Medical Policy
Intensity-Modulated Radiotherapy - IMRT of the Breast and Lung

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- Policy: Medicare
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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 BlueSM 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:

<table>
<thead>
<tr>
<th>Adjacent Tissue</th>
<th>Dose/Volume Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart</td>
<td>&gt;=25% of heart &gt;=30 Gy</td>
</tr>
<tr>
<td>Lung</td>
<td>&gt;=30% of ipsilateral lung &gt;=20 Gy OR &gt;=20% of combined lung volume &gt;=20 Gy</td>
</tr>
<tr>
<td>Skin/Chest wall/Soft tissue</td>
<td>&gt;=5% of intended breast &gt;=7% of prescribed dose OR Medical lesion where &gt;=10% of contralateral breast &gt;=10 Gy</td>
</tr>
</tbody>
</table>
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:

<table>
<thead>
<tr>
<th>Adjacent Tissue</th>
<th>Dose/Volume Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart</td>
<td>&gt;= 50% of heart &gt;= 30Gy</td>
</tr>
<tr>
<td>Lung</td>
<td>&gt;= 30% of non-cancerous combined lung volume &gt;=20 Gy</td>
</tr>
</tbody>
</table>

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**.

<table>
<thead>
<tr>
<th>Outpatient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
</tr>
<tr>
<td>Commercial PPO and Indemnity</td>
</tr>
<tr>
<td>Medicare HMO BlueSM</td>
</tr>
<tr>
<td>Medicare PPO BlueSM</td>
</tr>
</tbody>
</table>

**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

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

### HCPCS Codes

<table>
<thead>
<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G6015</td>
<td>Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic mlc, per treatment session</td>
</tr>
<tr>
<td>G6016</td>
<td>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</td>
</tr>
</tbody>
</table>

**Description**

For certain stages of many cancers, including breast and lung, randomized controlled trials 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**

**Conventional External-Beam Radiotherapy**

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 treatment planning, based on flat images and radiation beams with cross-sections of uniform intensity that were sequentially aimed at the tumor along two or three intersecting axes. Collectively, these methods are termed *conventional external-beam radiotherapy*.

**Three-Dimensional Conformal Radiotherapy**

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 3D-CRT.

**Intensity-Modulated Radiotherapy**
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.

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 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.

**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 randomized controlled trials and nonrandomized comparative studies. The relevant outcomes are overall survival, disease-
specific survival, quality of life, and treatment-related morbidity. There is modest evidence from randomized controlled trials for a decrease in acute skin toxicity with IMRT compared with 2-dimensional 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 one randomized controlled trial comparing IMRT with deep inspiration breath hold to 3D-CRT, two nonrandomized comparative studies on whole-breast IMRT, and a few studies on chest wall IMRT. These studies suggest that IMRT require less radiation exposure to nontarget areas and may improve short-term clinical outcomes. The available studies on the 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.

Strong 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.

Clinical vetting also provided strong support for IMRT when alternative RT dosimetry exceeds a threshold of 20-gray 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%).

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>8/2017</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
<tr>
<td>10/2016</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
<tr>
<td>9/2016</td>
<td>Clarified coding information.</td>
</tr>
<tr>
<td>2/2016</td>
<td>Local Coverage Determination (LCD) for Intensity Modulated Radiation Therapy (IMRT) (L3244) removed. 2/1/2016</td>
</tr>
<tr>
<td>11/2015</td>
<td>Added coding language.</td>
</tr>
<tr>
<td>1/2015</td>
<td>Clarified coding information.</td>
</tr>
<tr>
<td>8/2014</td>
<td>Clinical exception and notification clarified.</td>
</tr>
<tr>
<td>6/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
</tr>
<tr>
<td>6/2013</td>
<td>New references from BCBSA National medical policy.</td>
</tr>
</tbody>
</table>
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

References


