



MEDICAL COVERAGE GUIDELINES
SECTION: RADIOLOGY

ORIGINAL EFFECTIVE DATE: 07/28/06
LAST REVIEW DATE: 08/21/18
LAST CRITERIA REVISION DATE: 09/27/16
ARCHIVE DATE:

INTRAOPERATIVE RADIATION THERAPY

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Intraoperative radiation therapy (IORT) is a technique to increase the intensity of radiation delivered directly to tumors. The tumor and associated tissues at risk for metastatic spread are directly visualized during surgery and IORT is delivered directly to the tumor. Normal or uninvolved tissues are not exposed to radiation because they are removed or shielded from the treatment field.



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Criteria:

For intraoperative accelerated partial breast irradiation for treatment of breast cancer, see BCBSAZ Medical Coverage Guideline #0830, "*Brachytherapy for Treatment of Breast Cancer*".

- Intraoperative radiation therapy for the treatment of rectal cancer is considered *medically necessary* with documentation of **ANY** of the following:
 1. Recurrent disease
 2. T4 lesions with positive or close margins

- Intraoperative radiation therapy for all other indications not previously listed or if above criteria not met is considered *experimental or investigational* based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

Resources:

Literature reviewed 08/21/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

1. 8.01.08 BCBS Association Medical Policy Reference Manual. Intraoperative Radiation Therapy. Re-issue date 07/12/2018, issue date 10/08/2002.
2. Arians N, Foerster R, Rom J, et al. Outcome of patients with local recurrent gynecologic malignancies after resection combined with intraoperative electron radiation therapy (IOERT). *Radiat Oncol*. Mar 18 2016;11:44.
3. Ashman JB, Moss AA, Rule WG, et al. Preoperative chemoradiation and IOERT for unresectable or borderline resectable pancreas cancer. *J Gastrointest Oncol*. Dec 2013;4(4):352-360.
4. Backes FJ, Martin DD. Intraoperative radiation therapy (IORT) for gynecologic malignancies. *Gynecol Oncol*. Aug 2015;138(2):449-456.



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Resources: (cont.)

5. Backes FJ, Tierney BJ, Eisenhauer EL, Bahnson RR, Cohn DE, Fowler JM. Complications after double-barreled wet colostomy compared to separate urinary and fecal diversion during pelvic exenteration: time to change back? *Gynecol Oncol*. Jan 2013;128(1):60-64.
6. Barney BM, Petersen IA, Dowdy SC, Bakkum-Gamez JN, Klein KA, Haddock MG. Intraoperative Electron Beam Radiotherapy (IOERT) in the management of locally advanced or recurrent cervical cancer. *Radiat Oncol*. Apr 08 2013;8:80.
7. Cai S, Hong TS, Goldberg SI, et al. Updated long-term outcomes and prognostic factors for patients with unresectable locally advanced pancreatic cancer treated with intraoperative radiotherapy at the Massachusetts General Hospital, 1978 to 2010. *Cancer*. Dec 01 2013;119(23):4196-4204.
8. Call JA, Stafford SL, Petersen IA, Haddock MG. Use of intraoperative radiotherapy for upper-extremity soft-tissue sarcomas: analysis of disease outcomes and toxicity. *Am J Clin Oncol*. Feb 2014;37(1):81-85.
9. Calvo FA, Sole CV, Atahualpa F, et al. Chemoradiation for resected pancreatic adenocarcinoma with or without intraoperative radiation therapy boost: Long-term outcomes. *Pancreatology*. Nov-Dec 2013;13(6):576-582.
10. Calvo FA, Sole CV, Lozano MA, et al. Intraoperative electron beam radiotherapy and extended surgical resection for gynecological pelvic recurrent malignancies with and without external beam radiation therapy: long-term outcomes. *Gynecol Oncol*. Sep 2013;130(3):537-544.
11. Fastner G, Sedlmayer F, Merz F, et al. IORT with electrons as boost strategy during breast conserving therapy in limited stage breast cancer: long term results of an ISORT pooled analysis. *Radiother Oncol*. Aug 2013;108(2):279-286.
12. Habermehl D, Brecht IC, Bergmann F, et al. Adjuvant radiotherapy and chemoradiation with gemcitabine after R1 resection in patients with pancreatic adenocarcinoma. *World J Surg Oncol*. Apr 15 2015;13:149.
13. Habermehl D, Brecht IC, Bergmann F, et al. Chemoradiation in patients with isolated recurrent pancreatic cancer - therapeutical efficacy and probability of re-resection. *Radiat Oncol*. Jan 31 2013;8:27.



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INTRAOPERATIVE RADIATION THERAPY (cont.)

Resources: (cont.)

14. Sweeting R, Deal A, et al. Intraoperative electron radiation therapy as an important treatment modality in retroperitoneal sarcoma. *Journal of Surgical Research*. November, 2013; 185(1):245 - 249.
15. Tinkle CL, Weinberg V, Braunstein SE, et al. Intraoperative Radiotherapy in the Management of Locally Recurrent Extremity Soft Tissue Sarcoma. *Sarcoma*. 2015;2015:913565.
16. UpToDate. Local treatment for primary soft tissue sarcoma of the extremities and chest wall,. 2016.



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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilínígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idííkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idííkidgo beehaz'áanii hólo díí t'áa hazaadk'ehjí háká a'doowolgo bee haz'á doo baqah ilínígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

