

Corporate Medical Policy

Intensity Modulated Radiation Therapy (IMRT) of the Chest

File Name:	intensity_modulated_radiation_therapy_imrt_of_the_chest
Origination:	11/2009
Last CAP Review:	5/2019
Next CAP Review:	5/2020
Last Review:	5/2019

Description of Procedure or Service

Radiation therapy is an integral component in the treatment of the chest, including breast and lung cancers. Intensity modulated radiation therapy (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 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.

Radiation techniques

2D external beam radiation

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. Most early trials 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 2D external beam radiation therapy (EBRT).

3-dimensional conformal radiation (3D-CRT) 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 radiation therapy (IMRT)

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 computer software optimizes the location, shape and intensities of the beams ports, to achieve the treatment plan’s goals.

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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 under-dosing within the tumor and may decrease toxicity by avoiding overdosing.

Since 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.

Methodological 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.

Related Policies:

Intensity Modulated Radiation Therapy (IMRT) of the Prostate
Intensity Modulated Radiation Therapy (IMRT) of the Head and Neck
Intensity Modulated Radiation Therapy (IMRT) of the Abdomen and Pelvis
Intensity Modulated Radiation Therapy (IMRT) of the Central Nervous System
Intensity Modulated Radiation Therapy (IMRT) for Sarcoma of the Extremities
Maximum Units of Service

*****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

BCBSNC will provide coverage for Intensity Modulated Radiation Therapy (IMRT) of the chest when the criteria below are met.

Benefits Application

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.

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When Intensity Modulated Radiation Therapy (IMRT) of the chest is covered

Intensity-modulated radiation therapy (IMRT) may be considered medically necessary as a technique to treat breast cancer when at least one of the following four conditions (A, B, C, or D) is met:

- A. For members receiving treatment to the whole left breast for left-sided breast cancer after breast conserving surgery:
 - 1. When cardiac toxicity cannot be avoided by alternative radiation techniques; **AND**
 - 2. IMRT dosimetry for a set of beams beyond traditional “opposed tangents” demonstrates reduced cardiac toxicity. (See policy guidelines).
- B. For members with large breast volume:
 - 1. When treatment planning with 3D conformal, including the use of wedges and field-in-field techniques, and the use of higher photon energies (e.g. 10-16 MV), results in hot spots (focal regions with dose variation greater than 10% of target); **AND**
 - 2. The hot spots are able to be avoided by adding additional beam orientations (i.e. beyond tangents) with IMRT. (See policy guidelines).
- C. For members with recurrent tumors that have been previously irradiated, with or without an intact breast:
 - 1. When treatment planning with 3D conformal (including the use of wedges and field-in-field techniques, and the use of higher photon energies (e.g. 10-16 MV) results in unsafe doses to the lung, heart or other adjacent structures; **AND**
 - 2. IMRT dosimetry for a set of beams beyond traditional “opposed tangents” (with or without a separate field directed to the medial chest wall) demonstrates reduced risk of toxicity to those adjacent structures. (See policy guidelines).
- D. For members with target tissues that include the far medial chest wall, internal mammary nodal area or sternum, with or without an intact breast:
 - 1. When treatment planning with 3D conformal (including the use of wedges and field-in-field techniques, and the use of higher photon energies (e.g. 10-16 MV) results in unsafe doses to the lung, heart or other adjacent structures; **AND**
 - 2. IMRT dosimetry for a set of beams with orientations beyond traditional “opposed tangents” (with or without a separate field directed to the medial chest wall) demonstrates reduced risk of toxicity to those adjacent structures. (See policy guidelines).

Intensity-modulated radiation therapy (IMRT) may be considered medically necessary as a technique to deliver radiation therapy in patients with lung cancer, thoracic esophageal cancer or cancer of the gastroesophageal junction, thoracic lymphoma, or sarcoma when criteria under A. and B. have been met:

- A. Radiation therapy with curative intent is to be administered for a locally advanced intra-thoracic malignancy; **OR** the patient has had prior radiation in close proximity to the target, requiring modulation to decrease the dose to previously irradiated volumes.

AND

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B. Techniques are employed to consider and address intra-fraction motion during radiation delivery. (See Policy Guidelines).

When Intensity Modulated Radiation Therapy (IMRT) of the chest is not covered

Intensity modulated radiation therapy (IMRT) of the chest and thoracic esophagus is considered **not medically necessary** when the above criteria are not met.

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) of the chest wall is considered **investigational** as a technique of routine adjuvant post-mastectomy irradiation when the above criteria are not met.

Intensity-modulated radiation therapy (IMRT) is considered **not medically necessary** as a technique to deliver radiation therapy in patients receiving palliative treatment for lung cancer.

Policy Guidelines

The following clinical guidelines may be used with IMRT in **left-sided breast lesions**:

1. The target volume coverage results in cardiac radiation exposure that is expected to be greater than or equal to 25 Gy to 10 cc or more of the heart (V25 greater than or equal to 10 cc) with 3D conformal RT despite the use of a complex positioning device (such as breath hold technique or Vac-Lok™). The same CT dataset must be used for 3D and IMRT planning; (for example, one can- not use breath hold scan for IMRT plan and non-breath hold for 3D CRT plan).
2. 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 cc and the volume predicted by IMRT is 16 cc or less).
3. Treatment is being delivered to the whole breast through orientations beyond traditional tangents. In other words, IMRT is **not** justified for cardiac avoidance in the setting of “opposed tangents” as such cardiac sparing can often be readily achieved with techniques such as conformal blocking, alternative positioning and respiratory based techniques (e.g. breath-hold). The utility of IMRT with regard to cardiac sparing is only achieved when there are multiple beam orientations used beyond the standard “opposed tangent.”

The following additional clinical guidelines may be used with IMRT for **left-sided or right-sided breast lesions with a large breast volume, or recurrent tumors, or targets that include the far medial chest wall/internal mammary/sternal region**:

1. The target volume is large and includes an enlarged internal mammary node.
2. Traditional conformal radiation fields results in a lung V20 that exceeds 35%, and/or the heart V25 exceeds 10 cc, and/or the target dose heterogeneity exceeds 18%.
3. The use of a separate anterior electron (or mixed photon/electron) field to cover the medial chest wall and internal mammary nodal area is not practical since the target depth is too great, or the target is too wide, so there is too much lung potentially in the exit from an anterior field.
4. With the use of IMRT, there is a reduction in the absolute lung volume receiving >20 Gy of >10% (e.g. a reduction from 35% to 25%), **OR**, the absolute heart volume receiving 25 Gy or

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higher is reduced by at least 20% (e.g., volume predicted to receive 25 Gy by 3D RT is 20 cc and the volume predicted by IMRT is 16 cc or less), **OR**, the target dose heterogeneity is reduced by an absolute 8% (e.g. hot spot reduced from 118% to 110%).

5. Treatment is being delivered through orientations beyond traditional tangents (with or without a separate field directed to the medical chest wall). In other words, IMRT is **not** justified in the setting of “opposed tangents” or “opposed tangents” with an anterior field to cover the medial chest. The utility of IMRT with regard to reducing lung or heart doses, and in reducing hot spots, is largely achieved when there are multiple beam orientations used beyond the standard orientations.

IMRT delivery for lung and thoracic esophageal cancers that move during therapy can lead to dosimetric uncertainties, and care thus must be taken to assess the degree of motion and consider the risk for dosimetric uncertainties.

IMRT for the palliative treatment of lung cancer is considered **not medically necessary** since 2D radiation techniques are adequate for palliation.

CPT 77338 is reported once per IMRT plan and is limited to 3 units per 60 day treatment course.

Billing/Coding/Physician Documentation Information

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. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 77301, 77338, 77385, 77386, G6015, G6016

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

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.

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.

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Chun SG, Hu C, Choy H, et al. Impact of intensity-modulated radiation therapy technique for locally advanced non-small-cell lung cancer: a secondary analysis of the NRG Oncology RTOG 0617 randomized clinical trial. J Clin Oncol. Jan 2017;35(1):56-62. PMID 28034064
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Mosvas B, Chen H, et al. Quality of Life Analysis of a Radiation Dose-Escalation Study of Patients With NSCLC: A Secondary Analysis of the Radiation Therapy Oncology Group 0617 Randomized Clinical Trial. JAMA Oncol. 2016; 2(3): 359-367.
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Medical Director review 7/2018
Specialty Matched Consultant Advisory Panel 5/2019

Policy Implementation/Update Information

For Policy Titled: Intensity Modulated Radiation Therapy (IMRT) of the Breast and Lung

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,

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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)
- 11/13/12 Extensive revisions to entire policy including Description, When Not Covered, When Covered and Policy Guidelines sections. Policy statement under “When Covered” section on breast and lung IMRT changed from not medically necessary to may be considered medically necessary. Under “When Not Covered” section: policy statement added indicating chest wall IMRT routine adjuvant post-mastectomy is investigational. Partial breast irradiation remains investigational. Reference added. Specialty Matched Consultant Advisory Panel review 8/15/12. (lpr) 6/11/13 Specialty Matched Consultant Advisory Panel review 5/15/2013. No change to policy statement. Reference added. (lpr)
- 7/29/14 Specialty matched consultant advisory panel review meeting 6/24/2014. No change to policy statement. Reference added. (lpr)

For Policy Re-Titled: Intensity Modulated Radiation Therapy (IMRT) of the Chest

- 12/30/14 Under “When Covered” section added thoracic esophageal cancer as a covered indication. Changed the title of the policy to: IMRT of the Chest from: IMRT of the Breast and Lung. Added CPT codes 77385, 77386 and HCPCS codes G6015, G6016: Deleted CPT codes 77418, 0073T from Billing/Coding section effective 1/1/2015 for code update. Senior medical director review 11/2014. (lpr)
- 3/31/15 Corrected HCPCS code G6016 in “Billing/Coding” section. (lpr)
- 7/1/15 Under Policy Guidelines section added the statement: “CPT 77338 is reported once per IMRT plan and is limited to 3 units per 60 day treatment course.” Also added “Maximum Units of Service” to Related Policies under Description section. Reference added. Specialty Matched Consultant Advisory Panel review 5/27/2015. No change to policy statement. (lpr)
- 4/1/16 Under “When Covered” section for lung and thoracic esophageal cancer: added bullet #4 in Section B to address sparing the normal esophagus : “3D conformal will expose >17% of the esophagus to more than 60 Gy (V60); and IMRT dosimetry demonstrates an absolute reduction in the V60 to at least 10% below the V60 that is achieved with the 3D plan (e.g. from 20% down to 10%).” Changed statement in bullet #3 to read “reduction in the V30 to at least 10% instead of 15%.” Under “When Covered” section bottom of page 3 added: thoracic lymphoma as covered indication to statement of coverage for lung and thoracic esophageal cancer and also added cancer of the (GE) gastroesophageal junction as covered

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- indication. Senior Medical Director review 3/2016. Specialty Matched Consultant Advisory Panel review. Notification given 4/1/16 for effective date 5/31/16. (lpr)
- 5/31/16 Specialty Matched Consultant Advisory Panel review 5/25/16. No change to policy statement. (lpr)
- 7/1/16 Added sarcoma as medically necessary diagnosis under “When Covered” section page 3, “Intensity-modulated radiation therapy (IMRT) may be considered medically necessary as a technique to deliver radiation therapy in patients with lung cancer, thoracic esophageal cancer or cancer of the gastroesophageal junction, thoracic lymphoma, or sarcoma when **all** (A, B, and C) of the following conditions have been met.” Senior Medical Director approved March 2016. (lpr)
- 6/30/17 Specialty Matched Consultant Advisory Panel review 5/31/17. No change to policy statement. Reference added. (lpr)
- 8/25/17 Reference added. No change to policy statement. (lpr)
- 2/9/18 Revisions: Under “When Covered” section: for section under IMRT in patients with lung cancer, thoracic esophageal cancer or cancer of the gastroesophageal junction, thoracic lymphoma, or sarcoma when criteria under A. and B. have been met: A.Radiation therapy with curative intent is to be administered for a locally advanced intra-thoracic malignancy; **OR** The patient has had prior radiation in close proximity to the target, requiring modulation to decrease the dose to previously irradiated volumes; **AND B.**Techniques are employed to consider and address intra-fraction motion during radiation delivery. Under same section: removed statements #1-4 under B and re-numbered statement #5 as #1. References added. Senior Medical Director review 1/2018. (lpr)
- 8/10/18 Specialty Matched Consultant Advisory Panel review 5/2018. No changes to policy statements. Changed “conventional” to “2D” throughout the policy. Medical Director review 5/2018. (mco)
- 8/24/18 Corrected typo/spelling in Policy Guidelines. No change to policy statement. (lpr)
- 5/28/19 Specialty Matched Consultant Advisory Panel review 5/15/2019. No change to policy statement. (lpr)

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