

National Imaging Associates, Inc.*	
Clinical guidelines: BREAST CANCER	Original Date: March 2011
Radiation Oncology	Last Revised Date: February 2020
Guideline Number: NIA_CG_120	Implementation Date: January 2021

INDICATIONS FOR RADIATION THERAPY AND TREATMENT OPTIONS:

This guideline outlines several methods suitable for the employment of radiation therapy in conjunction with breast cancer treatment. These include the use of three-dimensional conformal radiation therapy (3D-CRT), intensity-modulated radiation therapy (IMRT), image guided radiation therapy (IGRT) and internal radiation (brachytherapy). IMRT is not indicated as a standard treatment option for breast cancer but may be indicated for selected cases of breast cancer with close proximity to critical structures. Most external beam treatments are delivered using a high energy linear accelerator. Brachytherapy is generally delivered using temporary HDR sources such as 192-Iridium (192-Ir) or Cesium-137 (137-Cs).

Whole Breast Radiation (NCCN, 2018; Smith, 2018)

Three-dimensional conformal radiation therapy (3D-CRT) is the appropriate technique for treatment of the whole breast following breast conserving surgery (lumpectomy, breast conservation surgery). Electron beam or photon beam are the most commonly used techniques for delivering boost radiotherapy.

Dosage Guidelines

- 45-50.4 Gy up to 28 fractions with boost 59-66.4 Gy up to 37 fractions
- Hypofractionated radiation therapy is considered medically necessary with 40-45 Gy at 2.66 Gy per fraction in 15 to 16 fractions.

Partial Breast Irradiation (Correa, 2017)

Accelerated partial breast irradiation (APBI) may be considered as the sole form of radiation therapy, in lieu of whole breast radiation following lumpectomy for selected cases. Patients with a small tumor, clear surgical margins after lumpectomy, and no lymph nodes containing cancer are typically eligible for APBI. APBI is considered appropriate for patients who meet all of the following criteria:

- Age 50 or older
- No use of adjuvant chemotherapy
- Lymph nodes negative

* National Imaging Associates, Inc. (NIA) is a subsidiary of Magellan Healthcare, Inc.

- Negative surgical margins
- Tumor size less than or equal to 3 cm (including ductal carcinoma in situ)
- Clinically or microscopically unifocal
- Absence of BRCA in 1/2 mutation, if applicable

Dosage Guidelines

- Appropriate fractionation schemes for APBI are 34 Gy in 10 fractions delivered twice per day with brachytherapy or 38.5Gy in 10 fractions twice per day with external beam photon therapy

Chest Wall Radiation (NCCN, 2018)

Three-dimensional conformal radiation therapy (3D-CRT) is the appropriate technique for treatment of the chest wall following mastectomy. Electron beam or photon beam are the most commonly used techniques for delivering boost radiotherapy.

Dosage Guidelines

- 45-50.4 Gy up to 28 fractions with boost 59-66.4 Gy up to 37 fractions

Other Considerations

- Re-irradiation following local or regional recurrence after prior mastectomy and prior breast or chest wall radiation may be appropriate.
- For inflammatory breast cancer, whole breast or chest wall radiation, consider nodal radiation with or without chest wall boost.

Dosage Guidelines

- 45-50.4 Gy up to 28 fractions with boost 59-66.4 Gy up to 37 fractions. *Standard radiation fractionation consists of 1.8 Gy to 2.0 Gy per day.*

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW:

Intensity modulated radiation therapy (IMRT) (NCCN, 2018)

IMRT is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for breast cancer. IMRT is strictly defined by the utilization of inverse planning modulation techniques. IMRT may be appropriate for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created. If IMRT is utilized, techniques to account for respiratory motion should be performed.

Clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery will need to:

- Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of a patient specific dose volume histograms and isodose plans. 3D-CRT techniques such as step-and-shoot or field-in-field should be considered for the comparison.
- Confirm the IMRT requested will be inversely planned (forward plans or 'field-in-field' plans are not considered IMRT).
- Provide tissue constraints for both the target and affected critical structures.

Brachytherapy

Interstitial brachytherapy boost treatment requires a peer review and documentation that improvement in dose delivery to the boost target cannot be delivered with external beam therapy. Other emerging techniques such as Non invasive Image Guided Breast Brachytherapy (NIIGBB) techniques are being investigated and are not considered a medically necessary treatment option for the treatment of breast cancer.

Proton Beam Radiation Therapy

Proton beam is not an approved treatment option for breast cancer. There are limited clinical studies comparing proton beam therapy to 3-D conformal radiation or IMRT. Overall, studies have not shown clinical outcomes to be superior to conventional radiation therapy.

Intraoperative radiation therapy (IORT)

- Single Fraction Electron-beam IORT is considered medically necessary in accordance with ASTRO guidelines (Correa, 2017) if the following criteria are met:
 - Individual is 50 years of age or older with invasive cancer
 - T Stage: Tis or T1
 - Clinically node negative
 - Negative surgical margins
- The use of electronic brachytherapy for IORT (such as Intrabeam, Xofig and Papillon systems) is considered experimental, investigational and/or unproven.

THE FOLLOWING APPLIES TO CMS (MEDICARE) MEMBERS ONLY:

For Proton Beam and Stereotactic Radiotherapy refer to Local Coverage Determination (LCD), if applicable.

BACKGROUND:

Breast cancer is the second most commonly diagnosed cancer among women, after skin cancer, and it accounts for nearly 25% of cancer diagnoses in U.S. women. After a breast cancer diagnosis is made, it is followed by a staging evaluation to determine extent of disease (local, regional, or metastatic) and prognostic findings. Importance is placed on tumor size, lymph node involvement (sentinel node), the histo-pathological interpretation, margins of resection, and hormonal and growth-factor receptor status. Treatment for breast cancer may consist of one of several mastectomy options or breast-conserving surgery and radiation therapy.

Radiation therapy is used to treat the breast and lymph node bearing areas after partial mastectomy or lumpectomy. Since breast cancers are relatively responsive to moderate doses of radiation therapy following tumor excision, treatment for cure may be achieved by external beam techniques or by partial breast irradiation techniques.

The methods suitable for delivering breast radiation therapy have been established through clinical trials providing strong evidence in support of radiation therapy as an effective breast cancer treatment. The traditional approach utilizes tangential radiation fields to the breast and chest wall; based on the clinical and pathological factors, this may be followed by boost to the site of excision (tumor bed). The axilla and supra-clavicular regions also may be included in a separate field based on analysis of prognostic risk factors. Improvements in technology, the observation that local tumor recurrence is most frequently observed near the site of excision, and the desire to limit the extent of radiation have led to restriction of the radiation to the tumor bed (partial breast irradiation) for selected cases.

POLICY HISTORY:

Review Date: February 2019

Review Summary: Added and updated references

Review Date: February 2020

Review Summary: Added and updated references

REFERENCES:

American Brachytherapy Society (ABS). Consensus Statement for Accelerated Partial Breast Irradiation. https://www.americanbrachytherapy.org/guidelines/Guidelines_Accelerated_Partial_Breast_Irradiation.pdf. Published 2013. Accessed April 24, 2018.

American Cancer Society (ACS). Breast Cancer Facts & Figures 2015-2016. <http://www.cancer.org/research/cancerfactsstatistics/breast-cancer-facts-figures>. Accessed June 3, 2016.

American College of Radiology (ACR). ACR Appropriateness Criteria®. Conservative Surgery and Radiation – Stage I and II Breast Cancer. <https://acsearch.acr.org/docs/69351/Narrative/>. Reviewed 2015. Accessed April 21, 2016.

American College of Radiology (ACR). ACR Appropriateness Criteria®. Locally and Advanced Breast Cancer. <https://acsearch.acr.org/docs/69346/Narrative/>. Reviewed 2016. Accessed April 21, 2016.

American Society for Radiation Oncology (ASTRO). Choosing Wisely®. <http://www.choosingwisely.org/societies/american-society-for-radiation-oncology/>. Published June 2017. Accessed April 24, 2018.

American Society of Therapeutic Radiation Oncology (ASTRO). Choosing Wisely®. http://www.choosingwisely.org/clinician-lists/#parentSociety=American_Society_for_Radiation_Oncology. Accessed August 8, 2017.

American Society of Therapeutic Radiation Oncology (ASTRO). Model Policies. Intensity Modulated Radiation Therapy (IMRT). https://www.astro.org/uploadedFiles/_MAIN_SITE/Daily_Practice/Reimbursement/Model_Policies/Content_Pieces/IMRTMP.pdf. Accessed August 8, 2017.

American Society of Therapeutic Radiation Oncology (ASTRO). News Release: Updated ASTRO Guideline Expands Pool of Suitable Candidates for Accelerated Partial Breast Irradiation. <https://www.astro.org/News-and-Publications/News-and-Media-Center/News-Releases/2016/Updated-ASTRO-guideline-expands-pool-of-suitable-candidates-for-accelerated-partial-breast-irradiation/>. Accessed August 8, 2017.

American Society of Therapeutic Radiation Oncology (ASTRO). Practical Radiation Oncology. Accelerated Partial Breast Irradiation: Executive summary for the update of an ASTRO Evidence-Based Consensus Statement. [http://www.practicalradonc.org/article/S1879-8500\(16\)30184-9/fulltext](http://www.practicalradonc.org/article/S1879-8500(16)30184-9/fulltext). Accessed August 8, 2017.

American Society of Therapeutic Radiation Oncology (ASTRO). Practical Radiation Oncology. Radiation therapy for the whole breast: Executive summary of an American Society for Radiation Oncology

(ASTRO) evidence-based guideline. [http://www.practicalradonc.org/article/S1879-8500\(18\)30051-1/fulltext](http://www.practicalradonc.org/article/S1879-8500(18)30051-1/fulltext). Published 2018. Accessed April 24, 2018.

Bentzen SM, Constine LS, Deasy JO, et al. Quantitative analyses of normal tissue effects in the clinic QUANTEC: An introduction to the scientific issues. Introductory paper. *Int J Radiat Oncol Biol Phys*. 2010; 76(3):S3-S9.

Correa C, Harris EE, Leonardi MC, et al. Accelerated partial breast irradiation: Executive summary for the update of an ASTRO evidence-based consensus statement. *Pract Radiat Oncol*. 2017; 7:73-9.

Jackson A, Marks LB, Bentzen SM, et al. The lessons of QUANTEC: Recommendations for reporting and gathering data on dose-volume dependencies of treatment outcome. *Int J Radiat Oncol Biol Phys*. 2010; 76(3):S155-S160.

National Comprehensive Cancer Network (NCCN). Breast Cancer Version 4.2018. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed on February 19, 2019.

Smith BD, Arthur DW, Buchholz TA, et al. Accelerated partial breast irradiation consensus statement from the American Society for Radiation Oncology (ASTRO). *Int J Radiat Oncol Biol Phys*. 2009; 74(4):987-1001.

Smith BD, Bellon JR, Blitzblau R, et al. Radiation therapy for the whole breast: Executive summary of an American Society for Radiation Oncology (ASTRO) evidence-based guideline. *Pract Radiat Oncol*. 2018; 8(3):145-152.

Vicini F, Beitsch P, Quiet C, et al. Five-year analysis of treatment efficacy and cosmesis by the American Society of Breast Surgeons MammoSite Breast Brachytherapy Registry Trial in patients treated with accelerated partial breast irradiation. *Int J Radiat Oncol Biol Phys*. May 14, 2010; 79(3):808-817.

Vicini FA, Arthur D, Wazer D, et al. Limitations of the American Society of Therapeutic Radiology and Oncology consensus panel guidelines on the use of accelerated partial breast irradiation. *Int J Radiat Oncol Biol Phys*. March 15, 2011; 79(4):977-984.

Wang EH, Mougalian SS, Soulos PR, et al. Adoption of intensity modulated radiation therapy for early stage breast cancer from 2004 through 2011. *Int J Radiat Oncol*. 2015; 91(2):303-311.

Wong WW, Pockaj BA, Vora SA, et al. Six-year outcome of a prospective study evaluating tumor bed boost with intra-operative electron irradiation followed by whole-breast irradiation for early-stage breast cancer. *Breast J*. March/April 2014; 20(2):125-130. <http://onlinelibrary.wiley.com/doi/10.1111/tbj.12235/abstract>. Accessed October 24, 2014.

Zauls AJ, Watkins JM, Wahlquist AE, et al. Outcomes in women treated with MammoSite brachytherapy or whole breast irradiation stratified by ASTRO Accelerated Partial Breast Irradiation

Consensus Statement Groups. [Published online ahead of print October 15, 2010]. *Int J Radiat Oncol Biol Phys*. January 1, 2012; 82(1):21-29.

Reviewed / Approved by



Sri Gorty, M.D., Physician Clinical Reviewer, Radiation Oncology

Disclaimer: Magellan Healthcare service authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. These policies are not meant to supplant your normal procedures, evaluation, diagnosis, treatment and/or care plans for your patients. Your professional judgement must be exercised and followed in all respects with regard to the treatment and care of your patients. These policies apply to all Magellan Healthcare subsidiaries including, but not limited to, National Imaging Associates (“Magellan”). The policies constitute only the reimbursement and coverage guidelines of Magellan. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies. Magellan reserves the right to review and update the guidelines at its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.