

<b>National Imaging Associates, Inc.*</b>	
<b>Clinical guideline:</b> <b>INTRAOPERATIVE RADIATION THERAPY (IORT)</b>	<b>Original Date: November 2013</b>
<b>CPT Codes: 77424, 77425</b>	<b>Last Revised Date: February 2020</b>
<b>Guideline Number: NIA_CG_226</b>	<b>Implementation Date: January 2021</b>

**INDICATIONS FOR IORT:**

**Breast Cancer:** Refer to NIA’s clinical guideline on Breast Cancer.

- 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.

**Cervical Cancer:** Refer to NIA’s clinical guideline on Cervical Cancer. IORT is indicated for local or regional recurrence of cervical cancer for centralized disease when previous radiation therapy has occurred (NCCN, 2018).

**Colon Cancer:** Refer to NIA’s clinical guideline on Colorectal Cancer. IORT can be used as a boost for recurrent cancer of T4 tumors with penetration/perforation and intermediate/positive margins. IORT can also be used as a boost for recurrent cancer (ACR, 2014).

**Pancreatic Cancer:** Refer to NIA’s clinical guideline on Pancreatic Cancer. IORT for pancreatic cancer requires review by a physician and may be reasonable for patients undergoing resection that may result in a closer involved margin (NCCN, 2018).

**Rectal Cancer:** Refer to NIA’s clinical guideline on Colorectal Cancer. IORT is indicated for rectal cancer with positive or close margins for T4 lesions or recurrent disease (NCCN, 2018).

**Soft Tissue Sarcoma:** IORT (with photons or electrons) is considered medically necessary as boost treatment at time of surgery for cervical cancer, colorectal cancer, pancreatic cancer and soft tissue sarcomas if either of the following criteria is met (NCCN, 2018):

- Tumor has a high risk of recurring; **OR**

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- Tumor cannot be completely removed (positive margins)

**FREQUENCY OF PROCEDURE:**

- A single fraction is allowed during surgery for the above situations.

**CONTRAINDICATIONS FOR IORT**

IORT is not indicated for any other cancer sites or scenarios other than those listed above, or when the above indications are not met. All other scenarios are considered investigational and not medically necessary.

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**BACKGROUND:**

Intraoperative Radiation Therapy (IORT) is a radiation treatment that is administered during surgery. It allows delivery of radiation directly to the target area for cancers that are difficult to remove during surgery or in situations in which there may be microscopic amounts of cancer remaining after removal. IORT delivers higher doses of radiation than can be used in conventional radiation therapy because the doctor can temporarily move nearby organs or shield them from radiation exposure.

IORT is often combined with conventional radiation therapy which is typically given prior to or during surgery.

**POLICY HISTORY:**

**Review Date:** February 2019

**Review Summary:** Added and updated references

**Review Date:** February 2020

**Review Summary:** Updated References

## REFERENCES:

- American College of Radiology (ACR) Appropriateness Criteria®.  
<https://acsearch.acr.org/docs/69498/Narrative/>. Published 2014. Accessed May 1, 2018.
- Bachireddy P, Tseng D, Horoschak M, et al. Orthovoltage intraoperative radiation therapy for pancreatic adenocarcinoma. *Radiat Oncol*. 2010; 5:105.
- Cantero-Muñoz P, Urién MA, Ruano-Ravina A. Efficacy and safety of intraoperative radiotherapy in colorectal cancer: A systematic review. *Cancer Lett*. 2011; 306(2):121-133.
- Chen AM, Bucci MK, Singer MI et al. Intraoperative radiation therapy for recurrent head-and-neck cancer: the UCSF experience. *Int J Radiat Oncol Biol Phys*. 2007; 67(1):122-129.
- Chua BH, Henderson MA, Milner AD. Intraoperative radiotherapy in women with early breast cancer treated by breast-conserving therapy. *ANZ J Surg*. 2011; 81(1-2):65-69.
- 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 Radiol Oncol*. 2017; 7(2):73-9.
- Dresen RC, Gosens MJ, Martijn H, et al. Radical resection after IORT-containing multimodality treatment is the most important determinant for outcome in patients treated for locally recurrent rectal cancer. *Ann Surg Oncol*. 2008; 15(7):1937-1947.
- Gao Y, Liu Z, Chen X, et al. Intraoperative radiotherapy electron boost in advanced and recurrent epithelial ovarian carcinoma: A retrospective study. *BMC Cancer*. 2011; 11:439.
- Haddock MG, Miller RC, Nelson H, et al. Combined modality therapy including intraoperative electron irradiation for locally recurrent colorectal cancer. *Int J Radiat Oncol Biol Phys*. 2011; 79(1):143-150.
- Holmes DR, Baum M, Joseph D. The TARGIT trial: Targeted intraoperative radiation therapy versus conventional postoperative whole-breast radiotherapy after breast-conserving surgery for the management of early-stage invasive breast cancer (a trial update). *Am J Surg*. October 2007; 194(4):507-510.
- Holmes DR. Intraoperative radiotherapy in breast conserving surgery. [Published online ahead of print May 21, 2014]. *J Surg Oncol*. July 2014; 110(1):68-74. doi: 10.1002/jso.23620.
- Leonardi MC, Maisonneuve P, Mastropasqua MG, et al. How do the ASTRO consensus statement guidelines for the application of accelerated partial breast irradiation fit intraoperative radiotherapy? A retrospective analysis of patients treated at the European Institute of Oncology. [Published online ahead of print January 13, 2012]. *Int J Radiat Oncol Biol Phys*. July 1, 2012; 83(3):806-813. doi: 10.1016/j.ijrobp.2011.08.014.
- Ogawa K, Karasawa K, Ito Y, et al. Intraoperative radiotherapy for resected pancreatic cancer: a multi-institutional retrospective analysis of 210 patients. *Int J Radiat Oncol Biol Phys*. 2010; 77(3):734-742.

- National Comprehensive Cancer Network (NCCN). Cervical Cancer. 1.2018. [https://www.nccn.org/professionals/physician\\_gls/pdf/cervical.pdf](https://www.nccn.org/professionals/physician_gls/pdf/cervical.pdf). Accessed April 24, 2018.
- National Comprehensive Cancer Network (NCCN). Colon Cancer. 2.2018. [https://www.nccn.org/professionals/physician\\_gls/pdf/colon.pdf](https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf). Accessed May 1, 2018.
- National Comprehensive Cancer Network (NCCN) Guidelines. Version 1.2018. Pancreatic Adenocarcinoma. [https://www.nccn.org/professionals/physician\\_gls/pdf/pancreatic.pdf](https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf). Accessed May 1, 2018.
- National Comprehensive Cancer Network (NCCN) Guidelines. Version 1.2018. Rectal Cancer. [https://www.nccn.org/professionals/physician\\_gls/pdf/rectal.pdf](https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf). Accessed May 1, 2018.
- National Comprehensive Cancer Network (NCCN) Guidelines. Version 2.2018. Soft Tissue Sarcoma. [https://www.nccn.org/professionals/physician\\_gls/pdf/sarcoma.pdf](https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf). Accessed May 1, 2018.
- Pawlik TM, Pisters PW, Mikula L, et al. Long-term results of two prospective trials of preoperative external beam radiotherapy for localized intermediate- or high-grade retroperitoneal soft tissue sarcoma. *Ann Surg Oncol*. 2006; 13(4):508-517.
- Rich BS, McEvoy MP, LaQuaglia MP et al. Local control, survival, and operative morbidity and mortality after re-resection, and intraoperative radiation therapy for recurrent or persistent primary high-risk neuroblastoma. *J Pediatr Surg*. 2011; 46(1):97-102.
- Roeder F, Ulrich A, Habl G, et al. Clinical phase I/II trial to investigate preoperative dose-escalated intensity-modulated radiation therapy (IMRT) and intraoperative radiation therapy (IORT) in patients with retroperitoneal soft tissue sarcoma: Interim analysis. *BMC Cancer*. August 27, 2014; 14:617. doi: 10.1186/1471-2407-14-617.
- Roeder F, Schulz-Ertner D, Nikoghosyan AV, et al. A clinical phase I/II trial to investigate preoperative dose-escalated intensity-modulated radiation therapy (IMRT) and intraoperative radiation therapy (IORT) in patients with retroperitoneal soft tissue sarcoma. *BMC Cancer*. July 12, 2012; 12:287. doi: 10.1186/1471-2407-12-287.
- Roeder F, Timke C, Oertel S, et al. Intraoperative electron radiotherapy for the management of aggressive fibromatosis. *Int J Radiat Oncol Biol Phys*. 2010; 76(4):1154-1160.
- Ruano-Ravina A, Almazán Ortega R, Guedea F. Intraoperative radiotherapy in pancreatic cancer: a systematic review. *Radiother Oncol*. 2008; 87(3):318-325.
- Sauer R, Sautter-Bihl ML, Budach W, et al. Accelerated partial breast irradiation – consensus statement of 3 German oncology societies. *Cancer*. 2007; 110(6):1187-1194.

Schuller DE, Ozer E, Agrawal A, et al. Multimodal intensification regimens for advanced, respectable, previously untreated squamous cell cancer of the oral cavity, oropharynx, or hypopharynx. *Arch Otolaryngol Head Neck Surg*. 2007; 133(4):320-326.

Showalter TN, Rao AS, Rani AP, et al. Does intraoperative radiation therapy improve local tumor control in patients undergoing pancreaticoduodenectomy for pancreatic adenocarcinoma? A propensity score analysis. *Ann Surg Oncol*. 2009; 16(8):2116-2122.

Skandarajah AR, Lynch AC, Mackay JR, et al. The role of intraoperative radiotherapy in solid tumors. *Ann Surg Oncol*. 2009; 16(3):735-744.

Sperk E, Welzel G, Keller A, et al. Late radiation toxicity after intraoperative radiotherapy (IORT) for breast cancer: results from the randomized phase III trial TARGIT A. *Breast Cancer Res Treat*. 2012; 135(1):253-260.

Tran QN, Kim AC, Gottschalk AR, et al. Clinical outcomes of intraoperative radiation therapy for extremity sarcomas. *Sarcoma*. 2006; 2006(1):91671.

Vaidya JS, Baum M, Tobias JS, et al. Long-term results of targeted intraoperative radiotherapy (TARGIT) boost during breast-conserving surgery. *Int J Radiat Oncol Biol Phys*. 2011; 81(4):1091-1097.

Vaidya JS, Joseph DJ, Tobias JS, et al. Targeted intraoperative radiotherapy versus whole breast radiotherapy for breast cancer (TARGIT-A trial): An international, prospective, randomised, non-inferiority phase 3 trial. *Lancet*. 2010; 376(9735):91-102.

Valentini V, Morganti AG, Macchia G, et al. Intraoperative radiation therapy in resected pancreatic carcinoma: long-term analysis. *Int J Radiat Oncol Biol Phys*. 2008; 70(4):1094-1099.

Willett CG, Czito BG, Tyler DS. Intraoperative radiation therapy. *J Clin Oncol*. 2007; 25:971-977.

Yoon SS, Chen YL, Kirsch DG, et al. Proton-beam, intensity-modulated, and/or intraoperative electron radiation therapy combined with aggressive anterior surgical resection for retroperitoneal sarcomas. *Ann Surg Oncol*. 2010; 17(6):1515-1529.

Zeidan YH, Yeh A, Weed D, et al. Intraoperative radiation therapy for advanced cervical metastasis: a single institution experience. *Radiat Oncol*. 2011; 6:72.

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