

Corporate Medical Policy

Intensity Modulated Radiation Therapy (IMRT) of Abdomen and Pelvis

File Name:	intensity_modulated_radiation_therapy_imrt_of_abdomen_and_pelvis
Origination:	11/2009
Last CAP Review:	8/2011
Next CAP Review:	8/2012
Last Review:	8/2011

Description of Procedure or Service

For certain stages of certain cancers, postoperative radiation therapy improves outcomes for many patients. Adding radiation to chemotherapy also improves outcomes for those with inoperable tumors that have not metastasized beyond regional lymph nodes. Over the past several decades, 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. Collectively, these methods are termed “conventional external-beam radiation therapy” (CRT).

Treatment planning evolved by using 3-dimensional images, usually from computed tomography (CT) scans, to delineate the tumor, its boundaries with adjacent normal tissue, and organs at risk for radiation damage. Radiation oncologists used these images, displayed from a “beam’s-eye view,” to shape each of several beams with compensators, blocks, or wedges to conform to the patient’s tumor geometry perpendicular to the beam’s axis. 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. However, “forward” planning used a trial and error process to select treatment parameters, including the number of beams and the intensity, shape, and incident axis of each. The radiation oncologist modified one or more parameters and re-calculated dose distributions, if analysis predicted underdosing for part of the tumor or overdosing of nearby normal tissue. Furthermore, because beams had uniform cross-sectional intensity wherever they bypassed shaping devices, it was difficult to match certain geometries, in particular concave surfaces. Collectively, these methods are termed 3-dimensional conformal radiation therapy (3D-CRT).

In the mid-1990s, 3D conformal methods were further developed to permit beam delivery with non-uniform cross-sectional intensity. This approach often relies on a device (a multileaf collimator, MLC) situated between the beam source and patient that moves along an arc around the patient. As it moves, a computer varies aperture size independently and continuously for each leaf. Thus, MLCs divide beams into narrow “beamlets,” with intensities that range from zero to 100% of the incident beam. With an alternative, termed tomotherapy, a small radiation portal emitting a single narrow beam moves spirally around the patient, with intensity varying as it moves. Each method (MLC-based or tomotherapy) is coupled to a computer algorithm 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

Intensity Modulated Radiation Therapy (IMRT) of Abdomen and Pelvis

and shape of beam ports, and beam and beamlet intensities, to achieve the treatment plan's goals. Collectively, these methods are termed intensity-modulated radiation therapy (IMRT).

Multiple studies have generated 3D-CRT and IMRT treatment plans from the same scans, then compared predicted dose distributions within the target and in adjacent organs at risk. Results of such planning studies show that IMRT improves on 3D-CRT with respect to conformality to, and dose homogeneity within, the target. Dosimetry using stationary targets generally confirms these predictions. Thus, radiation oncologists hypothesized that IMRT may improve treatment outcomes compared with those of 3D-CRT by one or more of the following mechanisms.

Increased conformality may permit escalated tumor doses without increasing normal tissue toxicity, and may thus improve local tumor control. Better dose homogeneity within the target may also improve local tumor control by avoiding underdosing (cold spots) within the tumor and may decrease toxicity by avoiding overdosing (hot spots). Finally, enhanced conformality for standard doses may reduce the dose outside the target volume and thus decrease toxicity.

However, IMRT aims radiation at the tumor from many more directions, and thus subjects more normal tissue to low-dose radiation than occurs with conventional EBRT or 3D-CRT. This technique may increase late effects of radiation therapy. In addition, because most tumors move as patients breathe, dosimetry with stationary targets may not accurately reflect doses delivered within target volumes and adjacent tissues in patients. Furthermore, treatment planning and delivery are more complex, time consuming and labor-intensive for IMRT than for 3D-CRT. Thus, clinical studies must test whether IMRT improves tumor control or reduces acute and late toxicities, when compared with 3D-CRT. Testing this hypothesis requires direct comparative data on outcomes for separate groups of similar patients treated with each method.

IMRT for prostate cancer, IMRT for cancer of the breast and lung, and IMRT for head and neck cancer are considered in separate policies.

******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** for patients with squamous cell cancer of the anus/anal canal.

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

Intensity Modulated Radiation Therapy (IMRT) of Abdomen and Pelvis

Intensity-modulated radiation therapy (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 rectal locations; and
- of the pelvis, including but not limited to gynecologic (e.g., cervical, endometrial) locations.

Policy Guidelines

A systematic review published in 2008 summarized evidence on the use of IMRT for a number of cancers, including head and neck, prostate, gynecologic, breast, lung, and gastrointestinal. The authors presented the review as an analysis of comparative clinical studies; in reality, they categorized several small case series using historical cohorts as controls as comparative studies for several tumor types. This method limits the value of the review in assessing the role of IMRT for the diseases addressed in this policy.

The 2009 NCCN Guidelines were reviewed in April 2009. They indicate that IMRT remains investigational for gastric cancer (http://www.nccn.org/professionals/physician_gls/pdf/gastric.pdf, v.2. 2009) and cervical cancer (http://www.nccn.org/professionals/physician_gls/PDF/cervical.pdf, v.1. 2009). Although IMRT is mentioned as an option in the guidelines for pancreatic cancer, they indicate a lack of consensus on radiotherapy dose and appropriate setting for use of IMRT in this disease (http://www.nccn.org/professionals/physician_gls/PDF/pancreatic.pdf, v.1.2009). IMRT is not mentioned in the guidelines for hepatobiliary cancers, although conformal or stereotactic radiotherapy are viewed as options for patients with unresectable lesions (http://www.nccn.org/professionals/physician_gls/PDF/hepatobiliary.pdf, v.2. 2009). Similarly, multiple conformal fields based on CT-treatment planning are mentioned as appropriate for uterine cancer, but IMRT technology is not specified (http://www.nccn.org/professionals/physician_gls/PDF/uterine.pdf, v.2. 2009).

The body of evidence available to assess the role of IMRT in the treatment of cancers of the upper abdomen and pelvis comprises several small case series, retrospective and prospective. No randomized trials have been reported that compared results with IMRT to any other CRT modality, nor do any of the case series include concurrently treated control patients. The available results may be viewed as hypothesis-generating for the design and execution of comparative trials of IMRT versus CRT that evaluate tumor control and survival outcomes in the context of adverse events and safety.

While IMRT is considered a major advance in the delivery of radiotherapy, numerous potential pitfalls and hazards associated with this technology merit further examination. A recent review addresses these issues in the context of gynecologic cancers, and concludes that “IMRT gives an overstated impression of accuracy and precision of treatment delivery.” The authors further assert that this has created a “tremendously false sense of security because the allure of precision from IMRT and inverse planning is at odds with the reality.” The review is written in the context of gynecologic cancers, however, “some, but not all, of these considerations would possibly be viewed differently if IMRT were being used to treat other diseases or parts of the body.”

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.

Intensity Modulated Radiation Therapy (IMRT) of Abdomen and Pelvis

Applicable codes: 77301, 77338, 77418, 0073T

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

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)

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.