

EFFECTIVE DATE: 02 | 15 | 2016

POLICY LAST UPDATED: 01 | 06 | 2015

OVERVIEW

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 RT that allows adequate RT to the tumor while minimizing the radiation dose to surrounding normal tissues and critical structures.

MEDICAL CRITERIA

BlueCHiP for Medicare and Commercial Products

Breast

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

- Significant cardiac radiation exposure cannot be avoided using alternative radiation techniques;
 - IMRT dosimetry demonstrates significantly reduced cardiac target volume radiation exposure
 - The target volume coverage results in cardiac radiation exposure that is expected to be greater than or equal to 25 Gy to 10 cm³ or more of the heart ($V_{25} \geq 10 \text{ cm}^3$) with 3D-CRT, despite the use of a complex positioning device (such as Vac-Lok™), **and**
 - With the use of IMRT, there is a reduction in the absolute heart volume receiving 25 Gy or higher by at least 20% (eg, volume predicted to receive 25 Gy by 3D RT is 20 cm³, and the volume predicted by IMRT is $\leq 16 \text{ cm}^3$).

IMRT may be considered medically necessary in individuals with large breasts, greater than 500 cm³ when the following criteria is met;

- Treatment planning with 3-dimensional (3D) conformal results in hot spots (focal regions with dose variation greater than 10% of target), and;
- The hot spots are able to be avoided with IMRT

Lung

Intensity-Modulated Radiotherapy of the Lung is considered medically necessary when the following criteria is met:

- Radiotherapy is being given with curative intent
- 3D conformal wall expose $>35\%$ of normal lung tissue to more than 20 Gy dose-volume (V_{20})
- IMRT dosimetry demonstrates reduction in the V_{20} to at least 10% below the V_{20} that is achieved with the 3D plan (eg, from 40% down to 30% or lower)

PRIOR AUTHORIZATION

BlueCHiP for Medicare and Commercial Products

Prior authorization is recommended and obtained via the online tool for participating providers.

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Products

Breast

Intensity-modulated radiotherapy (IMRT) may be considered medically necessary when the criteria above has been met.

IMRT of the breast is considered not medically necessary as a technique of partial-breast irradiation after breast conserving surgery and for IMRT of the chest wall as a technique of post-mastectomy irradiation because there is insufficient peer-reviewed scientific literature that demonstrates that the service is effective.

Lung

Intensity-modulated radiotherapy (IMRT) may be considered medically necessary when the criteria above has been met

IMRT is considered not medically necessary as a technique to deliver radiation therapy in patients receiving palliative treatment for lung cancer because conventional radiation techniques are adequate for palliation.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement, or Benefit Booklet for radiology benefit/coverage.

BACKGROUND

For certain stages of many cancers, including breast and lung, randomized controlled trials (RCTs) have shown that postoperative 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.

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 how it conforms 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 adverse 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.

For the treatment of breast cancer, based on randomized and nonrandomized comparative studies, whole-breast IMRT appears to produce clinical outcomes comparable with that of 3D-CRT. In addition, there is some evidence for decrease in acute skin toxicity with IMRT compared with 2D-RT. Dosimetry studies have demonstrated that IMRT reduces inhomogeneity of radiation dose, thus potentially providing a mechanism for reduced skin toxicity. One randomized controlled trial reported improvements in moist desquamation of skin, but did not report differences in grade 3 to 4 skin toxicity, pain symptoms, or quality of life. Another RCT reported no differences in cosmetic outcome at 2 years for IMRT compared with 2D-RT. There was strong support through clinical vetting for the use of IMRT in breast cancer for left sided breast lesions in which alternative types of RT cannot avoid toxicity to the heart. Based on the available evidence and results of input from clinical vetting, in conjunction with a strong indirect chain of evidence and the potential to reduce harms, IMRT may be considered medically necessary for whole breast irradiation when (1) alternate forms of RT cannot avoid cardiac toxicity and (2) IMRT dose planning demonstrates a substantial reduction in cardiac toxicity.

Studies on IMRT for partial-breast irradiation are limited and have not demonstrated improvements in health outcomes and is considered not medically necessary.

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. The risk of secondary lung cancers and cardiac toxicity needs to be further evaluated. Therefore, IMRT for chest wall

irradiation in postmastectomy breast cancer patients is considered not medically necessary as it has not demonstrated improvements in health outcomes.

For the treatment of lung cancer, based on nonrandomized comparative studies, IMRT appears to produce clinical outcomes comparable with that of 3D-CRT. Dosimetry studies report that IMRT can reduce radiation exposure to critical surrounding structures, especially in large lung cancers. Results of clinical vetting indicate 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. As a result of available evidence and clinical vetting, in conjunction with a strong indirect chain of evidence and potential to reduce harms, IMRT of the lung may be considered medically necessary for lung cancer when: (1) RT is given with curative intent, (2) alternate RT dosimetry demonstrates radiation dose exceeding 20 Gy dose-volume (V20) for at least 35% of normal lung tissue, and (3) IMRT reduces the 20-Gy dose-volume (V20) of radiation to the lung at least 10% below the V20 of 3D-CRT (e.g., 40% reduced to 30%).

IMRT for the palliative treatment of lung cancer is considered not medically necessary because conventional radiation techniques are adequate for palliation.

Practice Guidelines and Position Statements

The current National Comprehensive Cancer Network (NCCN) guidelines for breast cancer indicate that for whole-breast irradiation, uniform dose distribution and minimization of toxicity to normal tissue are the objectives and list various approaches to achieve this, including IMRT. The guidelines note accelerated partial-breast irradiation is generally considered investigational and should be limited to use in clinical trials. Additionally, IMRT is not mentioned as a technique in partial-breast irradiation. 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. Current NCCN guidelines for non-small-cell lung cancer indicate that “more advanced technologies are appropriate when needed to deliver curative radiation therapy safely. These technologies include (but are not limited to) IMRT. Nonrandomized comparisons of using advanced technologies versus older techniques demonstrate reduced toxicity and improved survival.”

The current NCCN guidelines for small cell lung cancer indicate “use of more advanced technologies is appropriate when needed to deliver adequate tumor dose while respecting normal tissue dose constraints.” IMRT is included in the technologies listed.

The American Society for Radiation Oncology published consensus guidance on radiation to the lung in 2010. The guidance recommends limiting the 20-Gy dose-volume of radiation to the lung to less than or equal to between 30% to 35% or less and mean lung dose to 20 to 23 or less Gy (with conventional fractionation) to reduce the risk of radiation pneumonitis to 20% or less.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers. Some local medical review policies, published by Medicare Part B carriers, have indicated that IMRT for the lung is considered medically necessary. These documents do not provide a detailed rationale for this conclusion.

CODING

BlueCHiP for Medicare and Commercial Products

A4648 Tissue marker, implantable, any type, each (Note: This code is not separately reimbursed for institutional providers.)

Note: To ensure correct pricing of HCPC code **A4648** for the Calypso 4D localization system, the procedure/clinical notes and the invoice must be submitted.

The following codes are covered for BlueCHiP for Medicare and commercial products when the criteria above is met:

Intensity-modulated radiation therapy

77301:

77338:

77385: Use alternate procedure code (G6015)

77386: Use alternate procedure code (G6015)

G6015: Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session (effective 1/1/2015)

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 (effective 1/1/2015)

RELATED POLICIES

None

PUBLISHED

Provider Update, February 2016

Provider Update, October 2015

Provider Update, August 2014

Provider Update, April 2012

Provider Update, September 2011

Provider Update, January 2010

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