Kansas City

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Intensity-Modulated Radiation Therapy (IMRT): Abdomen and Pelvis

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Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for IMRT of the abdomen and pelvis when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic 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.

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 (see Considerations), intensity-modulated radiation therapy (IMRT) may be considered **medically necessary** for the treatment of cancer of the abdomen and pelvis, including but not limited to:

- stomach (gastric);
- hepatobiliary tract;
- pancreas;
- rectal locations; or
- gynecologic tumors (including cervical, endometrial, and vulvar cancers).

When Policy Topic is not covered

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

Considerations

Radiation tolerance doses for normal tissues of the abdomen and pelvis

	TD 5/5 (Gy)[a]			**TD 50/5 (Gy)[b]**			
	Portion of organ involved			**Portion of organ involved**			
Site	**1/3**	**2/3**	**3/3**	**1/3**	**2/3**	**3/3**	**Complication endpoint**
Heart	60	45	40	70	55	50	Pericarditis
Lung	45	30	17.5	65	40	24.5	Pneumonitis
Spinal cord	50	50	47	70	70	NP	Myelitis/necrosis

Kidney	50	30	23	NP	40	28	Clinical nephritis
Liver	50	35	30	55	45	40	Liver failure
Stomach	60	55	50	70	67	65	Ulceration/perforation
Small intestine	50	NP	40	60	NP	55	Obstruction/perforation
Femoral head	NP	NP	52	NP	NP	65	Necrosis

[a]TD 5/5, the average dose that results in a 5% complication risk within 5 years

[b]TD 50/5, the average dose that results in a 50% complication risk within 5 years

NP: not provided

The tolerance doses in the table are a compilation from the following two sources:

Morgan MA (2011). Radiation Oncology. In DeVita, Lawrence and Rosenberg, *Cancer* (p.308). Philadelphia: Lippincott Williams and Wilkins.

Kehwar TS, Sharma SC. Use of normal tissue tolerance doses into linear quadratic equation to estimate normal tissue complication probability. http://www.rooj.com/Radiation%20Tissue%20Tolerance.htm

In order for IMRT to provide outcomes that are superior to 3DCRT, there must be a clinically meaningful decrease in the radiation exposure to normal structures with IMRT compared to 3DCRT. There is not a standardized definition for a clinically meaningful decrease in radiation dose. In principle, a clinically meaningful decrease would signify a significant reduction in anticipated complications of radiation exposure. In order to document a clinically meaningful reduction in dose, dosimetry planning studies should demonstrate a significant decrease in the maximum dose of radiation delivered per unit of tissue, and/or a significant decrease in the volume of normal tissue exposed to potentially toxic radiation doses. While radiation tolerance dose levels for normal tissues are well-established, the decrease in the volume of tissue exposed that is needed to provide a clinically meaningful benefit has not been standardized. Therefore, precise parameters for a clinically meaningful decrease cannot be provided.

Description of Procedure or Service

Radiation therapy 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. 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.”

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, which 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 to use multiple-shaped treatment fields. It uses a device (a multileaf collimator, MLC) which, coupled to 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 thus may 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.

Since 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.

Methodologic issues with IMRT studies
Multiple-dose planning 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. However, these types of studies offer indirect evidence on treatment benefit from IMRT, and it is difficult to relate results of dosing studies to actual effects on health outcomes.

Comparative studies of radiation-induced side effects from IMRT versus alternative radiation delivery are probably the most important type of evidence in establishing the benefit of IMRT. Such studies would answer the question of whether the theoretical benefit of IMRT in sparing normal tissue translates into real health outcomes. Single-arm series of IMRT can give some insights into the potential for benefit, particularly if an adverse effect that is expected to occur at high rates is shown to decrease by a large amount. Studies of treatment benefit are also important to establish that IMRT is at least as good as other types of delivery, but in the absence of such comparative trials, it is likely that benefit from IMRT is at least as good as with other types of delivery.

Note: Evidence for the following abdominal and pelvic cancers has not yet been reviewed and is beyond the scope of this current policy: bladder cancer, esophageal cancer, and sarcoma.

Rationale

This policy was originally created in 2009 and updated regularly with searches of the MEDLINE database. The most recent literature search was performed for the period of October 2012 through November 23, 2013. Following is a summary of the literature to date:

Introduction

Methods to plan and deliver intensity-modulated radiation therapy (IMRT) methods are not uniform.(1-3) IMRT may use beams that remain on as the multileaf collimator (MLC) moves around the patient (dynamic MLC), or that are turned off during movement and turned on when the MLC reaches prespecified positions ("step and shoot" technique). A third alternative uses a very narrow single beam that moves spirally around the patient (tomotherapy). Each of these methods uses different computer algorithms to plan treatment and yields somewhat different dose distributions in and outside the target. Patient position can alter target shape and thus affect treatment plans. IMRT may be delivered with the patient in the prone or supine position. However, data are unavailable to compare clinical outcomes for patients treated in prone versus supine positions, and consensus is lacking. Respiratory motion of the internal organs during radiation treatments is another concern when using IMRT to treat lesions in those compartments. Treatment plans are usually based on one imaging scan, a static 3-dimensional computed tomography (CT) image. They partially compensate for day-to-day (inter-fraction) variability in patient set-up, and for (intrafraction) motion of the target and organs at risk, by expanding the target volume with uniform margins around the tumor (generally 0.5–1 cm for all positional uncertainty).

Current methods seek to reduce positional uncertainty for tumors and adjacent normal tissues by various techniques. Patient immobilization cradles and skin or bony markers are used to minimize day-to-day variability in patient positioning. An active breathing control device combined with moderately deep inspiration breath-holding techniques may be used to improve conformality and dose distributions during IMRT. Other techniques being studied with internal tumors include gate beam delivery to the patient's respiratory movement or continuous monitor of tumor (by in-room imaging) or marker (internal or surface) positions to aim radiation more accurately at the target. The impact of these techniques on outcomes of IMRT for any cancer is unknown. However, it appears likely that respiratory motion alters the dose distributions actually delivered while treating patients from those predicted by plans based on static CT scans, or measured by dosimetry, using stationary (non-breathing) targets. In addition, many tumors have irregular edges that preclude drawing tight margins on CT scan slices when radiation oncologists contour the tumor volume. It is unknown whether omitting some tumor cells or including some normal cells in the resulting target affects outcomes of IMRT. Finally, tumor size may change over the course of treatment as tumors respond or progress, which has potential effects on radiation dose delivery and distribution. Whether outcomes might be improved by repeating scans and modifying treatment plans accordingly (termed adaptive radiation therapy) is unknown.

The Advanced Technology Consortium (ATC) has helped to develop general guidelines for protocols that incorporate IMRT as an option. These guidelines were communicated to all clinical trial groups by the National Cancer Institute (NCI) and clearly stated that respiratory motion could cause far more problems for IMRT than for traditional radiotherapy treatments (**ATC Guidelines for use of IMRT for intra-thoracic treatments**).

These considerations emphasize the need to compare clinical outcomes rather than treatment plan predictions to determine whether one radiotherapy method is superior to another.

Technology Assessments and Systematic Reviews

Two reviews summarized evidence on the use of IMRT for a number of cancers, including head and neck, prostate, gynecologic, breast, lung, and gastrointestinal. (4, 5) The authors presented the reviews as 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 reviews in assessing the role of IMRT for the diseases addressed in this policy.

Primary Literature

Literature searches have identified no studies that directly compare health outcomes with IMRT versus those in patients treated concurrently with any other type of radiotherapy for tumors of the thorax (e.g., esophagus), upper abdomen (e.g., stomach, pancreas, bile duct, liver), or pelvis (e.g., rectal, anal, gynecologic). Case series and single-arm studies of IMRT have been identified, including some with historical controls treated with non-IMRT methods.

Gastrointestinal Tract

Stomach
As outlined in a 2008 review article, IMRT has been investigated for treatment of gastric cancer in several studies, but at the time, only one reported clinical outcomes. (1) In a small (n=7) case series, patients with stage III gastric cancer received postoperative chemoradiotherapy with 5-fluorouracil (5FU) and leucovorin and IMRT delivered to a dose of 50.4 Gy in 1.8 Gy fractions. (6) Chemoradiotherapy with IMRT was well-tolerated, with no acute gastrointestinal (GI) tract toxicities (nausea, diarrhea, esophagitis) greater than grade 2.

The efficacy and safety of 2 different adjuvant chemoradiotherapy regimens using 3-dimensional conformal radiation (3D-CRT) (n=27) or IMRT (n=33) were evaluated in 2 consecutive cohorts of patients who underwent primarily D2 resection for gastric cancer. (7) The cohorts in this study were generally well-matched, with American Joint Committee on Cancer (AJCC) advanced stage (II-IV) disease. The majority (n=26, 96%) of those who received 3D-CRT were treated with 5-fluorouracil plus folinic acid (5FU/FA); the other patient received oxaliplatin plus capecitabine (XELOX). In the 3D-CRT cohort, 13 (50%) patients completed the 5FU/FA regimen, 13 halted early because of acute toxicity or progression and received a median 60% of planned cycles. Patients in the IMRT cohort received XELOX (n=23, 70%) or 5FU/FA (n=10, 30%). Five of 10 (50%) patients completed all planned 5FU/FA cycles, the other 5 received only a median 60% of cycles because of acute toxicity. Thirteen (56%) treated with XELOX completed all planned cycles; the other 10 received a median of 70% planned cycles because of toxicity. Radiation was delivered to a total prescribed dose of 45 Gy/1.8 Gy/fraction in 21 (81%) of the 3D-CRT cohort patients; 5 received less than 45 Gy because of intolerance to treatment. Thirty (91%) patients in the IMRT cohort received the planned 45 Gy dosage; 2 (6%) were unable to tolerate the full course, and 1 case planned for 50.4 Gy was halted at 47 Gy. The median overall survival (OS) was 18 months in the 3D-CRT cohort, and more than 70 months in the IMRT cohort (p=0.0492). The actuarial 2-year OS rates were 67% in the IMRT cohort and 37% in the 3D-CRT group (p not reported). Acute renal toxicity based on creatinine levels was generally lower in the IMRT cohort compared to the 3D-CRT group, with a significant difference observed at 6 weeks (p=0.0210). In the 3D-CRT group, LENT-SOMA grade 2 renal toxicity was observed in 2 patients (8%) whereas no grade 2 toxicity was reported in the IMRT group. In a subsequent report from this group, which included 27 3D-CRT patients and 38 IMRT patients, median OS times for 3D-CRT were 18 months versus 43 months for IMRT (p=0.0602). (8) In the 3D-CRT group, actuarial 5-year OS rates were 26% versus 47% in the IMRT group (p value not reported). Median disease-free survival in the 3D-CRT group was 14 months versus 35 months in the IMRT group, respectively (p=0.0693). The actuarial 5-year disease free survival rate was 22% for 3D-CRT and 44% for IMRT (p not reported).

Hepatobiliary
In a retrospective series with a historical control cohort, clinical results achieved with image-guided IMRT (n=24) were compared to results with CRT (n=24) in patients with primary adenocarcinoma of the biliary tract.(9) The majority of patients underwent postsurgical chemoradiotherapy with concurrent fluoropyrimidine-based regimens. IMRT treatment plans prescribed 46 to 56 Gy to the planning target volume (PTV) that includes the tumor and involved lymph nodes, in daily fractions of 1.8–2 Gy. CRT involved 3-D planning that delivered 46–50 Gy in 1.8–2 Gy daily fractions. Both groups received boost doses of 4–18 Gy as needed. The median estimated overall survival (OS) for all patients who completed treatment was 13.9 months (range: 9.0–17.6); the IMRT cohort had median OS of 17.6 months (range: 10.3–32.3), while the CRT cohort had a median OS of 9.0 months (range: 6.6–17.3).

Acute GI toxicities were mild to moderate, with no significant differences between patient cohorts. These results suggest that moderate dose escalation via conformal radiotherapy is technically and clinically feasible for treatment of biliary tract adenocarcinoma. However, while this series represents the largest group of patients with this disease treated with IMRT, generalization of its results is limited by the small numbers of patients, use of retrospective chart-review data, nonrepresentative case spectrum (mostly advanced/metastatic disease), and comparison to a nonconcurrent control radiotherapy cohort.

Two single-arm studies reported outcomes with IMRT in patients with hepatobiliary cancers. The first study involved 42 patients with advanced (33% AJCC stage IIIC, 67% stage IV) hepatocellular carcinoma (HCC) with multiple extrahepatic metastases.(10) Among the 42 cases, 33 (79%) had intrahepatic HCC with extrahepatic metastases, 9 (21%) had only extrahepatic lesions. The extrahepatic locations of HCC metastatic lesions included lung (n=19), lymph node and adrenal (n=20), other soft tissues (n=6), and bone (n=5). Helical tomotherapy was performed simultaneously for all lesions in each patient, with a total radiation dose of 50 and 40 Gy to 95% of the gross tumor volume (GTV) and PTV in 10 fractions divided over 2 weeks. All received capecitabine during the course of IMRT as a radiosensitizer. After completion of tomotherapy, additional transarterial or systemic chemotherapy was administered to patients eligible for it according to tumor location. Among 31 patients who underwent hepatic IMRT, a mean of 3 courses of (range: 1-6) transarterial chemolipiodolization was performed in 23. Among 9 patients with extrahepatic lesions only, 3 received an additional 3-7 cycles of systemic chemotherapy consisting of epirubicin, cisplatin, and 5FU. Median follow-up was 9.4 months (range: 1.9–25.3 months). Tumor response was reported separately for each organ treated with IMRT. The overall objective tumor response rate was 45% for intrahepatic HCC, 68% for pulmonary lesions, 60% for lymph node and adrenal cases, and 67% for soft tissue metastases. Three cases of local tumor progression occurred within the target radiation area, including 2 intrahepatic HCC and 1 abdominal lymph node metastasis. Median OS was 12.3 months, with 15% OS at 24 months. The most common acute adverse events were mild anorexia and constitutional symptoms that occurred 1-2 weeks after start of IMRT, regressed spontaneously or subsided with symptomatic care, and did not interfere with the scheduled delivery of IMRT. However, it is not possible to discern the impact of IMRT on adverse events because almost all occurred in patients who received chemotherapy following IMRT. However, most patients were reported to have tolerated therapy well, with no treatment-related mortality.

A second retrospective single-arm study involved 20 patients with primary, unresectable HCC who were treated with IMRT and concurrent capecitabine.(11) Patients had AJCC grade T1 (n=7) and T3 (n=13) HCC. IMRT was prescribed to a minimum tumor dose of 50 Gy in 20 fractions over 4 weeks, with the optimization goal of delivering the prescription dose to 95% of the PTV. Capecitabine was administered as radiosensitizer on the days of IMRT delivery. Eleven (55%) patients underwent at least 1 transarterial chemoembolization (range: 1-3 procedures) before radiotherapy planning. Eighteen of 20 (90%) patients completed the full course of IMRT, 2 died before follow-up imaging was obtained. The mean survival of 18 patients who completed IMRT was 9.6 months after its conclusion. Disease progression occurred in-field in 3 patients, 2 failed elsewhere in the liver. Four patients (25%) required hospitalization during therapy, due to encephalopathy (n=1), gastric ulcer (n=1), acute hepatitis (n=1), and sepsis (n=1). Four required a break from chemotherapy because of peripheral neuropathy (n=2), acute hepatitis (n=1), and sepsis (n=1). Grade 1 acute abdominal pain was observed in 15%, 30% reported grade 1 nausea, 5% experienced grade 2 nausea. No acute or late toxicity greater than grade 2 was reported.

Pancreatic

Few reports of case series provide clinical results with IMRT for pancreatic carcinoma. The largest series involved a retrospective analysis of 41 patients who received image-guided IMRT alone, postsurgically (41%), or with a number of concurrent primarily fluoropyrimidine-based chemotherapy regimens (88%). (12) The prescribed radiation dose to the PTV ranged from 41.4–60.4 Gy in daily fractions of 1.8–2 Gy. For all patients diagnosed with adenocarcinoma (85%), 1- and 2-year actuarial OS were 38% and 25%, respectively; median OS in resected patients was 10.8 months (range: 6.2–

55.1), as compared to 10.0 months (range: 3.4–28.0) in inoperable cases. Four patients (9.7%) were unable to complete radiotherapy as prescribed. Any upper GI acute toxicity (none grade 4) was reported in 29 (70%) patients, most commonly nausea, vomiting, and abdominal pain; any lower GI acute toxicity (less than 5% grade 4) was reported in 17 (42%) cases, primarily diarrhea.

A series of 20 patients with locally advanced pancreatic cancer without metastases were treated with dose-painted IMRT and chemotherapy. (13) Median OS was 11.6 months with 90% local control. Progression-free survival was 5.9 months. Grade 2 GI toxicity was 60% and grade 3 or more GI toxicity was 20%. The authors estimated the IMRT treatment plan significantly lowered V45 values for the small bowel (p=0.0002), stomach (p=0.007) and mean liver doses (p=0.001) compared to 3D-CRT. In a series of 25 patients with pancreatic and bile duct cancers (68% unresectable), 24 were treated with IMRT and concurrent 5FU, 1 refused chemotherapy. (14) Resected patients received 45–50.4 Gy to the PTV, whereas unresectable patients received 50.4–59.4 Gy. For all cancers, the median OS was 13.4 months, with 1- and 2-year OS of 55% and 22%, respectively. One- and 2-year median OS were 83% and 50%, respectively, among resected cases, and 40% and 8%, respectively, among unresected cases. IMRT was well-tolerated, with grade 2 or less acute upper GI toxicity in 80% of patients; grade 4late liver toxicity was reported in 1 patient who survived more than 5 years.

A retrospective series included 15 patients with pancreatic adenocarcinoma (7 resected, 8 unresectable) who underwent IMRT plus concurrent capecitabine. (15) Resected cases received 45–54 Gy to the gross tumor volume, unresected cases received 54–55 Gy to the gross tumor volume; all cases received 45 Gy to the draining lymph node basin. At a median follow-up of 8.5 months, no deaths were reported among the resected patients, compared to 2 deaths in the unresected cases, yielding a 1-year OS rate of 69% among the latter. No grade 4 toxicities were reported, with the vast majority of acute toxicities reported at grade 1 (nausea, vomiting, diarrhea, neutropenia, anemia).

Gynecologic

A series of reports from a single institution provided data on clinical outcomes achieved with IMRT in women with gynecologic malignancies. Patients from an initial series (16) were included in a subsequent report that comprised 40 patients who underwent IMRT to treat cancers of the cervix, endometrium, and other sites (3 patients). (17) Patients in this series underwent postsurgical IMRT (70%), with (58%) or without (42%) cisplatin chemotherapy, with a majority (60%) also undergoing postradiotherapy intracavitary brachytherapy (ICB). IMRT was prescribed to the PTV at a dose of 45 Gy, delivered in 1.8 Gy daily fractions; ICB delivered an additional 30–40 Gy to cervical cancer patients and 20–25 Gy to those with endometrial cancer. A well-matched nonconcurrent cohort of patients who underwent 4-field CRT (45 Gy to the PTV, 1.8 Gy daily fractions) using 3D planning and received cisplatin chemotherapy was used to compare acute GI and genitourinary (GU) toxicities between radiotherapy modalities. No grade 3 acute GI or GU toxicities were reported in IMRT or CRT recipients. Grade 2 GI toxicity was noted in 60% of the IMRT cohort versus 91% of the CRT group (p=0.002). No significant differences were noted in the incidence of grade 2 GU toxicity in IMRT recipients (10%) compared to the CRT cohort (20%). Three other reports from the same group provide data on acute hematologic toxicity, (18) chronic GI toxicities, (19) and acute GI toxicities (20) among patients who underwent IMRT with or without chemotherapy. It is unclear whether or not the patients in these reports are those from the initial studies or are new patients.

A small case series involved 10 patients who underwent IMRT with intracavitary brachytherapy boost for locally advanced (FIGO stage IIB and IIIB) cervical cancer. (21) During radiotherapy, all patients received cisplatin. Whole pelvic IMRT was administered to a dose of 50.4 Gy in 28 fractions, and intracavitary brachytherapy (ICB) was delivered to a dose of 30 Gy in 6 fractions. The mean OS was 25 months (range: 3-27 months), with actuarial OS of 67%. Acute toxicities included 1 patient with grade 3 diarrhea, 1 with grade 3 thrombocytopenia, and 3 with grade 3 leukopenia. One case of subacute grade 3 thrombocytopenia was noted. These data are insufficient to draw conclusions about the efficacy or safety of IMRT in cervical cancer.

Two subsequent studies examined the use of post-hysterectomy radiotherapy in women with high-risk cervical cancer. In the first study, 68 patients were treated with adjuvant pelvic radiotherapy, high dose-rate ICB, and concurrent chemotherapy. (22) The initial 35 cases received 4-field box CRT delivered to the whole pelvis; a subsequent 33 patients underwent IMRT. All patients received 50.4 Gy of radiation in 28 fractions and 6 Gy of high dose-rate vaginal cuff ICB in 3 insertions; cisplatin was administered concurrently to all patients. All patients completed the planned course of treatment. At median follow-up of 34.6 months (range: 12–52) in CRT recipients and 14 months (range: 6–25) in IMRT recipients, the 1- year locoregional control rate was 94% for CRT and 93% for IMRT. Grades 1 to 2 acute GI toxicities were noted in 36% and 80% of IMRT and CRT recipients, respectively (p=0.00012), while acute grade 1 to 2 GU toxicities occurred in 30% versus 60%, respectively (p=0.022). There was no significant difference between IMRT and CRT in the incidence of acute hematologic toxicities. Overall, the IMRT patients had lower rates of chronic GI (p=0.002) toxicities than the CRT patients.

A subsequent report from the same group included the initial 33 patients in that experience with an additional 21 cases. (23) At a median follow-up of 20 months, this study showed a 3-year disease-free survival rate of 78% and an OS rate of 98% in IMRT recipients.

Ghandi et al. reported on a prospective randomized study to compare whole-pelvic IMRT to whole-pelvic CRT in 44 patients with locally advanced cervical cancer. (24) Each treatment arm had 22 patients. OS at 27 months was 87.7% with IMRT versus 76% with CRT (p=0.645). However, fewer grade >2 and >3 GI toxicities were experienced in the IMRT group than the CRT group.

In 2013, Chen and colleagues reported on 101 patients with endometrial cancer treated with hysterectomy and adjuvant radiation therapy. (25) No significant differences between IMRT patients (n=65) and CRT patients (n=36) were found in 5-year OS, local failure-free survival and disease-free survival (82.9% vs. 93.5% [p=0.26], 93.7% vs. 89.3% [p=0.68], and 88.0% vs. 82.8% [p=0.83], respectively). However, the IMRT patients experienced less acute and late toxicities. Shih et al. reported results on 46 patients who received IMRT after hysterectomy and bilateral salpingo-oophorectomy for endometrial cancer, 78% of whom had stage III disease. (26) At a median of 52 months' follow-up, 5-year OS was 90% while toxicities were minimal.

Beriwal et al. reported on 42 patients treated for locally advanced vulvar carcinoma with IMRT and chemotherapy. (27) Sixteen patients (48.5%) had a complete pathologic response and 15 remained progression-free at a median of 26.5 months. Eight patients developed recurrence at the surgical site of the vulva. Chronic grade >3 GI or GU toxicity did not occur.

Anorectal

Recent studies have found IMRT with chemotherapy for the treatment of anal cancer reduces acute and late adverse events compared to 3D-CRT with chemotherapy. However, survival outcomes have not been significantly different between IMRT and CRT, and concerns exist over increases in locoregional recurrence with IMRT. In a retrospective review of 89 consecutive patients (52 IMRT and 37 3D-CRT), Chuong et al. found 3-year overall survival, progression-free survival, locoregional control and colostomy-free survival did not differ significantly in patients treated with IMRT compared to 3D-CRT (p>0.1). (28) Adverse events with 3D CRT were more frequent and severe and required more treatment breaks than IMRT (11 vs. 4; p=0.006) even though the median duration of treatment breaks did not differ significantly (12.2 vs. 8.0 days; p=0.35). IMRT patients had fewer acute grade >3 nonhematologic toxicity (p<0.0001), improved late grade >3 gastrointestinal toxicity (p=0.012) and fewer acute grade >3 skin toxicity (p<0.0001) than 3D-CRT patients. Dewas et al. retrospectively reviewed 51 patients with anal cancer treated with IMRT or 3D-CRT (24 IMRT and 27 3D-CRT). (29) Outcomes were also not significantly different between IMRT and 3D-CRT for 2-year overall survival, locoregional relapse-free survival and colostomy-free survival. Grade 3 acute toxicity occurred in 11 IMRT patients vs. 10 3D-CRT patients. Dasgupta and colleagues retrospectively reviewed 223 patients (45 IMRT and 178 CRT) to compare outcomes in patients treated for anal cancer. (30) The authors reported 2-year overall survival, distant metastases-free survival and locoregional recurrence-free survival were not significantly different between IMRT and CRT. A single-institution series included 17

patients with stage I/II cancer who underwent IMRT alone (n=3) or concurrent with 5FU alone (n=1) or 5FU with mitomycin C (MMC, n=13). (31) Patients generally received 45 Gy to the PTV at 1.8 Gy per fraction, followed by a 9 Gy boost to the gross tumor volume. Thirteen of 17 (76%) patients completed treatment as planned. None experienced acute or late grade 3 or above nonhematologic (GI or GU) toxicity. Grade 4 acute hematologic toxicity (leukopenia, neutropenia, thrombocytopenia) was reported in 5 of 13 (38%) patients who received concurrent chemoradiotherapy. At a median follow-up of 20.3 months, the 2-year OS rate was 91%.

A multicenter series included a cohort of 53 consecutive patients who received concurrent chemotherapy and IMRT. (32) Forty-eight (91%) received 5FU plus MMC, the rest received other regimens not including MMC. Radiation was delivered at 45 Gy to the PTV. Thirty-one (58%) patients completed therapy as planned, with breaks in the others because of grade 4 hematologic toxicities (40% of patients), painful moist desquamation, or severe GI toxicities. At the18-month follow-up, the local tumor control rate was 83.9% (range: 69.9–91.6%), with an OS rate of 93.4% (range: 80.6–97.8%). Univariate analyses did not reveal any factors significantly associated with tumor control or survival rates, whereas a multivariate analysis showed patients with stage IIIB disease experienced a significantly lower colostomy-free survival (hazard ratio 4.18; 95% CI: 1.062–16.417; p=0.041).

A gastrointestinal toxicity study was reported in 45 patients who received concurrent chemotherapy and IMRT for anal cancer. (33) Chemoradiotherapy is becoming the standard treatment for anal cancer, in part due to preservation of sphincter function. Patients had T1 (n=1), T2 (n=24), T3 (n=16), and T4 (n=2) tumors; N stages included Nx (n=1), N0 (n=31), N1 (n=8), N2 (n=3), and N3 (n=2). Concurrent chemotherapy primarily comprised 5-FU plus mitomycin C (MMC). IMRT was administered to a dose of 45 Gy in 1.8 Gy fractions, with areas of gross disease subsequently boosted with 9–14.4 Gy. Acute genitourinary toxicity was grade 0 in 25 (56%) cases, grade 1 in 10 (22%) patients, grade 2 in 5 (11%) patients, with no grade 3 or 4 toxicities reported; 5 (11%) patients had no genitourinary tract toxicities reported. Grades 3-4 leukopenia was reported in 26 (56%) cases, neutropenia in 14 (31%), and anemia in 4 (9%). Acute GI toxicity included grade 0 in 2 (4%) patients, grade 1 in 11 (24%), grade 2A in 25 (56%), grade 2B in 4 (9%), grade 3 in 3 (7%) and no grade 4 toxicities. Univariate analysis of data from these patients suggests a statistical correlation between the volume of bowel that received 30 Gy or more of radiation and the risk for clinically significant (grade 2 or higher) GI toxicities.

A retrospective analysis of toxicity and disease outcomes associated with IMRT was performed in 47 patients with anal cancer. (34) Thirty-one patients had squamous cell carcinoma (SCC). Patients had AJCC stage I (n=6, 13%), stage II (n=16, 36%), stage III (n=14, 31%), stage IV (n=6, 13%), or recurrent disease (n=3, 7%). IMRT was prescribed to a dose of at least 54 Gy to areas of gross disease at 1.8 Gy per fraction. Forty patients (89%) received concurrent chemotherapy with a variety of agents including MMC, 5FU, capecitabine, oxaliplatin, etoposide, vincristine, doxorubicin, cyclophosphamide, and ifosfamide in various combinations. The 2-year actuarial OS for all patients was 85%. Eight patients (18%) required treatment breaks. Toxicities included grade 4 leukopenia (7%) and thrombocytopenia (2%); grade 3 leukopenia (18%) and anemia (4%); and, grade 2 skin toxicity (93%). These rates were much lower than previous trials of chemoradiation, where grade 3 to 4 skin toxicity was noted in about 50% of patients and grade 3 to 4 GI toxicity noted in about 35%. In addition, the rate of treatment breaks was lower than in many studies; and some studies of chemoradiation include a break from radiation therapy. Some investigators believe that treatment breaks reduce the efficacy of this combined approach.

A small (n=6) case series of IMRT and concurrent infusional 5FU plus cisplatin was reported in patients with anal cancer and para-aortic nodal involvement. (35) IMRT was delivered to a median dose of 57.5 Gy to the CTV, with nodal areas of involvement treated to a median dose of 55 Gy. Five of 6 completed the entire prescribed course of IMRT. The 3-year actuarial OS rate was 63%. Four patients developed grade 3 acute toxicities that included nausea and vomiting, diarrhea, dehydration, small bowel obstruction, neutropenia, anemia, and leukopenia. Five of 6 had grade 2 skin toxicity.

Zhu and colleagues reported on a Phase II trial of neoadjuvant IMRT with chemotherapy for 42 patients with stage II/III rectal adenocarcinoma. (36) Surgical resection was performed in 38 patients and pathological complete response occurred in 6 patients. Skin, gastrointestinal tract and hematologic grade 3 toxicities were 26.2%, 14.3% and 4.7%, respectively. No grade 4 toxicity was seen. Patients who responded well (defined as tumor regression grade [TRG] 3-4) had OS of 83.9% versus 40.7% in patients who were poor responders (defined as TRG 1-2; [p=0.007]).

Zhu and colleagues also reported on a Phase II trial of IMRT with chemotherapy for 32 patients with rectal adenocarcinoma and unresectable distant metastases. (37) IMRT was delivered to the pelvis at 45 Gy with a concomitant 10 Gy boost to the gross tumor. Surgical resection of the rectal tumor was also performed in 14 patients. Dermatitis from the IMRT around the anal verge occurred most commonly in 18.8% of patients. OS was 17.5 months and progression-free survival was 12 months at a median follow-up of 12 months (range, 4-23 months). Local failure occurred in 2 patients.

Input from Academic Medical Centers and Physician Specialty Societies
In response to requests, input was received from one physician specialty society (4 reviewers) and 3 academic medical centers while this policy was under review for August 2012. While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted. The input was somewhat mixed, but there was support for use of IMRT in a number of cancers discussed above. In general, this support was based on finding different radiation doses to various organs based on treatment planning studies. There was some support for the use of IMRT when currently accepted normal dose constraints for safe delivery of radiation therapy could not be met without using IMRT.

In response to requests, input was received from one physician specialty society (2 reviewers) and 3 academic medical centers while this policy was under review for May 2010. While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted. There was support for use of IMRT in a number of cancers discussed above. In general, this support was based on finding different radiation doses to various organs based on treatment planning studies.

Ongoing Clinical Trials
A search of online site ClinicalTrials.gov on November 24, 2013 identified 33 Phase II or III clinical trials recruiting patients to evaluate the use of IMRT in gynecologic, pancreatic, colorectal, and hepatobiliary tract cancer (available online at: http://clinicaltrials.gov/ct2/results?term=imrt&recr=Open&rslt=&type=Intr&cond=anal+OR+anorectal+OR+pelvic+OR+pancreatic+OR+gastric+OR+hepatobiliary+OR+vulval+OR+endometrial+OR+uterine+OR+cervical&intr=&outc=&spons=&lead=&id=&state1=&cntry1=&state2=&cntry2=&state3=&cntry3=&locn=&gndr =&phase=1&phase=2&rcv_s=&rcv_e=&lup_s=&lup_e=).

Summary
The body of evidence available to assess the role of intensity-modulated radiation therapy (IMRT) in the treatment of cancers of the abdomen and pelvis generally comprises case series, both retrospective and prospective. Only one randomized trial has been reported that compared results of whole-pelvic IMRT to whole-pelvic conformal radiation therapy (CRT) for cervical cancer. Reports of case series including concurrently treated control patients are emerging. The available results are generally 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.

The comparative data on use of IMRT versus 3-dimensional conformal radiation (3D-CRT) in chemoradiotherapy for anal cancer shows marked differences in rates of acute toxicity. Thus, use of IMRT in cancer of the anus/anal canal may be considered medically necessary.

For other tumors of the abdomen and pelvis, the evidence from treatment planning studies has shown that the use of IMRT decreases radiation doses delivered to normal tissue adjacent to tumor. This potentially lowers the risk of adverse events (acute and late effects of radiation toxicity), although the clinical benefit of reducing the radiation dose to normal tissue using IMRT is theoretical. Due to the limitations in this evidence, this policy underwent clinical vetting. There was support for the use of IMRT in tumors of the abdomen and pelvis when normal tissues would receive unacceptable doses of radiation. The results of the vetting, together with an indirect 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 3-D conformal radiation predicts that the radiation dose to an adjacent organ would result in unacceptable normal tissue toxicity.

Guidelines and Position Statements

National Comprehensive Cancer Network (NCCN) Guidelines
The NCCN guidelines for anal carcinoma (http://www.nccn.org/professionals/physician_gls/PDF/anal.pdf, V.1.2014) state that IMRT "may be used in place of 3D conformal RT in the treatment of anal carcinoma;" and, that "Its use requires expertise and careful target design to avoid reduction in local control by so-called "marginal-miss."

The NCCN guidelines indicate that IMRT for gastric cancer "is appropriate in selected cases to reduce dose to normal structures such as heart, lungs, kidneys and liver." (http://www.nccn.org/professionals/physician_gls/pdf/gastric.pdf, V.2.2013). In designing IMRT plans "for structures such as the lungs, attention should be given to the volume receiving low to moderate doses, as well as the volume receiving high doses."

IMRT is not mentioned in the guidelines for hepatobiliary cancers. (http://www.nccn.org/professionals/physician_gls/PDF/hepatobiliary.pdf, V.2.2013).
Although IMRT is mentioned as an option in the NCCN guidelines for pancreatic adenocarcinoma with increasing use "in the adjuvant setting with the aim of increasing radiation dose to the gross tumor/tumor bed while minimizing toxicity to surrounding tissues.", the guidelines indicate a lack of consensus on maximum radiotherapy dose in this disease. (http://www.nccn.org/professionals/physician_gls/PDF/pancreatic.pdf, V.1.2013).

The NCCN guidelines on rectal cancer (http://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf, V.2.2014) indicate IMRT should only be used to treat rectal cancer in clinical trials "or in unique clinical situations including reirradiation of recurrent disease after previous radiotherapy."

In cervical cancer (http://www.nccn.org/professionals/physician_gls/PDF/cervical.pdf, V.3.2013), the NCCN guidelines indicate IMRT "may be helpful in minimizing the dose to the bowel and other critical structures in the post-hysterectomy setting and in treating the para-aortic nodes when necessary" such as "when high doses are required to treat gross disease in regional lymph nodes." IMRT "should not be used as routine alternatives to brachytherapy for treatment of central disease in patients with an intact cervix." The guidelines also mention that IMRT is "becoming more widely used" but issues with reproducibility, immobilization and definition of target "remain to be validated."

IMRT is not mentioned in the NCCN guidelines for uterine endometrial cancer. (http://www.nccn.org/professionals/physician_gls/PDF/uterine.pdf, V.1.2013).

IMRT is not mentioned in the NCCN guidelines for ovarian cancer. (http://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf, V.2.2013).

Medicare National Coverage
No national coverage determination (NCD) was identified. In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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Billing Coding/Physician Documentation Information

0073T Compensator-based beam modulation treatment delivery of inverse planned treatment using 3 or more high resolution (milled or cast) compensator convergent beam modulated fields, per treatment session

49327 Laparoscopy, surgical; with placement of interstitial devices(s) for radiation therapy guidance (e.g., fiducial markers, dosimeter), intra-abdominal, intra-pelvic, and/or retroperitoneum, including imaging guidance, if performed, single or multiple (List separately

in addition to code for primary procedure)

49411 Placement of interstitial device(s) for radiation therapy guidance (e.g., fiducial markers, dosimeter), percutaneous, intra-abdominal, intra-pelvic (except prostate), and/or retroperitoneum, single or multiple

49412 Placement of interstitial device(s) for radiation therapy guidance (e.g., fiducial markers, dosimeter), open, intra-abdominal, intra-pelvic, and/or retroperitoneum, including image guidance, if performed, single or multiple (List separately in addition to code for primary procedure)

77301 Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications

77338 Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan

77418 Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session

77421 Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy

Additional Policy Key Words

N/A

Policy Implementation/Update Information

11/1/09	New policy; considered investigational. This policy is effective 12/15/2009.
1/1/10	Updated coding.
5/13/10	Policy statement revised to indicate use in anal cancers may be considered medically necessary.
11/1/10	No policy statement changes.
1/1/11	Coding updated.
11/1/11	No policy statement changes.
11/1/12	No policy statement changes.
12/13/12	Policy statement changed to state that IMRT may be considered medically necessary for all anal cancers (not limited to squamous cell carcinoma). Policy statement changed to state that IMRT may be considered medically necessary for the treatment of tumors of the abdomen and pelvis when dosimetric planning predicts the volume of small intestine receiving doses >45 Gy with standard 3-D conformal radiation would result in unacceptable risk of small intestine injury. Added a policy statement that IMRT would be considered investigational for all other uses in the abdomen and pelvis. Paragraph added to policy guidelines regarding toxic radiation dose to tissues and definition of a clinically significant decrease in radiation dose.
2/1/14	No policy statement changes.