.

POLICY STATEMENT

Intensity-modulated radiotherapy (IMRT) may be considered **medically necessary** as a technique to deliver whole-breast irradiation in individuals receiving treatment for left-sided breast cancer after breast-conserving surgery when all the following conditions have been met:

- Significant cardiac radiation exposure cannot be avoided using alternative radiotherapy, and
- IMRT dosimetry demonstrates significantly reduced cardiac target volume radiation exposure (see Policy Guidelines section).

IMRT may be considered **medically necessary** in individuals with large breasts when treatment planning with 3-dimensional conformal radiotherapy results in hot spots (focal regions with dose variation > 10% of target) and the hot spots can be avoided with IMRT (see Policy Guidelines section).

IMRT of the breast is considered **investigational** as a technique of partial-breast irradiation after breast-conserving surgery.

IMRT of the chest wall is considered **investigational** as a technique of postmastectomy irradiation.

IMRT may be considered **medically necessary** as a technique to deliver radiotherapy in individuals 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-gray (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 individuals receiving palliative treatment for lung cancer.

IMRT is **not medically necessary** for the treatment of breast or 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 of 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

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	
Heart	60	45	40	70	55	50	Pericarditis
Lung	45	30	17.5	65	40	24.5	Pneumonitis
Spinal cord	50 (5 cm)	50 (10 cm)	47 (20 cm)	70 (5 cm)	70 (10 cm)	NP	Myelitis, necrosis

Compiled from: (1) Morgan MA, Ten Taken RK, Lawrence TS. Essentials of radiation therapy. In DeVita, Hellman, and Rosenberg, *Cancer: Principles & Practice of Oncology*. Philadelphia: Lippincott Williams and Wilkins; 2019; and (2) Kehwar TS, Sharma SC. Use of normal tissue tolerance doses into linear quadratic equation to estimate normal tissue complication probability. Available at: http://www.rooj.com/Radiation%20Tissue%20Tolerance.htm. Accessed May 15, 2023.
NP: not provided; TD: tolerance dose.

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

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

The following is an example of clinical guidelines that may be used with intensity-modulated radiotherapy (IMRT) in left-sided breast lesions:

- The target volume coverage results in cardiac radiation exposure that is expected to be greater than or equal to 25 gray (Gy) to 10 cm^3 or more of the heart (V25 ≥ 10 cm^3) with 3D-CRT, despite the use of a complex positioning device (eg, Vac-Lok), and
- With the use of IMRT, there is a reduction in the absolute heart volume receiving 25 Gy or more by at least 20% (eg, volume predicted to receive 25 Gy by 3D-CRT is 20 cm^3, and the volume predicted by IMRT is ≤ 16 cm^3).

The following are examples of criteria to define large breast size when using IMRT to avoid hot spots, as derived from randomized studies:

- Donovan et al (2007)[1,] enrolled individuals with a "higher than average risk of late radiotherapy-adverse effects," which included individuals having larger breasts. The authors stated that while breast size is not particularly good at identifying women with dose inhomogeneity falling outside current International Commission on Radiation Units and Measurements guidelines, they excluded women with small breasts (≤ 500 cm^3), who generally have fairly good dosimetry with standard 2-dimensional compensators.
- In the trial by Pignol et al (2008)[2,], which reported that the use of IMRT significantly reduced the proportion of individuals experiencing moist desquamation, breast size was categorized as small, medium, or large by cup size. Multivariate analysis found that smaller breast size was significantly associated with a decreased risk of moist desquamation (p<.001).

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.

Radiotherapy 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, Ray Dose (RaySearch Laboratories) in 2008, and the Accuray Precision Treatment Planning System in 2021 (Accuray Incorporated). 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 breast cancer who receive intensity-modulated radiotherapy (IMRT), the evidence includes systematic reviews, randomized controlled trials (RCTs), and nonrandomized comparative studies. Relevant outcomes are overall survival (OS), disease-specific survival, locoregional control, quality of life, and treatment-related morbidity. There is modest evidence from RCTs for a decrease in acute skin toxicity with IMRT compared with 2-dimensional radiotherapy (2D-RT) for whole-breast irradiation, and dosimetry studies have demonstrated that IMRT reduces inhomogeneity of radiation dose, thus potentially providing a mechanism for reduced skin toxicity. However, because whole-breast RT is now delivered by 3-dimensional conformal radiotherapy (3D-CRT), these comparative data are of limited value. Studies comparing IMRT with 3D-CRT include 1 RCT comparing IMRT with deep inspiration breath hold (DIBH) to 3D-CRT, 2 additional RCTs comparing IMRT to 3D-CRT in women who had undergone breast-conserving surgery (with 1 RCT evaluating simultaneous vs. sequential boost therapy), 2 nonrandomized comparative studies on whole-breast IMRT, and a few studies on chest wall IMRT. These studies suggest that IMRT requires less radiation exposure to nontarget areas and may improve upon, or provide similar improvement in, clinical outcomes. The available studies on chest wall IMRT for postmastectomy breast cancer patients have focused on treatment planning and techniques. However, when dose-planning studies have indicated that RT will lead to unacceptably high radiation doses, the studies suggest IMRT will lead to improved outcomes. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have lung cancer who receive IMRT, the evidence includes 1 RCT that focused on esophageal adverse events and multiple nonrandomized, retrospective, comparative studies. Relevant outcomes are OS, disease-specific survival, locoregional control, quality of life, 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 3D-CRT, while reducing toxicity. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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

Breast Cancer

In 2016, the American Society of Clinical Oncology (ASCO), American Society for Radiation Oncology, and the Society of Surgical Oncology developed a focused update of a prior ASCO guideline related to the use of postmastectomy radiotherapy (RT).[31,] The Expert Panel unanimously agreed that "available evidence shows that post mastectomy RT reduces the risk of locoregional failure, any recurrence, and breast cancer mortality for patients with T1 to T2 breast cancer with 1 to 3 positive axillary nodes. However, some subsets of these patients are likely to have such a low risk of locoregional failure that the absolute benefit of post mastectomy RT is outweighed by its potential toxicities." Additionally, the guideline noted that "the decision to recommend post mastectomy RT requires a great deal of clinical judgment."

American Society for Radiation Oncology

Breast Cancer

In 2018, the American Society for Radiation Oncology published evidence-based guidelines on whole-breast irradiation with or without low axilla inclusion. The guidance recommended a "preferred" radiation dosage of "4000 cGy [centigray] in 15 fractions or 4250 cGy in 16 fractions."[32,]

Lung Cancer

In 2018, the American Society for Radiation Oncology also published evidence-based guidelines on palliative RT for non-small-cell lung cancer (NSCLC). The guidelines recommended "moderately hypofractionated palliative thoracic radiation therapy" with chemotherapy as palliative care for stage III and IV incurable NSCLC.[33,]

In 2020, the American Society for Radiation Oncology also published evidence-based guidelines RT for small-cell lung cancer (SCLC).[34,] The guidelines listed IMRT as one of several treatment strategies for patients with pathologically confirmed limited stage-SCLC with no evidence of M1 disease. The guideline also notes that the use of "modulated techniques (eg, IMRT or volumetric modulated arc therapy) over 3-dimensional conformal treatment is recommended in an attempt to decrease normal tissue toxicities...however...there are limited data on advanced RT techniques in SCLC treatment."

National Comprehensive Cancer Network

Breast Cancer

Current National Comprehensive Cancer Network (NCCN) guidelines (v.4.2023) for breast cancer indicate the importance of individualizing RT planning and delivery. Specifically, the guidelines note that "treatment planning should be optimized to maximally improve homogeneity across the target volume while minimizing dose to organs at risk." A related discussion section in this guideline that has an update in progress states the following: "Computed tomography (CT)-based treatment planning is encouraged to delineate target volumes and adjacent organs at risk. Improved target dose homogeneity and sparing of normal tissues can be accomplished utilizing various "compensators such as wedges, forward planning using segments, and IMRT. Respiratory control techniques including deep inspiration breath-hold and prone positioning may be used to try to further reduce dose in adjacent normal tissues, such as the heart and lung."[35,] The guidelines indicate chest wall and regional lymph node irradiation may be appropriate postmastectomy in select patients, but IMRT is not mentioned as a technique for irradiation in these circumstances.

Lung Cancer

Current NCCN guidelines (v.3.2023) for NSCLC 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 therapy].... Nonrandomized comparisons of using advanced technologies versus older techniques demonstrate reduced toxicity and improved survival."[36,]

Current NCCN guidelines (v.3.2023) for SCLC indicate that "Use of more advanced technologies is appropriate when needed to deliver adequate tumor doses while respecting normal tissue dose constraints."[37,] Among the technologies listed is IMRT. The guidelines also state that "IMRT is preferred over 3D [3-dimensional] conformal external-beam RT on the basis of reduced toxicity in the setting of concurrent chemotherapy/RT."

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.

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

Date	Action	Description
September 2012	New policy	
June 2013	Replace policy	Policy updated with literature search. References added; practice guidelines updated. No change to policy statements.
June 2014	Replace policy	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.
June 2015	Replace policy	Policy updated with literature review. Reference 27 added. Title changed from "radiation therapy,. No change to policy statements.
September 2018	Replace policy	Policy updated with literature review through May 10, 2018; references added; some references removed. Policy statements unchanged.
September 2019	Replace policy	Policy updated with literature review through May 6, 2019; references added. Policy statements unchanged.
September 2020	Replace policy	Policy updated with literature review through June 4, 2020; references added. Policy statements unchanged.
September 2021	Replace policy	Policy updated with literature review through May 25, 2021. Policy statements unchanged.
September 2022	Replace policy	Policy updated with literature review through May 20, 2022; references added. Minor editorial refinements to policy statements; intent unchanged.
September 2023	Replace policy	Policy updated with literature review through May 15, 2023; no references added. Policy statements regarding IMRT as a technique to deliver radiotherapy in individuals receiving palliative treatment for lung cancer and for the treatment of breast or lung cancer for all indications not meeting the criteria listed in other policy statements was changed from €œnot medical necessary€□ to €œinvestigational.€□ Intent unchanged.