MASSACHUSETTS

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Medical Policy

Intensity-Modulated Radiotherapy - IMRT of the Breast and Lung

Table of Contents

Policy Number: 163

BCBSA Reference Number: 8.01.46
NCD/LCD: N/A

Related Policies

- Clinical Exception and Notification Form for Intensity Modulated Radiation Therapy (IMRT), #325
- IMRT of Central Nervous System Tumors, #910
- IMRT of the Abdomen and Pelvis, #165
- IMRT of the Head and Neck, #164
- IMRT of the Prostate, #090

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

Intensity-modulated radiotherapy (IMRT) may be considered **MEDICALLY NECESSARY** for the treatment of tumors of the breast when the tumor is in close proximity to organs at risk (heart, lung, chest wall, skin, and soft tissue) and 3-D CRT planning is not able to meet dose volume constraints for normal tissue tolerance as noted in the following table:

Adjacent Tissue	Dose/Volume Threshold
Heart	>=25% of heart >=30 Gy
Lung	>=30% of ipsilateral lung >=20 Gy **OR** >=20% of combined lung volume >=20 Gy
Skin/Chest wall/Soft tissue	>=5% of intended breast >=7% of prescribed dose **OR** Medical lesion where >=10% of contralateral breast >=10 Gy

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

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

IMRT may be considered **MEDICALLY NECESSARY** for the treatment of tumors of the lung when the tumor is in close proximity to organs at risk (heart, lung) and 3-D CRT planning is not able to meet dose volume constraints for normal tissue tolerance as noted in the following table:

Adjacent Tissue	Dose/Volume Threshold
Heart	>= 50% of heart >= 30Gy
Lung	>= 30% of non-cancerous combined lung volume >=20 Gy

Please note: Clinical Exception and Notification form (#325) **must** be filled out and submitted prior to all IMRT treatments.

Clinical Exception and Notification Form

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Providers **must** submit a request for an exception for a non-covered indication by completing the clinical exception and notification form. Click here for the IMRT Policy and Notification exception and notification form (#325).

Providers **must** complete the Clinical Exception and Notification Form when requesting coverage:

- For medically necessary indications described in medical policy 163, IMRT - Breast and Lung.
- For not medically necessary and investigational indications, described in medical policy 163, Breast and Lung.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Providers must complete the Clinical Exception and Notification Form prior to service.
Commercial PPO and Indemnity	Providers must complete the Clinical Exception and Notification Form prior to service.
Medicare HMO Blue℠	Prior authorization is **not required**.
Medicare PPO Blue℠	Prior authorization is **not required**.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

CPT Codes

CPT codes:	Code Description
77301	Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications
77338	Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan
77385	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple
77386	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex

HCPCS Codes

HCPCS codes:	Code Description
G6015	Intensity modulated treatment delivery, single or multiple fields/arcs,via narrow spatially and temporally modulated beams, binary, dynamic mlc, per treatment session
G6016	Compensator-based beam modulation treatment delivery of inverse planned treatment using 3 or more high resolution (milled or cast) compensator, convergent beam modulated fields, per treatment session

Description

For certain stages of many cancers, including breast and lung, randomized controlled trials (RCTs) have shown that postoperative radiotherapy (RT) improves outcomes for operable patients. Adding radiation to chemotherapy also improves outcomes for those with inoperable lung tumors that have not metastasized beyond regional lymph nodes.

Radiotherapy Techniques

Radiation therapy may be administered externally (ie, a beam of radiation is directed into the body) or internally (ie, a radioactive source is placed inside the body, near a tumor).[3,] External radiotherapy (RT) techniques include "conventional" or 2-dimensional (2D) RT, 3-dimensional (3D) conformal RT, and intensity-modulated radiation therapy (IMRT).

Conventional External-Beam Radiotherapy

Methods to plan and deliver RT have evolved that permit more precise targeting of tumors with complex geometries. Conventional 2D treatment planning utilizes X-ray films to guide and position radiation beams.[3,] Bony landmarks bones visualized on X-ray are used to locate a tumor and direct the radiation beams. The radiation is typically of uniform intensity.

Three-Dimensional Conformal Radiotherapy

Radiation treatment planning has evolved to use 3D images, usually from computed tomography (CT) scans, to more precisely delineate the boundaries of the tumor and to discriminate tumor tissue from adjacent normal tissue and nearby organs at risk for radiation damage. Three-dimensional conformal RT (3D-CRT) involves initially scanning the patient in the position that will be used for the radiation treatment.[3,] The tumor target and surrounding normal organs are then outlined in 3D on the scan. Computer software assists in determining the orientation of radiation beams and the amount of radiation the tumor and normal tissues receive to ensure coverage of the entire tumor in order to minimize radiation

exposure for at risk normal tissue and nearby organs. Other imaging techniques and devices such as multileaf collimators (MLCs) may be used to "shape" the radiation beams. Methods have also been developed to position the patient and the radiation portal reproducibly for each fraction and to immobilize the patient, thus maintaining consistent beam axes across treatment sessions.

Intensity-Modulated Radiotherapy
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.[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 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.

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.

Summary

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.

For individuals who have breast cancer who receive IMRT, the evidence includes systematic reviews, RCTs, and nonrandomized comparative studies. Relevant outcomes are OS, 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 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 3D-CRT, these comparative data are of limited value.

Studies comparing IMRT with 3D-CRT include 1 RCT comparing IMRT with DIBH to 3D-CRT, 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 short-term clinical outcomes. The available studies on chest wall IMRT for postmastectomy breast cancer patients have only 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 a meaningful improvement in the net health outcome.

Evidence supports the use of IMRT for left-sided breast lesions in which alternative types of RT cannot avoid toxicity to the heart. Based on available evidence, input from clinical vetting, a strong chain of evidence, and the potential to reduce harms, IMRT may be considered medically necessary for whole-breast irradiation when (1) alternative forms of RT cannot avoid cardiac toxicity, and (2) IMRT dose-planning demonstrates a substantial reduction in cardiac toxicity. IMRT for the palliative treatment of lung cancer is considered not medically necessary because conventional radiation techniques are adequate for palliation.

For individuals who have lung cancer who receive IMRT, the evidence includes nonrandomized, retrospective, comparative studies. Relevant outcomes are 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 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 RT dosimetry exceeds a threshold of 20-Gy dose-volume (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%).

Policy History

Date	Action
9/2020	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
9/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
9/2018	BCBSA National medical policy review. No changes to policy statements. New references added. Summary clarified.
8/2017	New references added from BCBSA National medical policy.
10/2016	New references added from BCBSA National medical policy.
9/2016	Clarified coding information.
2/2016	Local Coverage Determination (LCD) for Intensity Modulated Radiation Therapy (IMRT) (L3244) removed. 2/1/2016
11/2015	Added coding language.
6/2015	BCBSA National medical policy review. Title changed from “radiation therapy” to “radiotherapy.” Effective 6/1/2015.
1/2015	Clarified coding information.
8/2014	Clinical exception and notification clarified.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
6/2013	New references from BCBSA National medical policy.
2/2013	BCBSA National medical policy review.

	Changes to policy statements. Effective 2/4/2013.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
9/1/2011	Medical Policy 163 effective 9/1/2011 describing covered and non-covered indications.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

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