



National Imaging Associates, Inc.*	
Clinical guideline: INTRAOPERATIVE RADIATION THERAPY (IORT)	Original Date: November 2013
CPT Codes: 77424, 77425	Last Revised Date: January 2022
Guideline Number: NIA_CG_226	Implementation Date: January 2023

INDICATIONS FOR IORT

Most requests for radiation therapy are addressed by NIA treatment site clinical guidelines. However, there may be requests that are not. For such requests, determinations will be made on a case-by-case basis utilizing the following guidelines (when applicable) but not limited to: National Comprehensive Cancer Network (NCCN), American Society for Radiation Oncology ASTRO (i.e., Model Policies; Evidence-Based Consensus Statement), ACR Appropriateness Criteria, American Society of Clinical Oncology (ASCO) and/or peer reviewed literature.

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

- Single Fraction Electron-beam IORT is considered medically necessary in accordance with ASTRO guidelines¹ 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.²

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.³

* National Imaging Associates, Inc. (NIA) is a subsidiary of Evolent Health LLC.

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.⁴

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.⁵

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 met⁶:

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

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

Date	Summary
January 2022	No changes
February 2021	No changes
February 2020	Updated References
February 2019	Added and updated references

REFERENCES

1. 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*. Mar-Apr 2017;7(2):73-79. doi:10.1016/j.prro.2016.09.007
2. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Cervical Cancer Version 1.2022. National Comprehensive Cancer Network (NCCN). Updated October 26, 2021. Accessed December 10, 2021. https://www.nccn.org/professionals/physician_gls/pdf/cervical.pdf
3. American College of Radiology. ACR Appropriateness Criteria®: Recurrent Rectal Cancer. Updated 2014. Accessed December 10, 2021. <https://acsearch.acr.org/docs/69498/Narrative>
4. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Pancreatic Adenocarcinoma Version 2.2021. National Comprehensive Cancer Network (NCCN). Updated February 25, 2021. Accessed December 9, 2021. https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf
5. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Rectal Cancer Version 2.2021. National Comprehensive Cancer Network (NCCN). Updated September 10, 2021. Accessed December 10, 2021. https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf
6. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Soft Tissue Sarcoma Version 2.2021. National Comprehensive Cancer Network (NCCN). Updated April 28, 2021. Accessed December 10, 2021. https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf

ADDITIONAL RESOURCES

1. Bachireddy P, Tseng D, Horoschak M, et al. Orthovoltage intraoperative radiation therapy for pancreatic adenocarcinoma. *Radiat Oncol*. Nov 8 2010;5:105. doi:10.1186/1748-717x-5-105
2. Cantero-Muñoz P, Urién MA, Ruano-Ravina A. Efficacy and safety of intraoperative radiotherapy in colorectal cancer: a systematic review. *Cancer Lett*. Jul 28 2011;306(2):121-33. doi:10.1016/j.canlet.2011.02.020
3. 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*. Jan 1 2007;67(1):122-9. doi:10.1016/j.ijrobp.2006.08.038
4. Chua BH, Henderson MA, Milner AD. Intraoperative radiotherapy in women with early breast cancer treated by breast-conserving therapy. *ANZ J Surg*. Jan 2011;81(1-2):65-9. doi:10.1111/j.1445-2197.2010.05431.x
5. 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*. Jul 2008;15(7):1937-47. doi:10.1245/s10434-008-9896-z
6. Gao Y, Liu Z, Chen X, Luo W, Zhang L, Wang J. Intraoperative radiotherapy electron boost in advanced and recurrent epithelial ovarian carcinoma: a retrospective study. *BMC Cancer*. Oct 11 2011;11:439. doi:10.1186/1471-2407-11-439

7. 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*. Jan 1 2011;79(1):143-50. doi:10.1016/j.ijrobp.2009.10.046
8. 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*. Oct 2007;194(4):507-10. doi:10.1016/j.amjsurg.2007.06.018
9. Holmes DR. Intraoperative radiotherapy in breast conserving surgery. *J Surg Oncol*. Jul 2014;110(1):68-74. doi:10.1002/jso.23620
10. 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. *Int J Radiat Oncol Biol Phys*. Jul 1 2012;83(3):806-13. doi:10.1016/j.ijrobp.2011.08.014
11. 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*. Jul 1 2010;77(3):734-42. doi:10.1016/j.ijrobp.2009.09.010
12. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Colon Cancer Version 3.2021. National Comprehensive Cancer Network (NCCN). Updated September 10, 2021. Accessed December 10, 2021. https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf
13. 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*. Apr 2006;13(4):508-17. doi:10.1245/aso.2006.05.035
14. Rich BS, McEvoy MP, LaQuaglia MP, Wolden SL. 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*. Jan 2011;46(1):97-102. doi:10.1016/j.jpedsurg.2010.09.068
15. 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*. Aug 27 2014;14:617. doi:10.1186/1471-2407-14-617
16. Roeder F, Timke C, Oertel S, et al. Intraoperative electron radiotherapy for the management of aggressive fibromatosis. *Int J Radiat Oncol Biol Phys*. Mar 15 2010;76(4):1154-60. doi:10.1016/j.ijrobp.2009.03.067
17. 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*. Jul 12 2012;12:287. doi:10.1186/1471-2407-12-287
18. Ruano-Ravina A, Almazán Ortega R, Guedea F. Intraoperative radiotherapy in pancreatic cancer: a systematic review. *Radiother Oncol*. Jun 2008;87(3):318-25. doi:10.1016/j.radonc.2007.12.002

19. Sauer R, Sautter-Bihl ML, Budach W, et al. Accelerated partial breast irradiation: consensus statement of 3 German Oncology societies. *Cancer*. Sep 15 2007;110(6):1187-94. doi:10.1002/cncr.22910
20. Schuller DE, Ozer E, Agrawal A, Grecula JC, Rhoades CA, Young DC. Multimodal intensification regimens for advanced, resectable, previously untreated squamous cell cancer of the oral cavity, oropharynx, or hypopharynx: a 12-year experience. *Arch Otolaryngol Head Neck Surg*. Apr 2007;133(4):320-6. doi:10.1001/archotol.133.4.320
21. Showalter TN, Rao AS, Rani Anne P, et al. Does intraoperative radiation therapy improve local tumor control in patients undergoing pancreaticoduodenectomy for pancreatic adenocarcinoma? A propensity score analysis. *Ann Surg Oncol*. Aug 2009;16(8):2116-22. doi:10.1245/s10434-009-0498-1
22. Skandarajah AR, Lynch AC, Mackay JR, Ngan S, Heriot AG. The role of intraoperative radiotherapy in solid tumors. *Ann Surg Oncol*. Mar 2009;16(3):735-44. doi:10.1245/s10434-008-0287-2
23. 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*. Aug 2012;135(1):253-60. doi:10.1007/s10549-012-2168-4
24. Tran QN, Kim AC, Gottschalk AR, et al. Clinical outcomes of intraoperative radiation therapy for extremity sarcomas. *Sarcoma*. 2006;2006(1):91671. doi:10.1155/srcm/2006/91671
25. 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*. Nov 15 2011;81(4):1091-7. doi:10.1016/j.ijrobp.2010.07.1996
26. 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*. Jul 10 2010;376(9735):91-102. doi:10.1016/s0140-6736(10)60837-9
27. Valentini V, Morganti AG, Macchia G, et al. Intraoperative radiation therapy in resected pancreatic carcinoma: long-term analysis. *Int J Radiat Oncol Biol Phys*. Mar 15 2008;70(4):1094-9. doi:10.1016/j.ijrobp.2007.07.2346
28. Willett CG, Czito BG, Tyler DS. Intraoperative radiation therapy. *J Clin Oncol*. Mar 10 2007;25(8):971-7. doi:10.1200/jco.2006.10.0255
29. 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*. Jun 2010;17(6):1515-29. doi:10.1245/s10434-010-0935-1
30. Zeidan YH, Yeh A, Weed D, et al. Intraoperative radiation therapy for advanced cervical metastasis: a single institution experience. *Radiat Oncol*. Jun 15 2011;6:72. doi:10.1186/1748-717x-6-72

Reviewed / Approved by NIA Clinical Guideline Committee

GENERAL INFORMATION

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

Disclaimer: *National Imaging Associates, Inc. (NIA) 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 Evolent Health LLC subsidiaries including, but not limited to, National Imaging Associates (“NIA”). The policies constitute only the reimbursement and coverage guidelines of NIA. 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. NIA 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.*