Medical Coverage Policy | Intensity-Modulated Radiotherapy: Abdomen and Pelvis

EFFECTIVE DATE: 02|15|2016
POLICY LAST UPDATED: 09|05|2017

OVERVIEW

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

MEDICAL CRITERIA

BlueCHiP for Medicare and Commercial Products

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

When dosimetric planning with standard 3-dimensional conformal radiotherapy predicts that the radiation dose to an adjacent organ would result in unacceptable normal tissue toxicity, 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).

IMRT would be considered not medically necessary for all other uses in the abdomen and pelvis.

PRIOR AUTHORIZATION

Prior authorization is recommended and obtained via the online tool for participating providers.

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Products

Intensity-modulated radiotherapy of the abdomen and pelvis may be considered medically necessary when the criteria above is met**.**

IMRT would be considered **not medically necessary** for all other uses in the abdomen and pelvis as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement, or Benefit Booklet for radiology benefit/coverage.

BACKGROUND

Radiation Techniques

Conventional External-Beam Radiotherapy

Over the past several decades, methods to plan and deliver radiotherapy 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 radiotherapy.

Three-Dimensional Conformal Radiation
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 radiotherapy (3D-CRT).

Intensity-Modulated Radiotherapy
IMRT, which uses computer software, CT images, and magnetic resonance imaging, offers better conformality than 3D-CRT because 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]) that, 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 beam 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.

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.

The body of evidence available to assess the role of IMRT in the treatment of cancers of the abdomen and pelvis generally comprises case series, both retrospective and prospective. Only 1 randomized trial has been reported that compared results of whole-pelvic IMRT with whole-pelvic conformal radiotherapy (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 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 3D conformal radiation predicts that the radiation dose to an adjacent organ would result in unacceptable normal tissue toxicity.

The evidence on IMRT for gynecologic cancer includes limited comparative evidence on survival outcomes following IMRT or 3D-CRT. However, available results are generally consistent that IMRT leads to a reduction in GI and GU toxicity. Based on evidence with other cancers of the pelvis and abdomen that are in close proximity 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.

For individuals who have gastrointestinal tract cancer who receive IMRT, the available comparative evidence, together with dosimetry studies of organs at risk, suggests that IMRT may improve survival and decrease 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 anorectal cancer who receive IMRT,The comparative data on use of IMRT versus 3D-CRT in chemoradiotherapy for anal cancer has shown reductions 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.

CODING

BlueCHiP for Medicare and Commercial Products

A4648: Tissue marker, implantable, any type, each (Note: This code is not separately reimbursed for institutional providers.)

Note: To ensure correct pricing of HCPC code **A4648** for the Calypso 4D localization system, the procedure/clinical notes and the invoice must be submitted.

The following codes are covered for BlueCHiP for Medicare and commercial products when the criteria above is met:

Intensity-modulated radiation therapy

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

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

77385: Intensity modulated radiation treatment delivery (IMRT), includes guicance and tracking, when performed; simple (Institutional providers)

77386: Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex (Institutional providers)

G6015: Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session: (Professional providers)

G6016: 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: (Professional providers)

RELATED POLICIES

Preauthorization via Web-Based Tool for Procedures

PUBLISHED

Provider Update, October 2017
Provider Update, February 2016
Provider Update, November 2015
Provider Update, October 2015
Provider Update, August 2014
Provider Update, April 2012
Provider Update, September 2011
Provider Update, January 2010

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intensity-modulated radiotherapy versus conventional pelvic radiotherapy for locally advanced rectal carcinoma. J Radiat Res. Mar 01 2017;58(2):247-259. PMID 27738080

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