

Corporate Medical Policy

Intensity Modulated Radiation Therapy (IMRT) of Abdomen and Pelvis

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Last Review:	10/2018

Description of Procedure or Service

Radiotherapy may be an integral component in the treatment of cancers of the abdomen and pelvis. Intensity-modulated radiation therapy (IMRT) has been proposed as a method of radiation therapy that allows adequate radiation therapy to the tumor while minimizing the radiation dose to surrounding normal tissues and critical structures.

Background

Radiation techniques

Conventional external-beam radiation therapy. Methods to plan and deliver radiation therapy have evolved in ways that permit more precise targeting of tumors with complex geometries. Most early trials used 2-dimensional treatment planning, based on flat images and radiation beams with cross-sections of uniform intensity that were sequentially aimed at the tumor along 2 or 3 intersecting axes.

3-dimensional conformal radiation (3D-CRT). Treatment planning evolved by using 3-dimensional images, usually from computed tomography (CT) scans, to delineate the boundaries of the tumor and discriminate tumor tissue from adjacent normal tissue and nearby organs at risk for radiation damage. Computer algorithms were developed to estimate cumulative radiation dose delivered to each volume of interest by summing the contribution from each shaped beam. Methods also were developed to position the patient and the radiation portal reproducibly for each fraction and immobilize the patient, thus maintaining consistent beam axes across treatment sessions. Collectively, these methods are termed 3-dimensional conformal radiation therapy (3D-CRT).

Intensity-modulated radiation therapy (IMRT). IMRT, uses computer software, CT images, and magnetic resonance imaging (MRI), offers better conformality than 3D-CRT as it is able to modulate the intensity of the overlapping radiation beams projected on the target and uses multiple-shaped treatment fields. Treatment planning and delivery are more complex, time consuming, and labor intensive for IMRT than for 3D-CRT. The technique uses a multileaf collimator, (MLC) which, when coupled with a computer algorithm, allows for “inverse” treatment planning. The radiation oncologist delineates the target on each slice of a CT scan and specifies the target’s prescribed radiation dose, acceptable limits of dose heterogeneity within the target volume, adjacent normal tissue volumes to avoid, and acceptable dose limits within the normal tissues. Based on these parameters and a digitally reconstructed radiographic image of the tumor and surrounding tissues and organs at risk, computer software optimizes the location, shape, and intensities of the beams ports to achieve the treatment plan’s goals.

Increased conformality may permit escalated tumor doses without increasing normal tissue toxicity, and may thus improve local tumor control with decreased exposure to surrounding normal tissues, potentially reducing acute and late radiation toxicities. Better dose homogeneity within the target may also improve local tumor control by avoiding underdosing within the tumor and may decrease toxicity by avoiding overdosing.

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Technologic development has produced advanced techniques which may further improve RT treatment by improving dose distribution. These techniques are considered variations of IMRT. Volumetric modulated arc therapy (VMAT) involves delivery of radiation from a continuous rotation of the radiation source. The principal advantage of VMAT is greater efficiency in treatment delivery time, reducing radiation exposure and improving target radiation delivery due to less patient motion. Image-guided RT involves the incorporation of imaging before and/or during treatment to more precisely deliver RT to the target volume.

Note: The following abdominal and pelvic cancer is not addressed by current policy: sarcoma.

Related Policies:

Intensity Modulated Radiation Therapy (IMRT) of the Prostate
Intensity Modulated Radiation Therapy (IMRT) of the Chest
Intensity Modulated Radiation Therapy (IMRT) of the Head and Neck
Intensity Modulated Radiation Therapy (IMRT) of the Central Nervous System
Intensity Modulated Radiation Therapy (IMRT) for Sarcoma of the Extremities
Maximum Units of Service

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

Policy

BCBSNC will provide coverage for Intensity Modulated Radiation Therapy (IMRT) of the abdomen and pelvis when determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

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.

When Intensity-Modulated Radiation Therapy (IMRT) of the abdomen and pelvis is covered

Intensity modulated radiation therapy may be considered medically necessary as an approach to delivering radiation therapy for patients with cancer of the anus/anal canal.

Intensity-modulated radiation therapy (IMRT) may be considered medically necessary for the treatment of other cancers of the abdomen and pelvis, when the following criteria are met:

- 1) When dosimetric planning with standard 3-D conformal radiation predicts that the radiation dose to an adjacent organ would result in unacceptable normal tissue toxicity; **AND**
- 2) Dosimetric planning with IMRT predicts that the radiation dose to an adjacent organ would result in normal tissue tolerance (See Policy Guidelines); **AND**
- 3) When one of the following clinical conditions is present:
 - a. Treatment to a site that abuts or overlaps with a previously-irradiated site;
 - b. Patients with a history of:
 - i. Crohn's disease,
 - ii. Ulcerative colitis,

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- iii. Previous bowel obstruction,
- iv. Unilateral or bilateral hip prosthesis, or
- v. Hysterectomy,
- c. Gynecological or gastrointestinal cancer with gross nodal disease;
- d. Vaginal, vulvar, endometrial, or cervical cancer, when treatment plan includes inguinal and/or pelvic nodes;
- e. Muscle-invasive bladder cancer, as part of definitive bladder preserving therapy, when the treatment plan includes pelvic nodes;
- f. Lymphoma involving aortic/periaortic nodes;
- g. Retroperitoneal sarcomas of the abdominal cavity.

When Intensity-Modulated Radiation Therapy (IMRT) of the abdomen and pelvis is not covered

Intensity-modulated radiation therapy (IMRT) is considered **investigational** for all other uses in the abdomen and pelvis.

Policy Guidelines

IMRT may be an appropriate alternative to standard 3D conformal radiation therapy when dosimetric planning predicts one of the following scenarios:

- a. If the mean liver dose is > 30 Gy with 3D, there is at least a 5 Gy reduction with IMRT.
- b. If the V20 of the combined kidneys is >30% with 3D, there is at least 10% reduction (i.e. from 40 % to 30 %) with IMRT.
- c. If the spinal cord dose cannot be kept within tolerance with 3D (e.g. maximum dose \leq 50 Gy), there is an absolute reduction in the maximum cord dose by at least 4 Gy with IMRT (e.g. from 54 Gy down to 50 Gy or lower).
- d. If the small bowel dose cannot be kept within tolerance with 3D (e.g. maximum dose \leq 50 Gy), there is an absolute reduction in the maximum small bowel dose by at least 4 Gy with IMRT (e.g. from 54 Gy down to 50 Gy or lower).

For individuals who have gastrointestinal (GI) tract cancers who receive IMRT, the evidence includes Non-randomized comparative studies and retrospective series. Relevant outcomes are overall survival, disease-specific survival, quality of life, and treatment-related morbidity. IMRT has been compared with 3-dimensional conformal radiotherapy (3D-CRT) for the treatment of stomach, hepatobiliary, and pancreatic cancers with some studies reporting longer overall survival and decreased toxicity with IMRT. The evidence on hepatobiliary cancer includes a series with historical controls; it found an increase in median survival with no difference in toxicity. Two comparative studies (1 prospective, 1 retrospective) were identified on IMRT for pancreatic cancer. The prospective comparative study found an increase in survival with a reduction in GI toxicity, while the retrospective study found a decrease in GI toxicity. The available comparative evidence, together with dosimetry studies of organs at risk, would suggest that IMRT improves survival and decreases toxicity compared to 3D-CRT in patients with GI cancers. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have gynecologic cancers who receive IMRT, the evidence includes 2 randomized controlled trials and several nonrandomized comparative studies. Relevant outcomes are overall survival, disease-specific survival, quality of life, and treatment-related morbidity. There is limited comparative evidence on survival outcomes following IMRT or 3D-CRT. However, available results are generally consistent that IMRT reduces GI and genitourinary toxicity. Based on evidence with other cancers of the pelvis and abdomen that are proximate to organs at risk, it is expected that overall survival with IMRT would be at least as good as 3D-CRT, with a decrease in toxicity. A reduction in

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GI toxicity is likely to improve the quality of life in patients with gynecologic cancer. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have anorectal cancer who receive IMRT, the evidence includes a small randomized controlled trial (N=20), nonrandomized comparative studies, and case series. Relevant outcomes are overall survival, disease-specific survival, quality of life, and treatment-related morbidity. Survival outcomes have not differed significantly between patients receiving IMRT and 3D-CRT. However, studies have found patients receiving IMRT with chemotherapy for the treatment of anal cancer experience fewer acute and late adverse events than patients receiving 3D-CRT plus chemotherapy, primarily in GI toxicity. A reduction in GI toxicity is likely to improve the quality of life in patients with anorectal cancer. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Based on clinical input, there was support for the use of IMRT in tumors of the abdomen and pelvis when normal tissues would receive unacceptable doses of radiation. Through a chain of evidence, this reduced toxicity potentially lowers the risk of adverse events (acute and late effects of radiation toxicity). The results of vetting, together with a chain of evidence and the potential to reduce harms, led to the decision that IMRT may be considered medically necessary for the treatment of tumors of the abdomen and pelvis when dosimetric planning with standard 3D-CRT predicts that the radiation dose to an adjacent organ would result in unacceptable normal tissue toxicity.

CPT 77338 is reported once per IMRT plan and is limited to 3 units per 60 day treatment course.

Billing/Coding/Physician Documentation Information

This policy 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. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 77301, 77338, 77385, 77386, G6015, G6016

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Randall ME, Ibbott GS. Intensity-modulated radiation therapy for gynecologic cancers: pitfalls, hazards, and cautions to be considered. *Semin Radiat Oncol* 2006; 16(3):138-43.

Veldeman L, Madani I, Hulstaert F et al. Evidence behind use of intensity-modulated radiotherapy: a systematic review of comparative clinical studies. *Lancet Oncol* 2008; 9(4):367-75.

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.49, 4/24/09

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.49, 5/2010

Specialty Matched Consultant Advisory Panel 8/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.49, 12/13/12

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BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.49, 12/12/13
Specialty Matched Consultant Advisory Panel 6/2014
Senior Medical Director review 11/2014
BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.49, 12/11/14
Specialty Matched Consultant Advisory Panel 5/2015
Senior Medical Director review 3/2016
Specialty Matched Consultant Advisory Panel 4/2016
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BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.49, 8/11/16
Specialty Matched Consultant Advisory Panel 5/2017
BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.49, 7/13/17
Specialty Matched Consultant Advisory Panel 5/2018
Medical Director review 5/2018
Medical Director review 7/2018
BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.49, 7/12/18
National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Bladder cancer. Version 5.2018. https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf
Medical Director review 9/2018

Policy Implementation/Update Information

- 12/21/09 New policy issued. BCBSNC will not provide coverage for Intensity Modulated Radiation Therapy (IMRT) of the abdomen and pelvis. IMRT is considered investigational for the treatment of tumors: of the upper abdomen, including but not limited to stomach, hepatobiliary tract, and pancreas; of the lower abdomen, including but not limited to anorectal locations; and of the pelvis, including but not limited to gynecologic (e.g., cervical, endometrial) locations. Notification given 12/21/09. Effective date 3/30/10. (adn)
- 6/22/10 Specialty Matched Consultant Advisory Panel 5/24/10. Policy statement change—added statement under “When covered” section indicating: “Intensity modulated radiation therapy may be considered medically necessary for patients with squamous cell cancer of the anus/anal canal.” Reference added. (lr)
- 9/30/11 Specialty Matched Consultant Advisory Panel 8/31/2011. No changes to policy statement. (lpr)
- 7/1/13 Specialty Matched Consultant Advisory Panel 8/2012 and 5/2013. Extensive revisions made to entire policy. Under “When Covered” section policy statement changed to state that IMRT is considered medically necessary for all anal cancers as well as when dosimetric planning with standard 3-D conformal radiation predicts that the radiation dose to an adjacent organ would result in unacceptable normal tissue toxicity, intensity-modulated radiation therapy (IMRT) may be considered medically necessary for the treatment of cancer of the abdomen and pelvis. Also added #3 a-e under “When Covered” section. Under “When Not Covered” section added a policy statement that IMRT would be considered investigational for all other uses in the abdomen and pelvis. Medical director review 5/2013. (lpr)

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- 8/27/13 Added endometrial to “When Covered” statement #3 d. for gynecological indications when treatment includes inguinal and/or pelvic nodes. Medical director review 8/2013. (lpr)
- 2/11/14 Reference added. No change to policy statement. (lpr)
- 7/29/14 Specialty matched consultant advisory panel review meeting 6/24/2014. No change to policy statement. (lpr)
- 12/30/14 Under “When Covered” section 3. c. and f. :added pancreas, liver, gastroesophageal junction and lower esophageal cancer to covered indications which may be medically necessary as part of the GI system. Removed “esophageal cancer” from Note under Description section. Under related policies section IMRT Breast and Lung title changed to IMRT Chest. Added CPT codes 77385, 77386 and added HCPCS codes G6015, G6016; Deleted CPT codes 77418, 0073T from Billing/Coding section effective 1/1/2015 for code update. Reference added. Senior medical director review 11/2014. (lpr)
- 7/1/15 Under Policy Guidelines section added the statement: “CPT 77338 is reported once per IMRT plan and is limited to 3 units per 60 day treatment course. Also added “Maximum Units of Service” to the Related Policies under the Description section. Specialty Matched Consultant Advisory Panel review 5/27/2015. No change to policy statement. (lpr)
- 4/1/16 Added covered indication for Lymphoma involving aortic/periaortic nodes (e) and retroperitoneal sarcomas of the abdominal cavity (f) under “When Covered” section. Deleted statement (“including liver and pancreas”) under “When Covered” section 3(c). Deleted references to vaginal or cervical cancer when brachytherapy will not be performed and GE junction/lower esophagus under “When Covered” section. Senior medical director review 3/2016. Specialty Matched Consultant Advisory Panel review. Notification given 4/1/16 for effective date 5/31/16. (lpr)
- 5/31/16 Specialty Matched Consultant Advisory Panel review 5/25/16. No change to policy statement. (lpr)
- 9/30/16 Updated Description and Policy Guidelines sections. No change to policy statement. Reference added. (lpr)
- 6/30/17 Specialty Matched Consultant Advisory Panel review 5/31/2017. No change to policy statement. (lpr)
- 8/25/17 Updated Policy Guidelines section. Reference added. No change to policy statement. (lpr)
- 8/10/18 Specialty Matched Consultant Advisory Panel review 5/2018. Reference added. No change to policy statement. (lpr)
- 11/9/18 Under “When Covered’ section: Added medically necessary criteria for bladder cancer #3.e. Updated Policy Guidelines section. Reference added. Medical Director review. (lpr)

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.