MASSACHUSETTS

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Medical Policy

Intensity-Modulated Radiotherapy - IMRT of the Breast and Lung

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Policy Number: 163

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

Related Policies

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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** if the procedure is performed inpatient.

Outpatient

- For services described in this policy, see below for situations 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

Radiotherapy (RT) is an integral component in the treatment of breast and lung cancers. Intensity-modulated radiotherapy (IMRT) has been proposed as a method of radiation therapy that allows adequate radiation therapy to the tumor while minimizing the radiation dose to surrounding normal tissues and critical structures.

For certain stages of many cancers, including breast and lung, randomized controlled trials have shown that postoperative radiation therapy 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.

Radiation techniques

Conventional external beam radiotherapy. Over the past several decades, methods to plan and deliver RT have evolved in ways that permit more precise targeting of tumors with complex geometries. Most early trials used 2-dimensional radiation therapy (2D-RT) treatment planning, based on flat images and radiation beams with cross-sections of uniform intensity that were sequentially aimed at the tumor along 2 or 3 intersecting axes. Collectively, these methods are termed conventional external beam radiation therapy (EBRT).

Three-dimensional conformal radiation. Treatment planning evolved by using 3-dimensional images, usually from computed tomography (CT) scans, to delineate the boundaries of the tumor and discriminate tumor tissue from adjacent normal tissue and nearby organs at risk for radiation damage. Computer algorithms were developed to estimate cumulative radiation dose delivered to each volume of interest by summing the contribution from each shaped beam. Methods also were developed to position the patient and the radiation portal reproducibly for each fraction and immobilize the patient, thus maintaining

consistent beam axes across treatment sessions. Collectively, these methods are termed 3-dimensional conformal radiation therapy (3D-CRT).

Intensity-modulated radiotherapy. IMRT, which uses computer software, CT images, and magnetic resonance imaging (MRI), offers better conformality than 3D-CRT, as it is able to modulate the intensity of the overlapping radiation beams projected on the target and to use multiple-shaped treatment fields. It uses a device (a multileaf collimator [MLC]) which, coupled to 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 and surrounding tissues and organs at risk, computer software optimizes the location, shape, and intensities of the beams ports, to achieve the treatment plan's goals.

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.

Because most tumors move as patients breathe, dosimetry with stationary targets may not accurately reflect doses delivered within target volumes and adjacent tissues in patients. Furthermore, treatment planning and delivery are more complex, time-consuming, and labor-intensive for IMRT than for 3D-CRT. Thus, clinical studies must test whether IMRT improves tumor control or reduces acute and late toxicities when compared with 3D-CRT.

Methodologic issues with IMRT studies

Multiple-dose planning studies have generated 3D-CRT and IMRT treatment plans from the same scans, then compared predicted dose distributions within the target and in adjacent organs at risk. Results of such planning studies show that IMRT improves on 3D-CRT with respect to conformality to, and dose homogeneity within, the target. Dosimetry using stationary targets generally confirms these predictions. Thus, radiation oncologists hypothesized that IMRT may improve treatment outcomes compared with those of 3D-CRT. However, these types of studies offer indirect evidence on treatment benefit from IMRT, and it is difficult to relate results of dosing studies to actual effects on health outcomes.

Comparative studies of radiation-induced side effects from IMRT versus alternative radiation delivery are probably the most important type of evidence in establishing the benefit of IMRT. Such studies would answer the question of whether the theoretical benefit of IMRT in sparing normal tissue translates into real health outcomes. Single-arm series of IMRT can give some insights into the potential for benefit, particularly if an adverse effect that is expected to occur at high rates is shown to decrease by a large amount. Studies of treatment benefit are also important to establish that IMRT is at least as good as other types of delivery, but in the absence of such comparative trials, it is likely that benefit from IMRT is at least as good as with other types of delivery.

Summary

For individuals who have breast cancer who receive IMRT, the evidence includes randomized controlled trials and nonrandomized comparative studies. Relevant outcomes are overall survival, disease-specific survival, 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 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 radiotherapy is now delivered by 3D-CRT, these comparative data are of limited value. Studies comparing IMRT with 3D-CRT include a nonrandomized comparative study on whole-breast IMRT. This study suggested that IMRT might improve short-term clinical outcomes. Longer follow-up is needed to evaluate the effect of partial-breast IMRT on recurrence and survival. No studies have reported on health outcomes after IMRT for chest wall irradiation in postmastectomy

breast cancer patients. Available studies have only focused on treatment planning and techniques. However, when dose-planning studies have indicated that radiotherapy will lead to unacceptably high radiation doses, 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.

For individuals who have lung cancer who receive IMRT, the evidence includes nonrandomized, retrospective, comparative studies. Relevant outcomes are overall survival, disease-specific survival, 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 and reduce toxicity. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Policy History

Date	Action
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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