Medical Coverage Policy | Intensity-Modulated Radiotherapy of the Breast and Lung

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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 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 (V25 ≥10 cm3) 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% (e.g., volume predicted to receive 25 Gy by 3D RT is 20 cm_3, and the volume predicted by IMRT is ≤16 cm_3).

IMRT may be considered medically necessary in individuals with large breasts, greater than 500 cm_3 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 (V20); and
- IMRT dosimetry demonstrates reduction in the V20 to at least 10% below the V20 that is achieved with the 3D plan (e.g., 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 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 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 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 3D 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 conformal radiation therapy (3D-CRT).

Intensity-Modulated Radiotherapy
Intensity-modulated radiotherapy, which uses computer software and CT 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. 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's 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 development has produced advanced techniques that may further improve RT treatment by improving dose distribution. These techniques are considered variations of IMRT. Volumetric modulated arc therapy (VMAT) involves delivery of radiation from a continuous rotation of the radiation source. The principal advantage of VMAT 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.

Multiple-dose planning studies generate 3-dimensional conformal radiotherapy (3D-CRT) and intensity modulated radiotherapy (IMRT) treatment plans from the same scans, and then compare predicted dose distributions within the target area and adjacent organs. Results of such planning studies show that IMRT improves on 3D-CRT with respect to conformality to, and dose homogeneity within, the target. They also demonstrate less radiation exposure to nontarget areas. Dosimetry studies using stationary targets generally confirm these predictions. However, because patients move during treatment, dosimetry with stationary targets only approximate actual radiation doses received. Based on these dosimetry studies, radiation oncologists expect IMRT to improve treatment outcomes compared with those of 3D-CRT. However, these types of studies offer only 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 would constitute definitive evidence in establishing the benefit of IMRT. 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.

In general, when the indication for IMRT is to avoid radiation to sensitive areas, dosimetry studies have been considered sufficient evidence to demonstrate that harm would be avoided by using IMRT. For other indications for IMRT, such as using IMRT to provide better tumor control, comparative studies of health outcomes are needed to demonstrate such a benefit.

For individuals with breast cancer who receive IMRT, relevant outcomes are overall survival, disease progression, quality of life, and treatment-related morbidity. Studies on IMRT compared to 3D-CRT include one randomized controlled trial (RCT) on partial breast IMRT and one nonrandomized comparative study on whole-breast IMRT. These studies suggest that IMRT may 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. The risk of secondary lung cancers and cardiac toxicity needs to be further evaluated. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with lung cancer who receive IMRT, the evidence includes nonrandomized, retrospective, comparative studies. Relevant outcomes are overall survival, disease progression, quality of life, and treatment-related morbidity. Dosimetry studies report that IMRT can reduce radiation exposure to critical surrounding structures, especially in large lung cancers. However, based on nonrandomized comparative studies, IMRT appears to produce clinical outcomes comparable with that of 3D-CRT. Interpretation is limited by the potential for bias in treatment assignment and/or change in treatments over time in these

retrospective studies. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 state that "greater target dose homogeneity and sparing of normal tissues can be accomplished using compensators such as wedges, forward planning using segments, and IMRT. 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 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 (effective date 1/1/2015)
77386 Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex (effective date 1/1/2015)
G6015 Intensity modulated treatment delivery (IMRT), 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, November 2016
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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