

## Corporate Medical Policy

# Intensity Modulated Radiation Therapy (IMRT) of Breast and Lung

<b>File Name:</b>	intensity_modulated_radiation_therapy_imrt_of_breast_and_lung
<b>Origination:</b>	11/2009
<b>Last CAP Review:</b>	8/2011
<b>Next CAP Review:</b>	8/2012
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### Description of Procedure or Service

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For certain stages of many cancers, including breast and lung, randomized clinical 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. Over the past several decades, methods to plan and deliver radiation therapy have evolved in ways that permit more precise targeting of tumors with complex geometries. The relevant trials on breast and lung cancers were done before contemporary radiation therapy methods evolved. They used two-dimensional 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).

Treatment planning first evolved by using 3-dimensional images, usually from computed tomography (CT) scans, to delineate the tumor, its boundaries with adjacent normal tissue, and organs at risk for radiation damage. Radiation oncologists used these images, displayed from a “beam’s-eye view,” to shape each of several beams (e.g., with compensators, blocks, or wedges) to conform to the patient’s tumor geometry perpendicular to the beam’s axis. 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. However, “forward” planning used a trial and error process to select treatment parameters (the number of beams and the intensity, shape, and incident axis of each). The planner/therapist modified one or more parameters and re-calculated dose distributions, if analysis predicted underdosing for part of the tumor or overdosing of nearby normal tissue. Furthermore, since beams had uniform cross-sectional intensity wherever they bypassed shaping devices, it was difficult to match certain geometries (e.g., concave surfaces). Collectively, these methods are termed 3-dimensional conformal radiation therapy (3D-CRT).

Over the past decade, other methods were developed to permit beam delivery with non-uniform cross-sectional intensity. This often relies on a device (a multi-leaf collimator, MLC) situated between the beam source and patient, that moves along an arc around the patient. As it moves, a computer varies aperture size independently and continuously for each leaf. Thus, MLCs divide beams into narrow “beamlets,” with intensities that range from zero to 100% of the incident beam. With an alternative, termed tomotherapy, a small radiation portal emitting a single narrow beam moves spirally around the patient, with intensity varying as it moves. Each method (MLC-based or tomotherapy) is coupled to a computer algorithm for “inverse” treatment planning. The planner/radiotherapist 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 and shape of beam

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ports, and beam and beamlet intensities, to achieve the treatment plan's goals. Collectively, these methods are termed intensity-modulated radiation therapy (IMRT).

Multiple 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 by one or more of the following mechanisms.

Increased conformality may permit escalated tumor doses without increasing normal tissue toxicity, and may thus improve local tumor control. Better dose homogeneity within the target may also improve local tumor control by avoiding underdosing (cold spots) within the tumor and may decrease toxicity by avoiding overdosing (hot spots). Finally, enhanced conformality for standard doses may reduce dose outside the target volume and thus decrease toxicity.

However, IMRT aims radiation at the tumor from many more directions, and thus subjects more normal tissue to low-dose radiation than occurs with conventional EBRT or 3D-CRT. This may increase late effects of radiation therapy. In addition, since breast and lung 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. Testing this hypothesis requires direct comparative data on outcomes for separate groups of similar patients treated with each method.

***\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

## Policy

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**BCBSNC will not provide coverage for Intensity Modulated Radiation Therapy (IMRT) of the breast and lung. It is considered investigational and/or not medically necessary. BCBSNC does not cover investigational and/or not medically necessary services.**

## Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

## When Intensity Modulated Radiation Therapy (IMRT) of the breast and lung is covered

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Not applicable.

## When Intensity Modulated Radiation Therapy (IMRT) of the breast and lung is not covered

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# Intensity Modulated Radiation Therapy (IMRT) of Breast and Lung

Intensity-modulated radiation therapy (IMRT) is considered **not medically necessary** as a technique to deliver whole breast irradiation in patients receiving treatment for breast cancer after breast-conserving surgery, because the clinical outcomes with this treatment have not been shown to be superior to other approaches such as 3D-conformal radiation therapy, yet IMRT is generally more costly than these alternatives.

Intensity modulated radiation therapy (IMRT) of the breast is considered **investigational**, as a technique of partial breast irradiation after breast-conserving surgery.

Intensity-modulated radiation therapy (IMRT) is considered **not medically necessary** as a technique to deliver radiation therapy in patients receiving treatment for lung cancer, because the clinical outcomes with this treatment have not been shown to be superior to other approaches such as 3D-conformal radiation therapy, yet IMRT is generally more costly than these alternatives.

## Policy Guidelines

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Existing non-randomized comparative studies indicate that IMRT is similar but not superior to 3D-CRT for improving health outcomes of patients with either breast or lung cancers.

## Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: 77301, 77338, 77418, 0073T*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## Scientific Background and Reference Sources

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Donovan E, Bleakley N, Denholm E et al. Randomised trial of standard 2D radiotherapy (RT) versus intensity modulated radiotherapy (IMRT) in patients prescribed breast radiotherapy. *Radiother Oncol* 2007; 82(3):254-64.

Selvaraj RN, Beriwal S, Pourarian RJ et al. Clinical implementation of tangential field intensity modulated radiation therapy (IMRT) using sliding window technique and dosimetric comparison with 3D conformal therapy (3DCRT) in breast cancer. *Med Dosim* 2007; 32(4):299-304.

Leonard C, Carter D, Kercher J et al. Prospective trial of accelerated partial breast intensity-modulated radiotherapy. *Int J Radiat Oncol Biol Phys* 2007; 67(5):1291-8.

Pignol JP, Olivetto I, Rakovitch E et al. A multicenter randomized trial of breast intensity-modulated radiation therapy to reduce acute radiation dermatitis. *J Clin Oncol* 2008; 26(13):2085-92.

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McDonald MW, Godette KD, Butker EK, et al. Long-term outcomes of IMRT for breast cancer: a single-institution cohort analysis. *Int J Radiat Oncol Biol Phys* 2008; 72(4):1031-40.

Sura S, Gupta V, Yorke E et al. Intensity-modulated radiation therapy (IMRT) for inoperable non-small cell lung cancer: the Memorial Sloan-Kettering Cancer Center (MSKCC) experience. *Radiother Oncol* 2008; 87(1):17-23.

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.46, 4/24/09

Specialty Matched Consultant Advisory Panel 5/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.46, 5/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.46, 10/8/10

Specialty Matched Consultant Advisory Panel 8/2011

## Policy Implementation/Update Information

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- 12/21/09 New policy issued. BCBSNC will not provide coverage for intensity modulated radiation therapy (IMRT) of the breast or lung. IMRT of the breast is considered investigational, including, but not limited to its use as a technique of partial breast irradiation or as an alternative to whole breast irradiation after breast-conserving surgery. IMRT of the lung is considered investigational, including, but not limited to, its use as a technique of dose escalation in the treatment of lung cancer. Notification given 12/21/09. Effective date 3/30/10. (adn)
- 6/22/10 Specialty Matched Consultant Advisory Panel 5/24/10. Policy statement change—added statement under “When not covered” section indicating “Intensity-modulated radiation therapy (IMRT) is considered **not medically necessary** as a technique to deliver whole breast irradiation in patients receiving treatment for breast cancer after breast conserving surgery and in patients receiving treatment for lung cancer.” Also added statement under “When not covered” section indicating “Intensity-modulated radiation therapy (IMRT) is considered **not medically necessary** as a technique to deliver radiation therapy in patients receiving treatment for lung cancer, because the clinical outcomes with this treatment have not been shown to be superior to other approaches such as 3D-conformal radiation therapy, yet IMRT is generally more costly than these alternatives.” References added. (lpr)
- 8/17/10 Under “when not covered section: removed the phrase “including but not limited to its use” within the statement “ IMRT of the breast is considered investigational as a technique of partial breast irradiation after breast-conserving surgery”. (lpr)
- 9/13/11 Specialty Matched Consultant Advisory Panel review 8/31/2011. No changes to the policy statement. (lpr)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.