Medical Policy
Intraoperative Radiotherapy

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Policy Number: 278
BCBSA Reference Number: 8.01.08
NCD/LCD: N/A

Related Policies
- Accelerated Breast Irradiation after Breast-Conerving Surgery for Early Stage Breast Cancer and Breast Brachytherapy, #326

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare HMO BlueSM and Medicare PPO BlueSM Members

Use of intraoperative radiotherapy may be considered MEDICALLY NECESSARY in the following situation:
- Rectal cancer with positive or close margins with T4 lesions or recurrent disease.

Use of intraoperative radiotherapy is considered INVESTIGATIONAL for all other oncologic applications.

Prior Authorization Information
Inpatient
- For services described in this policy, precertification/preauthorization IS REQUIRED for all products if the procedure is performed inpatient.

Outpatient
- For services described in this policy, see below for products where prior authorization might be required if the procedure is performed outpatient.

<table>
<thead>
<tr>
<th>Product</th>
<th>Prior Authorization Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>Prior authorization is not required.</td>
</tr>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>Prior authorization is not required.</td>
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<tr>
<td>Medicare HMO BlueSM</td>
<td>Prior authorization is not required.</td>
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<tr>
<td>Medicare PPO BlueSM</td>
<td>Prior authorization is not required.</td>
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</tbody>
</table>
CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>77424</td>
<td>Intraoperative radiation treatment delivery, x-ray, single treatment session</td>
</tr>
<tr>
<td>77425</td>
<td>Intraoperative radiation treatment delivery, electrons, single treatment session</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10 Procedure Codes</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>DDY7CZZ</td>
<td>Intraoperative Radiation Therapy (IORT) of Rectum</td>
</tr>
</tbody>
</table>

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT codes above if medical necessity criteria are met:

<table>
<thead>
<tr>
<th>ICD-10 Diagnosis Codes</th>
<th>Code Description</th>
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</thead>
<tbody>
<tr>
<td>C20</td>
<td>Malignant Neoplasm Of Rectum</td>
</tr>
<tr>
<td>D01.2</td>
<td>Carcinoma In Situ Of Rectum</td>
</tr>
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</table>

Description
Intraoperative radiotherapy (IORT) increases the intensity of radiation delivered directly to tumors. The tumor and associated tissues at risk for micrometastatic spread are directly visualized during surgery. 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.

Summary
For individuals who have rectal cancer who receive adjunctive IORT, the evidence includes an RCT, nonrandomized comparative studies, and systematic reviews of these studies. Relevant outcomes are overall survival, disease-specific survival, change in disease status, and treatment-related morbidity. Adjunctive use of IORT as part of a multimodal treatment could permit an increase in radiation dose without increasing complications. However, a phase 3 RCT and meta-analysis of IORT for locally advanced rectal cancer did not find improved outcomes with IORT in combination with EBRT and surgery. Nonrandomized comparative studies and a meta-analysis of these studies have shown some benefit in health outcomes with adjunctive IORT for recurrent rectal cancer, but these studies are limited by a high risk of selection bias, heterogeneous patient populations, and heterogeneous delivery of other treatments. Large RCTs are needed to determine the effect of IORT with greater certainty. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have gastric cancer who receive adjunctive IORT, the evidence includes RCTs and a systematic review of RCTs. Relevant outcomes are overall survival, disease-specific survival, change
in disease status, and treatment-related morbidity. A meta-analysis of 8 RCTs found a benefit of IORT in locoregional control (but not overall survival) when used with EBRT. When IORT was administered without adjuvant EBRT in patients with stage III disease, overall survival improved. Thus, IORT might be considered an alternative to EBRT in patients undergoing surgery for stage III gastric cancer. Randomized studies comparing benefits and harms of the 2 treatments are needed to determine the efficacy of IORT with greater certainty. It cannot be determined whether IORT provides any benefit for overall survival in this patient population (gastric cancer patients) when used with EBRT. Further study is needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have soft tissue sarcomas who receive adjunctive IORT, the evidence includes a systematic review, a small RCT, and several nonrandomized comparative studies. Relevant outcomes are overall survival, disease-specific survival, change in disease status, and treatment-related morbidity. Overall, the study quality is low. The limited data suggest that IORT might improve local control and overall survival, but adverse events might outweigh any treatment benefit. RCTs are needed to determine the risks and benefits of IORT for soft tissue sarcomas with greater certainty. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have gynecologic cancers who receive adjunctive IORT, the evidence includes a nonrandomized trial and case series. Relevant outcomes are overall survival, disease-specific survival, change in disease status, and treatment-related morbidity. The contribution of adjuvant IORT cannot be determined from the available literature. There is no evidence that IORT improves survival rates, and there may be severe complications related to the therapy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have head and neck cancers who receive adjunctive IORT, the evidence includes case series. Relevant outcomes are overall survival, disease-specific survival, change in disease status, and treatment-related morbidity. The strongest evidence is from a retrospective analysis of patients who had recurrent salivary gland carcinomas and were at risk of radiation toxicity due to prior treatment with EBRT. Some patients received IORT plus salvage surgery, and multivariate analysis found that use of IORT was a significant predictor of improved outcomes. Although these findings suggested an improvement in health outcomes for head and neck cancers that cannot be treated with EBRT due to toxicity, there was a high risk of selection bias in this study. Comparative trials are needed to determine the efficacy of IORT with greater certainty. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have pancreatic cancer who receive adjunctive IORT, the evidence includes large case series, cohort studies, and systematic reviews of these studies. Relevant outcomes are overall survival, disease-specific survival, change in disease status, and treatment-related morbidity. The systematic reviews found no evidence that IORT was more effective than other therapies in treating pancreatic cancer. No evidence was identified that evaluated outcomes when IORT was and was not added to multimodal therapy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have RCC who receive adjunctive IORT, the evidence includes case series. Relevant outcomes are overall survival, disease-specific survival, change in disease status, and treatment-related morbidity. No controlled trials were identified to determine whether adjunctive IORT improves health outcomes when added to multimodal therapy with surgical resection and EBRT. Grade 3 or higher toxicity after IORT has been reported in a substantial percentage of patients. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have glioblastoma or neuroblastoma or fibromatosis who receive adjunctive IORT, the evidence includes case series. Relevant outcomes are overall survival, disease-specific survival, change in disease status, and treatment-related morbidity. Compared with other therapies, it is unclear whether IORT improves overall survival. However, compared with historical controls, IORT for patients with previously untreated malignant gliomas had no survival benefit when given in conjunction with multimodal therapy. In addition, complication rates may be high. Comparative trials
are needed to evaluate the safety and efficacy of this treatment modality. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Policy History**

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<thead>
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<th>Date</th>
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<tr>
<td>3/2018</td>
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<td>1/2017</td>
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<td>11/2015</td>
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<td>9/2015</td>
<td>Clarified coding information.</td>
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<td>10/2014</td>
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<td>8/2014</td>
<td>Coding information clarified.</td>
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<td>12/2013</td>
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<td>5/2009</td>
<td>BCBSA National medical policy review. No changes to policy statements.</td>
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<td>8/2008</td>
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<td>7/2007</td>
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**Information Pertaining to All Blue Cross Blue Shield Medical Policies**

Click on any of the following terms to access the relevant information:
- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

**References**


