The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Preauthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary; supporting documentation must be submitted to Use Management, but if for treatment of cancer of the colon or rectum documentation must be submitted to radiation oncology services vendor.* Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

Description

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 two-dimensional treatment planning based on flat images, and radiation beams with cross-sections of uniform intensity that were sequentially aimed at the tumor along two or three intersecting axes. Collectively, these methods are termed “conventional external-beam radiation therapy” (CRT).

Treatment planning evolved by using three-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 three-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 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 external-beam radiation therapy 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.

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

Related Protocol:
Intensity-Modulated Radiation Therapy (IMRT): Cancer of the Head and Neck or Thyroid

Corporate Medical Guideline
Intensity-modulated radiation therapy (IMRT) is considered investigational for the treatment of tumors (malignancies) of the abdomen and pelvis including:

• stomach (gastric), hepatobiliary tract, and pancreas; and
• gynecologic tumors including cervical, endometrial and vulvar cancers.

Bladder cancer, esophageal cancer, and sarcoma, as well as colon and rectal cancers are not addressed in the above medical guideline.

Medicare Advantage
For Medicare Advantage IMRT may be considered medically necessary as an approach to delivering radiation therapy for patients with abdominal or pelvic cancers, such as but not limited to cancers of the pancreas, liver,
adrenal gland, esophagus, bladder, uterus and vagina and one of the following criteria is met:

- Where sparing the surrounding normal tissue is essential OR
- Only IMRT techniques would decrease the probability of grade 2 or grade 3 radiation toxicity as compared to conventional radiation in greater than 15 percent of irradiated similar cases OR
- Important dose limiting structures adjacent to, but outside the PTV are sufficiently close and require IMRT to assure for safety and morbidity reduction OR
- An immediately adjacent volume has been irradiated and abutting portals must be established with high precision OR
- Gross Tumor Volume (GTV) margins are in close proximity to critical structures that must be protected to avoid unacceptable morbidity.

**Note:** The decision process for using IMRT requires an understanding of accepted practices that take into account the risks and benefits of such therapy compared to conventional treatment techniques. While IMRT technology may empirically offer advantages over conventional or three-dimensional conformal radiation, a comprehensive understanding of all consequences is required before applying this technology.

**Limitations:**

IMRT is not considered medically necessary when the type of cancer and at least one of the criteria listed in the indications of coverage section of this Protocol is not present, or where sparing surrounding normal tissue is not essential.

**Note:** This Protocol does not address IMRT for treatment of cancers of the colon and rectum.

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


26. NHIC Carrier LCD for IMRT (L3244) 1/1/11.