Medical Coverage Policy | Intensity Modulated Radiotherapy: Abdomen and Pelvis

EFFECTIVE DATE: 02|15|2016
POLICY LAST UPDATED: 01|06|2016

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 radiotherapy to the tumor while minimizing the radiation dose to surrounding normal tissues and critical structures. IMRT versus 3-dimensional (3D) conformal radiation in chemoradiotherapy for anal cancer shows marked differences in rates of acute toxicity.

MEDICAL CRITERIA

BlueCHiP for Medicare and Commercial Products

Intensity-modulated radiotherapy may be considered **medically necessary** for treatment of tumors of the abdomen and pelvis including but not limited to stomach (gastric), hepatobiliary tract, pancreas, rectal locations including cancer of the anus/anal canal, or gynecologic tumors (including cervical, endometrial, and vulvar cancers), when the criteria below is met:

- Dosimetric planning with standard 3D conformal radiation predicts that the radiation dose to an adjacent organ would result in unacceptable normal tissue toxicity.
- 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.

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 3D conformal radiation predicts that the radiation dose to an adjacent organ would result in unacceptable normal tissue toxicity

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 there is insufficient peer-reviewed literature that demonstrates that the procedure/service is effective.

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 (2D) 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 3D 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.

Practice Guidelines and Position Statements
National Comprehensive Cancer Network Guidelines
The National Comprehensive Cancer Network (NCCN) guidelines for anal carcinoma38 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'." NCCN guidelines for gastric cancer39 indicate that IMRT "is appropriate in selected cases to reduce dose to normal structures such as heart, lungs, kidneys and liver." 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.

Although IMRT is mentioned as an option in 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.

NCCN guidelines on rectal cancer42 indicate IMRT should only be used in clinical trials "or in unique clinical situations including reirradiation of recurrent disease after previous radiotherapy."

In cervical cancer, 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 is not mentioned in NCCN guidelines for uterine endometrial cancer.

IMRT is not mentioned in NCCN guidelines for ovarian cancer.

American College of Radiology
The 2014 American College of Radiology (ACR) Appropriateness Criteria panel recommends IMRT for the treatment of anal cancer is usually appropriate if performed outside of a protocol setting but is still undergoing study. ACR criteria note the most appropriate radiation dose for anal cancer has not been determined and quality control and technical problems are considered challenging with IMRT such as in target volume contouring.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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:

77338:

77385: Use alternate procedure code (G6015)

77386: Use alternate procedure code (G6015)

G6015: Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session (effective 1/1/2015)

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 (effective 1/1/2015)

RELATED POLICIES

None

PUBLISHED

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

REFERENCES

1. 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.
2. Meyer JJ, Czito BG, Willett CG. Intensity-modulated radiation therapy for gastrointestinal tumors. Curr Oncol Rep 2008; 10(3):206-11.
3. 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.
4. Taylor A, Powell ME. Conformal and intensity-modulated radiotherapy for cervical cancer. Clin Oncol (R Coll Radiol) 2008; 20(6):417-25.
5. Staffurth J. A review of the clinical evidence for intensity-modulated radiotherapy. Clin Oncol (R Coll Radiol) 2010; 22(8):643-57.

6. National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in oncology. Anal CarcinomaV.1.2015.http://www.nccn.org/professionals/physician_gls/pdf/anal.pdf. Accessed November 12, 2014.

7. NationalComprehensiveCancerNetwork (NCCN). Clinical practice guidelines in oncology. Gastric Cancer. V.1.2014.http://www.nccn.org/professionals/physician_gls/pdf/gastric.pdf. Accessed November 12, 2014.

8. National Comprehensive Cancer Network (NCCN). Clincal practice guidelines in oncology. Hepatobiliary Cancers. V.2.2014. http://www.nccn.org/professionals/physician_gls/PDF/hepatobiliary.pdf. Accessed November 12, 2014.

9. National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in oncology. Pancreatic Adenocarcinoma. V.2.2014 http://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf. Accessed November 12, 2014

10. National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in oncology. Rectal Cancer. V.1.2015.http://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf. Accessed November 14, 2014.

11. National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in oncology. Cervical Cancer. V.2.2015. http://www.nccn.org/professionals/physician_gls/PDF/cervical.pdf. Accessed November 12, 2014.

12. National Comprehensive Cancer Network (NCCN). Clincal practice guidelines in oncology. Uterine Neoplasms. V.2.2015. http://www.nccn.org/professionals/physician_gls/PDF/uterine.pdf. Accessed November 12, 2014.

13. National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in oncology. Ovarian Cancer. V.3.2014. http://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed November 14, 2014.

14. Expert Panel on Radiation Oncology-Rectal/Anal C, Hong TS, Pretz JL, et al. ACR Appropriateness Criteria(R)

15. Anal Cancer. Gastrointest Cancer Res. Jan 2014;7(1):4-14. PMID 24558509