MASSACHUSETTS

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Medical Policy

Intensity-Modulated Radiation Therapy - IMRT - Abdomen and Pelvis

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Policy Number: 165

BCBSA Reference Number: 8.01.49
NCD/LCD: N/A

Related Policies

- Clinical Exception and Notification Form for Intensity Modulated Radiation Therapy (IMRT), #325
- IMRT of the Prostate, #090
- IMRT of the Head and Neck, #164
- IMRT of the Breast and Lung, #163
- IMRT of the Central Nervous System, #910

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue[SM] and Medicare PPO Blue[SM] Members

Intensity-modulated radiation therapy as an approach to delivering radiation therapy for patients with cancer of the anus/anal canal may be **MEDICALLY NECESSARY**.

Intensity-modulated radiation therapy (IMRT) may be **MEDICALLY NECESSARY** for all vulvar malignancies.

Please note: The following form **must be** filled out and submitted prior to any of the below IMRT treatments Clinical Exception and Notification form (#325).

IMRT for anal malignancies or vulvar malignancies does not require submission of this clinical exception and notification form. Services may be performed and claims submitted without notification.

Intensity-modulated radiation therapy (IMRT) may be **MEDICALLY NECESSARY** for the treatment of tumors of the abdomen and pelvis when the tumor is in close proximity to organs at risk and 3-D CRT planning is not able to meet dose volume constraints for normal tissue tolerance as noted in the following tables:

For tumors of esophagus, stomach, pancreas, hepatobiliary tract, rectum, colon, and small bowel:

Tissue	Dose/Volume Threshold
Heart	>=50% of heart would receive >=30Gy
Lung	>=30% of combined lung volume would receive >=20Gy **OR** Mean lung dose >=20Gy
Spinal Cord	Any portion would receive a dose above 45Gy
Liver	>=60% of liver volume would receive >=30Gy **OR** Mean liver dose >=32Gy
Kidney	>=33% of combined kidney volume would receive >=20Gy (two functional kidneys are present) **OR** For one functioning kidney or kidney transplant, IMRT provides a lower dose than achievable with 3D
Small Intestine	>=195cc would receive >=45Gy
Stomach	>10% would receive >=45Gy **OR** >=5% would receive >=50Gy
Femoral Head	Would receive >=45Gy

For tumors of the cervix or endometrium:

Tissue	Dose/Volume Threshold
Rectosigmoid	>=60% of rectosigmoid area would receive >=30Gy
Bladder	>=35% would receive >=45Gy
Femoral Head	Would receive >=45Gy
Small Intestine	Would receive >=45Gy

Intensity-modulated radiation therapy (IMRT) is **INVESTIGATIONAL** for all other uses in the abdomen and pelvis.

Clinical Exception and Notification Form

Providers **must** submit a request for an exception for a non-covered indication by completing the clinical exception and notification form. Click here for the IMRT Policy and Notification exception and notification form (#325).

Providers **must** complete the Clinical Exception and Notification Form when requesting coverage:

- For dose dependent medically necessary indications described in medical policy 165, IMRT - Abdomen and Pelvis.
- For not medically necessary and investigational indications, described in medical policy 165, IMRT - Abdomen and Pelvis.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** if the procedure is performed inpatient.

Outpatient

- For services described in this policy, see below for situations where prior authorization might be required if the procedure is performed outpatient.

	Outpatient
Commercial Managed Care (HMO and POS)	Providers must complete the Clinical Exception and Notification Form prior to service.
Commercial PPO and Indemnity	Providers must complete the Clinical Exception and Notification Form prior to service.
Medicare HMO Blue℠	Prior authorization is **not required**.
Medicare PPO Blue℠	Prior authorization is **not required**.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity and Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
77301	Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specification
77338	Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan
77385	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple
77386	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex

HCPCS Codes

HCPCS codes:	Code Description
G6015	Intensity modulated treatment delivery, single or multiple fields/arcs,via narrow spatially and temporally modulated beams, binary, dynamic mlc, per treatment session
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

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT/HCPCS codes above if medical necessity criteria are met:

ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
C21.1	Malignant neoplasm of anal canal
C21.0	Malignant neoplasm of anus, unspecified
C21.2	Malignant neoplasm of cloacogenic zone
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal
C51.9	Malignant neoplasm of vulva, unspecified

DESCRIPTION

RADIOTHERAPY TECHNIQUES

Conventional External-Beam Radiotherapy

Methods to plan and deliver radiotherapy (RT) 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 Radiotherapy

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

Intensity-modulated radiotherapy (IMRT) uses computer software and CT and magnetic resonance images, to offer better conformality than 3D-CRT, because it modulates the intensity of the overlapping radiation beams projected on the target and uses multiple shaped treatment fields. Treatment planning and delivery are more complex, time-consuming, and labor intensive for IMRT than for 3D-CRT. The technique uses a multileaf collimator [MLC]), which, when coupled with 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, 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.

Technologic development has produced advanced techniques that may further improve RT treatment by improving dose distribution. These techniques are considered variations of IMRT. Volumetric modulated arc therapy delivers radiation from a continuous rotation of the radiation source. The principal advantage of volumetric modulated arc therapy is greater efficiency in treatment delivery time, reducing radiation

exposure and improving target radiation delivery due to less patient motion. Image-guided RT involves the incorporation of imaging before and/or during treatment to more precisely deliver RT to the target volume. IMRT methods to plan and deliver RT are not uniform. IMRT may use beams that remain on as MLCs move around the patient (dynamic MLC) or that are off during movement and turn on once 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 method 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. Treatment plans are usually based on a single imaging scan, a static 3D-CT image. 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. 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.

Note that the evidence for the following abdominal and pelvic cancers has not yet been reviewed and is beyond the scope of this review: bladder, kidney, ureter, and esophageal cancer and sarcoma.

Summary

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

For individuals who have gastrointestinal (GI) tract cancers who receive intensity-modulated radiotherapy (IMRT), the evidence includes nonrandomized comparative studies and retrospective series. Relevant outcomes are overall survival, disease-specific survival, quality of life, and treatment-related morbidity. IMRT has been compared with 3-dimensional conformal radiotherapy (3D-CRT) for the treatment of stomach, hepatobiliary, and pancreatic cancers. Evidence has been inconsistent with the outcome of survival, with some studies reporting increased survival among patients receiving IMRT compared with patients receiving 3D-CRT, and other studies reporting no difference between groups. However, most studies found that patients receiving IMRT experienced significantly less GI toxicity compared with patients receiving 3D-CRT. The available comparative evidence, together with dosimetry studies of organs at risk, would suggest that IMRT decreases toxicity compared with 3D-CRT in patients who had 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 gynecologic cancers who receive IMRT, the evidence includes 2 small randomized controlled trials and several nonrandomized comparative studies. Relevant outcomes are overall survival, disease-specific survival, quality of life, and treatment-related morbidity. There is limited comparative evidence on survival outcomes following IMRT or 3D-CRT. However, results are generally consistent that IMRT reduces GI and genitourinary toxicity. Based on evidence with other cancers of the pelvis and abdomen that are proximate 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. A reduction in GI toxicity is likely to improve the quality of life in patients with gynecologic cancer. 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 evidence includes a small randomized controlled trial (N=20), nonrandomized comparative studies, and case series. Relevant outcomes are overall survival, disease-specific survival, quality of life, and treatment-related morbidity. Survival outcomes have not differed significantly between patients receiving IMRT and 3D-CRT. However, studies have found that patients receiving IMRT plus chemotherapy for the treatment of anal cancer experience fewer acute and late adverse events than patients receiving 3D-CRT plus chemotherapy, 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.

Input was obtained in 2010 and 2012. It supported the use of IMRT in tumors of the abdomen and pelvis when normal tissues would receive unacceptable doses of radiation. Through a chain of evidence, this reduced toxicity potentially lowers the risk of adverse events (acute and late effects of radiation toxicity). This input and a chain of evidence related to 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-CRT predicts that the radiation dose to an adjacent organ would result in unacceptable normal tissue toxicity.

Policy History

Date	Action
2/2019	Clarified coding language
10/2018	BCBSA National medical policy review. Description, summary and references updated. Policy statement(s) unchanged.
9/2018	BCBSA National medical policy review. No changes to policy statements. New references added. Background and summary clarified.
2/2018	Clarified coding information.
8/2017	New references added from BCBSA National medical policy.
10/2016	New references added from BCBSA National medical policy.
2/2016	Local Coverage Determination (LCD) for Intensity Modulated Radiation Therapy (IMRT) (L3244) removed. 2/1/2016
11/2015	Added coding language.
2/2015	New references added from BCBSA National medical policy.
1/2015	Clarified coding information.
8/2014	Clinical exception and notification clarified.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
3/2014	New references added from BCBSA National medical policy.
6/2013	BCBSA National medical policy review. New medically necessary and investigational indications described. Effective 6/1/2013.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
9/1/2011	Medical Policy 165 effective 9/1/2011.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References

1. Boda-Heggemann J, Hofheinz RD, Weiss C, et al. Combined adjuvant radiochemotherapy with IMRT/XELOX improves outcome with low renal toxicity in gastric cancer. *Int J Radiat Oncol Biol Phys.* Nov 15 2009;75(4):1187-1195. PMID 19409725
2. Boda-Heggemann J, Weiss C, Schneider V, et al. Adjuvant IMRT/XELOX radiochemotherapy improves long-term overall- and disease-free survival in advanced gastric cancer. *Strahlenther Onkol.* May 2013;189(5):417-423. PMID 23558673
3. Fuller CD, Dang ND, Wang SJ, et al. Image-guided intensity-modulated radiotherapy (IG-IMRT) for biliary adenocarcinomas: Initial clinical results. *Radiother Oncol.* Aug 2009;92(2):249-254. PMID 19324442

4. Lee KJ, Yoon HI, Chung MJ, et al. A comparison of gastrointestinal toxicities between intensity-modulated radiotherapy and three-dimensional conformal radiotherapy for pancreatic cancer. *Gut Liver.* Mar 23 2016;10(2):303-309. PMID 26470767
5. Prasad S, Cambridge L, Huguet F, et al. Intensity modulated radiation therapy reduces gastrointestinal toxicity in locally advanced pancreas cancer. *Pract Radiat Oncol.* Mar-Apr 2016;6(2):78-85. PMID 26577010
6. Naik A, Gurjar OP, Gupta KL, et al. Comparison of dosimetric parameters and acute toxicity of intensity-modulated and three-dimensional radiotherapy in patients with cervix carcinoma: A randomized prospective study. *Cancer Radiother.* Jul 2016;20(5):370-376. PMID 27368915
7. Gandhi AK, Sharma DN, Rath GK, et al. Early clinical outcomes and toxicity of intensity modulated versus conventional pelvic radiation therapy for locally advanced cervix carcinoma: a prospective randomized study. *Int J Radiat Oncol Biol Phys.* Nov 1 2013;87(3):542-548. PMID 24074927
8. Shih KK, Hajj C, Kollmeier M, et al. Impact of postoperative intensity-modulated radiation therapy (IMRT) on the rate of bowel obstruction in gynecologic malignancy. *Gynecol Oncol.* Oct 2016;143(1):18-21. PMID 27486131
9. Chen CC, Wang L, Lu CH, et al. Comparison of clinical outcomes and toxicity in endometrial cancer patients treated with adjuvant intensity-modulated radiation therapy or conventional radiotherapy. *J Formos Med Assoc.* Dec 2014;113(12):949-955. PMID 24144528
10. Chen MF, Tseng CJ, Tseng CC, et al. Clinical outcome in posthysterectomy cervical cancer patients treated with concurrent Cisplatin and intensity-modulated pelvic radiotherapy: comparison with conventional radiotherapy. *Int J Radiat Oncol Biol Phys.* Apr 1 2007;67(5):1438-1444. PMID 17394944
11. Rattan R, Kapoor R, Bahl A, et al. Comparison of bone marrow sparing intensity modulated radiotherapy (IMRT) and three-dimensional conformal radiotherapy (3DCRT) in carcinoma of anal canal: a prospective study. *Ann Transl Med.* Feb 2016;4(4):70. PMID 27004217
12. Sun Z, Adam MA, Kim J, et al. Intensity-modulated radiation therapy is not associated with perioperative or survival benefit over 3D-conformal radiotherapy for rectal cancer. *J Gastrointest Surg.* Jan 2017;21(1):106-111. PMID 27510332
13. Huang CM, Huang MY, Tsai HL, et al. A retrospective comparison of outcome and toxicity of preoperative image-guided intensity-modulated radiotherapy versus conventional pelvic radiotherapy for locally advanced rectal carcinoma. *J Radiat Res.* Mar 01 2017;58(2):247-259. PMID 27738080
14. Chuong MD, Freilich JM, Hoffe SE, et al. Intensity-modulated radiation therapy vs. 3D conformal radiation therapy for squamous cell carcinoma of the anal canal. *Gastrointest Cancer Res.* Mar 2013;6(2):39-45. PMID 23745158
15. Dasgupta T, Rothenstein D, Chou JF, et al. Intensity-modulated radiotherapy vs. conventional radiotherapy in the treatment of anal squamous cell carcinoma: a propensity score analysis. *Radiother Oncol.* May 2013;107(2):189-194. PMID 23692961
16. Dewas CV, Maingon P, Dalban C, et al. Does gap-free intensity modulated chemoradiation therapy provide a greater clinical benefit than 3D conformal chemoradiation in patients with anal cancer? *Radiat Oncol.* Nov 2012;7:201. PMID 23190693
17. Devisetty K, Mell LK, Salama JK, et al. A multi-institutional acute gastrointestinal toxicity analysis of anal cancer patients treated with concurrent intensity-modulated radiation therapy (IMRT) and chemotherapy. *Radiother Oncol.* Nov 2009;93(2):298-301. PMID 19717198
18. Pepek JM, Willett CG, Wu QJ, et al. Intensity-modulated radiation therapy for anal malignancies: a preliminary toxicity and disease outcomes analysis. *Int J Radiat Oncol Biol Phys.* Dec 1 2010;78(5):1413-1419. PMID 20231064
19. National Comprehensive Cancer Network (NCCN). NCCN Clinical practice guidelines in oncology: Gastric Cancer. Version 2.2018. https://www.nccn.org/professionals/physician_gls/pdf/gastric.pdf. Accessed May 31, 2018.
20. National Comprehensive Cancer Network (NCCN). NCCN Clinical practice guidelines in oncology: Hepatobiliary Cancers. Version 1.2018. https://www.nccn.org/professionals/physician_gls/PDF/hepatobiliary.pdf. Accessed May 31, 2018.
21. National Comprehensive Cancer Network (NCCN). NCCN Clinical practice guidelines in oncology: Pancreatic Adenocarcinoma. Version 1.2018. https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf. Accessed May 31, 2018.

22. National Comprehensive Cancer Network (NCCN). NCCN Clinical practice guidelines in oncology: Cervical Cancer. Version 1.2018. https://www.nccn.org/professionals/physician_gls/PDF/cervical.pdf. Accessed May 31, 2018.
23. National Comprehensive Cancer Network (NCCN). NCCN Clinical practice guidelines in oncology: Uterine Neoplasms. Version 2.2018. https://www.nccn.org/professionals/physician_gls/PDF/uterine.pdf. Accessed May 31, 2018.
24. National Comprehensive Cancer Network (NCCN). NCCN Clinical practice guidelines in oncology: Ovarian Cancer. Version 2.2018. https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed May 31, 2018.
25. National Comprehensive Cancer Network (NCCN). NCCN Clinical practice guidelines in oncology: Anal Carcinoma. Version 1.2018. https://www.nccn.org/professionals/physician_gls/pdf/anal.pdf. Accessed May 31, 2018.
26. National Comprehensive Cancer Network (NCCN). NCCN Clinical practice guidelines in oncology: Rectal Cancer. Version 1.2018. https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf. Accessed May 31, 2018.
27. Expert Panel on Radiation Oncology-Rectal/Anal Cancer, Hong TS, Pretz JL, et al. ACR Appropriateness Criteria(R)-Anal Cancer. *Gastrointest Cancer Res.* Jan 2014;7(1):4-14. PMID 24558509