

## Evidence Based Guideline

### Intraoperative Radiation Therapy

**File Name:** intraoperative\_radiation\_therapy  
**Origination:** 8/1985  
**Last CAP Review:** 5/2011  
**Next CAP Review:** NA  
**Last Review:** 11/2011

**Active guideline, no longer scheduled for routine literature review.**

#### Description of Procedure or Service

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Intraoperative radiation therapy (IORT) is designed to increase the intensity of radiation directly delivered to tumors. The tumor and associated tissues at risk for micrometastatic spread are directly visualized at operation. IORT is delivered directly to the tumor, and normal or uninvolved tissues are not exposed to radiation because they are removed or shielded from the treatment field. It can be delivered by electron beams produced by linear accelerators (also called IOERT), or high-dose rate brachytherapy (HDR-IORT). Most clinical experience involves IOERT.

IORT is performed with applicators and cones that attach to the treatment head of high-energy medical linear accelerators that are designed to direct radiation to defined surface structures. Most patients are subsequently treated with external beam photon irradiation (EBRT).

The INTRABEAM® system was first approved for use by the U.S. Food and Drug Administration (FDA) for intracranial tumors in 1999 and was subsequently approved for whole body use in 2005. The INTRABEAM® spherical applicators are indicated for use with the INTRABEAM® system to deliver a prescribed dose of radiation to the treatment margin or tumor bed during intracavity or intraoperative radiotherapy treatments. The Mobetron mobile electron beam accelerator designed for use in the operating room received 510(k) marketing clearance in 1998.

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

#### Evidence Based Guideline for Intraoperative Radiation Therapy

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Intraoperative Radiation Therapy may be appropriate for locally advanced colorectal cancer.

Use of intraoperative radiation therapy may be appropriate in the following situation:

- Rectal cancer with positive or close margins with T4 lesions or recurrent disease.

#### Medical Evidence regarding Intraoperative Radiation Therapy indicates it is not recommended in the following situations

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Intraoperative Radiation Therapy is not recommended for any type of cancer other than those listed above.

# Intraoperative Radiation Therapy

Use of intraoperative radiation therapy is not recommended for all other oncologic applications.

The literature on IORT consists mainly of retrospective reports of small case series with historic controls from single institutions published over a period of more than 20 years, recent systematic reviews, when available, were relied on for summary information. Intraoperative radiation therapy (IORT) was first performed in the early 1900s and has been used for treatment of a variety of primary and recurrent solid tumors since the 1960s. Nevertheless, evaluation of its effectiveness is limited by the absence of randomized controlled trials (RCTs). A number of phase 1 and phase 2 trials of IORT in the treatment of soft tissue sarcomas and rectal, breast, brain, head and neck, and upper gastrointestinal cancers are underway at this time.

## 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.

## Billing/Coding/Physician Documentation Information

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This guideline 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: 77424, 77425, 77469, S8049*

## Scientific Background and Reference Sources

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BCBSA Medical Policy Reference Manual - 3/96

Medical Policy Advisory Group Review 3/99

Specialty Matched Consultant Advisory Panel - 10/2000

Crucitti F, Doglietto GB, Frontera D. Integrated radiosurgical treatment of resectable pancreatic head carcinoma. *Pancreas*. 1998 Jan;16(1):31-9.

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Farrell TJ, Barbot DJ, Rosato FE. Pancreatic resection combined with intraoperative radiation therapy for pancreatic cancer. *Ann Surg*. 1997 Jul;226(1):66-9.

Letters to Editor. *Annals of Surgery*. 1999;230(6)

Kokubo M, Nishimura Y, Shibamoto Y, et al. Analysis of the clinical benefit of intraoperative radiotherapy in patients undergoing macroscopically curative resection for pancreatic cancer. *Int J Radiat Oncol Biol Phys* 2000 Nov 1;48(4):1081-1087.

Raben A, Mychalczak B. Brachytherapy for non-small cell lung cancer and selected neoplasms of the chest. *Chest* 1997 Oct;112(4):276-86.

Rich TA, Skibber JM, Dubrow RA, et al. Preoperative infusional chemoradiation, selective intraoperative radiation, and resection for locally advanced pelvic recurrence of colorectal adenocarcinoma. *Annals of Surgery* 1996 Feb;223(2):177-186.

# Intraoperative Radiation Therapy

Shasha D, Harrison LB, Enker W. Brachytherapy in the treatment of colorectal malignancies. Hematology/oncology clinics of North America 1999 June;13(3):559-575.

Eble MJ, Lehnert T, Treiber M, et al. Moderate dose intraoperative and external beam radiotherapy for locally recurrent rectal carcinoma. Radiotherapy and Oncology. 1998;49:169-174.

Gunderson LL, Nelson H, Martenson JA, et al. Locally advanced primary colorectal cancer: intraoperative electron and external beam radiation + 5-FU. Int J Radiation Oncology Biol Phys 1997;17(1):601-14.

Nakfoor BM, Willett CG, Sheilito PC, et al. The impact of 5-fluorouracil and intraoperative electron beam radiation therapy on the outcome of patients with locally advanced primary rectal and rectosigmoid cancer. Annals of Surgery. 1998;228(2):194-200.

Schild SE, Gunderson LL, Haddock MG, et al. The treatment of locally advanced colon cancer. Int. J. Radiation Oncology Biol. Phys. 1997;17(1):51-58.

Medical Policy Advisory Group - 12/2000

Specialty Matched Consultant Advisory Panel - 6/2002

BCBSA Medical Policy Reference Manual – 8.01.08, 10/6/2009

Senior Medical Director - 12/2009

Specialty Matched Consultant Advisory Panel 5/2010

BCBSA Medical Policy Reference Manual 8.01.08, 12/9/2010

Specialty Matched Consultant Advisory Panel 5/2011

## Policy Implementation/Update Information

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8/85	Original policy: Experimental/Investigative
3/88	Reviewed: Investigational
12/92	Evaluated: Investigational
7/96	BCBSA Medical Policy Reference Manual , 3/96
3/99	Reaffirmed.
6/99	Reformatted, Description of Procedure or Service revised, Medical Term Definition added.
11/00	Specialty Matched Consultant Advisory Panel review. Extensive literature review through MEDLINE and MDConsult. No change to criteria of policy.
12/00	Consultant review. Current literature supports the use of IORT for locally advanced colorectal cancer. Policy modified to reflect this change. Medical Policy Advisory Group review. Approve. System coding changes.
2/02	Coding format change.
7/02	Specialty Matched Consultant Advisory Panel meeting 6/26/2002. No changes. Code S8049

## Intraoperative Radiation Therapy

added to Billing/Coding section.

- 6/03 Policy status changed to: "Active policy, no longer scheduled for routine literature review".
- 4/04 Benefits Application and Billing/Coding sections updated for consistency.
- 9/18/06 Medical Policy changed to Evidence Based Guideline. (btw)
- 2/16/10 Reviewed by Senior Medical Director 12/6/09. Updated "Description" section. Reworded Evidence-Based Guideline information. "Use of intraoperative radiation therapy may be appropriate in the following situation: Rectal cancer with positive or close margins with T4 lesions or recurrent disease. Use of intraoperative radiation therapy is not recommended for all other oncologic applications." References added. (btw)
- 6/22/10 Specialty Matched Consultant Advisory Panel 5/24/10. No changes to EBG statement. EBG policy number removed. (lr)
- 6/7/11 Specialty Matched Consultant Advisory Panel review 5/25/2011. No changes to EBG statement. (lpr)
- 11/22/11 Added CPT codes 77424, 77425, 77469 to Billing/Coding section effective 1/1/2012. (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.