

### Clinical Policy: Intensity-Modulated Radiotherapy

Reference Number: CP.MP.69
Date of Last Revision: 04/24

Coding Implications
Revision Log

See <u>Important Reminder</u> at the end of this policy for important regulatory and legal information.

#### **Description**

Medical necessity criteria for intensity-modulated radiotherapy (IMRT). IMRT is an advanced form of 3-dimensional (3-D) conformal radiation therapy that delivers a more precise radiation dose to the tumor while sparing healthy surrounding tissue. While IMRT empirically offers advances over other radiation therapies, accepted practices and the risks and benefits of IMRT over conventional or 3-D conformal radiation must be considered.

#### Policy/Criteria

- **I.** It is the policy of Louisiana Healthcare Connections that IMRT is **medically necessary** for any of the following indications:
  - A. Age  $\leq$  18 years;
  - B. Target volume is in close proximity to critical structures that must be protected;
  - C. The volume of interest must be covered with narrow margins to adequately protect immediately adjacent structures;
  - D. An immediately adjacent area has been previously irradiated and abutting portals must be established with high precision;
  - E. The target volume is concave or convex, and critical normal tissues are within or around that convexity or concavity;
  - F. Dose escalation is planned to deliver radiation doses in excess of those commonly utilized for similar tumors with conventional treatment;
  - G. Indications by cancer site include any of the following:
    - 1. Primary or benign tumor(s) of the central nervous system, including brain, brain stem, and spinal cord;
    - 2. Primary tumor(s) of the spine where spinal cord tolerance may be exceeded by conventional treatment;
    - 3. Primary or benign lesion(s) of the head and neck area including orbits, sinuses, skull base, aerodigestive tract (lips, mouth, tongue, tonsils, nose, throat, vocal cords and part of the trachea and esophagus), salivary glands, and thyroid;
    - 4. Anal or perianal cancer, excluding locally recurrent perianal cancer;
    - 5. Prostate cancer, definitive (curative) treatment;
    - 6. Vulvar cancer, definitive (curative) treatment;
    - 7. Cervical cancer, curative treatment, any of the following:
      - a. Post-hysterectomy;
      - b. For treatment that includes para-aortic nodes;
      - c. For high doses of radiation in the presence of gross disease in regional lymph nodes:
    - 8. Select breast cancer cases, any of the following:
      - a. Homogeneity of dose cannot be achieved with conventional three-dimensional planning techniques;
      - b. Left-sided breast cancers when treating the internal mammary lymph nodes;



- c. When using external beam accelerated partial breast irradiation (APBI);
- 9. Uterine neoplasms;
- 10. Pancreatic cancer;
- 11. Stage III non-small cell lung cancer;
- 12. Esophageal cancer;
- 13. Mediastinal tumors (e.g.; lymphomas and thymomas);
- 14. Endometrial cancer;
- 15. Select rectal cancer cases where there is lymph node involvement or require treatment of the inguinal lymph nodes;
- 16. Soft tissue sarcoma when organ at risk dose constraints cannot be met.

#### **Background**

A major goal of radiation therapy is the delivery of an appropriate dose of radiation to the targeted tissue while minimizing radiation exposure to the surrounding healthy tissue. The introduction of intensity-modulated radiotherapy (IMRT) allows for significant improvement of dose distributions by irradiating sub-regions of the target to different levels. It uses a computer-based planning method called inverse planning that allows the delivery of generally narrow, patient specific, spatially and often temporally modulated beams of radiation to solid tumors within a patient.<sup>1</sup>

IMRT changes the intensity of radiation in different parts of a single radiation beam while treatment is delivered. The dose of radiation given by each beam can also vary, enabling IMRT to simultaneously treat multiple areas within the target to different dose levels. Theoretical concerns about IMRT include dose inhomogeneity, additional time required for planning computation and quality assurance (QA) verification, and exposure of larger volumes of normal tissues to a lower dose of radiation.<sup>2-3</sup>

There were numerous studies done, including a multicenter, randomized, double-blind trial that indicated IMRT improved the homogeneity of the radiation dose distribution and decreased acute toxicity, when used for breast cancer.<sup>4-8</sup>

The National Comprehensive Cancer Network (NCCN) recommends IMRT in a number of cancer types, including cancers whose radiation treatment may affect organs or other critical structures at risk.

#### **Coding Implications**

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2023, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only and may not support medical necessity. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.



NOTE: Coverage is subject to each requested code's inclusion on the corresponding LDH fee schedule. Non-covered codes are denoted (\*) and are reviewed for Medical Necessity for members under 21 years of age on a per case basis.

<b>CPT</b> ®	Description
Codes	
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
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	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 three or more high resolution (milled or cast) compensator, convergent beam modulated fields, per treatment session

Reviews, Revisions, and Approvals		Approval
	Date	Date
Converted corporate to local policy.	12/1/2020	
Annual review. References reviewed and updated. Reviewed by	2/22	
specialist. Changed "Last Review Date" in the header to "Date of Last		
Revision" and "Date" in revision log to "Revision Date". Added "and		
may not support medical necessity" to coding implications		
Background updated. ICD-10 code table removed.	1/23	4/10/23
Annual review. Added Criteria I.G.9. uterine neoplasms. Added Criteria	09/23	11/27/23
I.G.10. pancreatic cancer. Added Criteria I.G.11. stage III non-small cell		
lung cancer. Background updated with no impact on criteria. References		
reviewed and updated. Reviewed by external specialist. Note for non-		
covered codes added.		
Annual review. Removed I.G.8.a.i-iii regarding "maximum dose	05/24	7/16/24
volume", "volume of breast tissue", and "hot spots in inframammary		
fold", leaving I.G.8.a. regarding "homogeneity of dose". Changed		
I.G.8.b. to "Left-sided breast cancers when treating the internal		
mammary lymph nodes", and I.G.8.c. to "When using external beam		
accelerated partial breast irradiation (APBI)". Added additional		
indications to criteria I.G.12 Esophageal cancer, I.G.13. Mediastinal		
tumors (e.g., lymphomas and thymomas); I.G.14. Endometrial cancer;		



Reviews, Revisions, and Approvals		Approval
	Date	Date
I.G.15. Select rectal cancer cases where there is lymph node		
involvement or require treatment of the inguinal lymph nodes; I.G.16.		
Soft tissue sarcoma when organ at risk dose constraints cannot be met.		
References reviewed and updated.		

#### References

- 1. Local coverage determination (L36711). Centers for Medicare and Medicaid Services Web site. <a href="http://www.cms.hhs.gov/mcd/search.asp">http://www.cms.hhs.gov/mcd/search.asp</a>. Published December 1, 2016 (revised January 01, 2021). Accessed March 8, 2024.
- 2. Koyfman SA. General principles of radiation therapy for head and neck cancer. UpToDate. www.uptodate.com. Updated October 30, 2023. Accessed March 8, 2024.
- 3. Mitin T. Radiation therapy techniques in cancer treatment. UpToDate. <a href="www.uptodate.com">www.uptodate.com</a>. Updated March 16, 2023. Accessed March 8, 2024.
- 4. National Comprehensive Cancer Network®. NCCN Guidelines Version 2.2023 Uterine Neoplasms. <a href="https://www.nccn.org/professionals/physician\_gls/pdf/uterine.pdf">https://www.nccn.org/professionals/physician\_gls/pdf/uterine.pdf</a>. Updated March 6, 2024. Accessed March 8, 2024.
- 5. National Comprehensive Cancer Network®. NCCN Guidelines Version 1.2023 Vulvar Cancer. <a href="https://www.nccn.org/professionals/physician\_gls/pdf/vulvar.pdf">https://www.nccn.org/professionals/physician\_gls/pdf/vulvar.pdf</a>. Updated December 31, 2023. Accessed March 8, 2024.
- 6. National Cancer Institute (NCI). ATC guidelines for use of IMRT (including intra-thoracic treatments). May 2006. Accessed March 8, 2024.
- 7. Donovan E, Bleakley N, Denholm E, et al. Randomised trial of standard 2D radiotherapy (RT) versus intensity modulated radiotherapy (IMRT) in patients prescribed breast radiotherapy. *Radiother Oncol.* 2007;82(3):254 to 264. Doi:10.1016/j.radonc.2006.12.008
- 8. McDonald MW, Godette KD, Butker EK, Davis LW, Johnstone PA. Long-term outcomes of IMRT for breast cancer: a single-institution cohort analysis. *Int J Radiat Oncol Biol Phys*. 2008;72(4):1031 to 1040. Doi:10.1016/j.ijrobp.2008.02.053
- 9. Gebhardt MC, Baldini EH, Ryan CW. Overview of multimodality treatment for primary soft tissue sarcoma of the extremities and superficial trunk. UpToDate. <a href="www.uptodate.com">www.uptodate.com</a>. Updated February 22, 2023. Accessed March 8, 2024.
- 10. National Comprehensive Cancer Network<sup>®</sup>. NCCN Guidelines Version 4.2023 Breast cancer. <a href="https://www.nccn.org/professionals/physician\_gls/pdf/breast.pdf">https://www.nccn.org/professionals/physician\_gls/pdf/breast.pdf</a>. Updated January 25, 2024. Accessed March 8, 2024.
- 11. National Comprehensive Cancer Network®. NCCN Guidelines Version 1.2023 Cervical Cancer. <a href="https://www.nccn.org/professionals/physician\_gls/pdf/cervical.pdf">https://www.nccn.org/professionals/physician\_gls/pdf/cervical.pdf</a>. Updated February 23, 2024. Accessed March 8, 2024.
- 12. National Comprehensive Cancer Network®. NCCN Guidelines Version 1.2023 Prostate Cancer. <a href="https://www.nccn.org/professionals/physician\_gls/pdf/prostate.pdf">https://www.nccn.org/professionals/physician\_gls/pdf/prostate.pdf</a>. Updated March 8, 2024. Accessed March 8, 2024.
- 13. Sheets NC, Goldin GH, Meyer AM, et al. Intensity-modulated radiation therapy, proton therapy, or conformal radiation therapy and morbidity and disease control in localized prostate cancer. *JAMA*. 2012;307(15):1611 to 1620. Doi:10.1001/jama.2012.460



- 14. Staffurth J; Radiotherapy Development Board. A review of the clinical evidence for intensity-modulated radiotherapy. *Clin Oncol (R Coll Radiol)*. 2010;22(8):643 to 657. Doi:10.1016/j.clon.2010.06.013
- 15. Su JM. Intracranial germ cell tumors. UpToDate. <a href="www.uptodate.com">www.uptodate.com</a>. Updated May 19, 2023. Accessed March 8, 2024.
- 16. Synderman C. Chordoma and chondrosarcoma of the skull base. UpToDate. www.uptodate.com. Updated February 27, 2024. Accessed March 8, 2024.
- 17. National Comprehensive Cancer Network<sup>®</sup>. NCCN Guidelines Version 1.2023 Central Nervous System Cancers. <a href="https://www.nccn.org/professionals/physician\_gls/pdf/cns.pdf">https://www.nccn.org/professionals/physician\_gls/pdf/cns.pdf</a>. Updated March 24, 2023. Accessed March 8, 2024.
- 18. National Comprehensive Cancer Network<sup>®</sup>. NCCN Guidelines Version 2.2023 Anal Carcinoma. <a href="https://www.nccn.org/professionals/physician\_gls/pdf/anal.pdf">https://www.nccn.org/professionals/physician\_gls/pdf/anal.pdf</a>. Updated December 20, 2023. Accessed March 8, 2024.
- 19. National Comprehensive Cancer Network<sup>®</sup>. NCCN Guidelines Version 1.2023 Gastric Cancer. <a href="https://www.nccn.org/professionals/physician\_gls/pdf/gastric.pdf">https://www.nccn.org/professionals/physician\_gls/pdf/gastric.pdf</a>. Updated March 7, 2024. Accessed March 8, 2024.
- 20. National Comprehensive Cancer Network®. NCCN Guidelines Version 2.2023 Head and Neck Cancers (Version 2.2022). <a href="https://www.nccn.org/professionals/physician\_gls/pdf/head-and-neck.pdf">https://www.nccn.org/professionals/physician\_gls/pdf/head-and-neck.pdf</a>. Updated February 29, 2024. Accessed March 8, 2024.
- 21. National Comprehensive Cancer Network<sup>®</sup>. NCCN Guidelines Version 2.2023 Thyroid Carcinoma. <a href="https://www.nccn.org/professionals/physician\_gls/pdf/thyroid.pdf">https://www.nccn.org/professionals/physician\_gls/pdf/thyroid.pdf</a>. Updated February 1, 2024. Accessed March 8, 2024.
- 22. DiBiase SJ, Roach M. External beam radiation therapy for localized prostate cancer. UpToDate. www.uptodate.com. Updated October 5, 2023. Accessed March 8, 2024.
- 23. Galloway T, Amdur RJ. Management and prevention of complications during initial treatment of head and neck cancer. UpToDate. <a href="www.uptodate.com">www.uptodate.com</a>. Updated October 25, 2023. Accessed March 8, 2024.
- 24. Gray HJ. Adjuvant treatment of intermediate-risk endometrial cancer. UpToDate. www.uptodate.com. Updated October 30, 2023. Accessed March 8, 2024.
- 25. Karajannis MA, Marcus KJ. Focal brainstem glioma. UpToDate. <a href="www.uptodate.com">www.uptodate.com</a>. Updated March 20, 2023. Accessed March 8, 2024.
- 26. MacKay RI, Staffurth J, Poynter A, Routsis D; Radiotherapy Development Board. UK guidelines for the safe delivery of intensity-modulated radiotherapy. *Clin Oncol (R Coll Radiol)*. 2010;22(8):629 to 635. Doi:10.1016/j.clon.2010.06.017
- 27. Pignol JP, Olivotto I, Rakovitch E, et al. A multicenter randomized trial of breast intensity-modulated radiation therapy to reduce acute radiation dermatitis. *J Clin Oncol*. 2008;26(13):2085 to 2092. Doi:10.1200/JCO.2007.15.2488
- 28. Rusthoven KE, Carter DL, Howell K, et al. Accelerated partial-breast intensity-modulated radiotherapy results in improved dose distribution when compared with three-dimensional treatment-planning techniques. *Int J Radiat Oncol Biol Phys.* 2008;70(1):296 to 302. Doi:10.1016/j.ijrobp.2007.08.047
- 29. Local coverage determination: intensity modulated radiation therapy (IMRT) (L36773). Centers for Medicare and Medicaid Services Web site. <a href="http://www.cms.hhs.gov/mcd/search.asp">http://www.cms.hhs.gov/mcd/search.asp</a>. Published November 07, 2016. (revised July 31, 2019). Accessed March 8, 2024.



- 30. Dagan R, Amdur RJ, Yeung AR, Dziegielewski PT. Tumors of the nasal cavity. UpToDate. www.uptodate.com. Updated March 14, 2023. Accessed March 8, 2024
- 31. Chino J, Annunziata CM, Beriwal S, et al. Radiation Therapy for Cervical Cancer: Executive Summary of an ASTRO Clinical Practice Guideline. *Pract Radiat Oncol*. 2020;10(4):220 to 234. Doi:10.1016/j.prro.2020.04.002
- 32. Hui EP, Chan AT, Le QT. Treatment of early and locoregionally advanced nasopharyngeal carcinoma. UpToDate. <a href="www.uptodate.com">www.uptodate.com</a>. Updated September 12, 2023. Accessed March 8, 2024.
- 33. Ryan DP, Willett CG. Treatment of anal cancer. UpToDate. <a href="www.uptodate.com">www.uptodate.com</a>. Updated July 24, 2023. Accessed March 8, 2024.
- 34. Loeffler JS. Overview of the treatment of brain metastases. UpToDate. <a href="www.uptodate.com">www.uptodate.com</a>. Updated November 29, 2023. Accessed March 8, 2024.
- 35. Peikert T, Owen D. Radiation-induced lung injury. UpToDate. <a href="www.uptodate.com">www.uptodate.com</a>. Updated September 26, 2023. Accessed March 8, 2024.
- 36. Marks LB, Constine LS, Adams MJ. Cardiotoxicity of radiation therapy for breast cancer and other malignancies. UpToDate. <a href="www.uptodate.com">www.uptodate.com</a>. Updated December 13, 2023. Accessed March 8, 2024.
- 37. Butler-Xu YS, Marietta M, Zahra A, TenNapel M, Mitchell M. The effect of breast volume on toxicity using hypofractionated regimens for early stage breast cancer for patients. *Adv Radiat Oncol.* 2018;4(2):261 to 267. Published 2018 Nov 1. Doi:10.1016/j.adro.2018.10.005
- 38. National Comprehensive Cancer Network®. NCCN Guidelines Version 2.2023. Pancreatic Adenocarcinoma. <a href="https://www.nccn.org/professionals/physician\_gls/pdf/pancreatic.pdf">https://www.nccn.org/professionals/physician\_gls/pdf/pancreatic.pdf</a>. Updated December 13, 2023. Accessed March 8, 2024.
- 39. Livi L, Meattini I, Marrazzo L, et al. Accelerated partial breast irradiation using intensity-modulated radiotherapy versus whole breast irradiation: 5-year survival analysis of a phase 3 randomised controlled trial. *Eur J Cancer*. 2015;51(4):451 to 463. Doi:10.1016/j.ejca.2014.12.013
- 40. Meattini I, Marrazzo L, Saieva C, et al. Accelerated Partial-Breast Irradiation Compared With Whole-Breast Irradiation for Early Breast Cancer: Long-Term Results of the Randomized Phase III APBI-IMRT-Florence Trial. *J Clin Oncol*. 2020;38(35):4175 to 4183. Doi:10.1200/JCO.20.00650
- 41. National Comprehensive Cancer Network<sup>®</sup>. NCCN Guidelines Version 3.2023. Non-Small Cell Lung Cancer. <a href="https://www.nccn.org/professionals/physician\_gls/pdf/nscl.pdf">https://www.nccn.org/professionals/physician\_gls/pdf/nscl.pdf</a>. Updated February 9, 2024. Accessed March 8, 2024.
- 42. National Comprehensive Cancer Network<sup>®</sup>. NCCN Guidelines Version 1.2024. Esophageal and Esophagogastric Junction Cancers. <a href="https://www.nccn.org/professionals/physician\_gls/pdf/esophageal.pdf">https://www.nccn.org/professionals/physician\_gls/pdf/esophageal.pdf</a>. Updated March 7, 2024. Accessed March 18, 2024.
- 43. National Comprehensive Cancer Network<sup>®</sup>. NCCN Guidelines Version 1.2024. Thymomas and Thymic Carcinomas. <a href="https://www.nccn.org/professionals/physician\_gls/pdf/thymic.pdf">https://www.nccn.org/professionals/physician\_gls/pdf/thymic.pdf</a> Updated November 21, 2023. Accessed March 18, 2024.
- 44. National Comprehensive Cancer Network<sup>®</sup>. NCCN Guidelines Version 2.2024. T-Cell Lymphomas. <a href="https://www.nccn.org/professionals/physician\_gls/pdf/t-cell.pdf">https://www.nccn.org/professionals/physician\_gls/pdf/t-cell.pdf</a>. Updated March 14, 2024. Accessed March 18, 2024.
- 45. American College of Radiology End User License Agreement. Accessed March 18, 2024. https://acsearch.acr.org/docs/3097398/Narrative



- 46. National Comprehensive Cancer Network®. NCCN Guidelines Version 1.2024 Rectal Cancer. <a href="https://www.nccn.org/professionals/physician\_gls/pdf/rectal.pdf">https://www.nccn.org/professionals/physician\_gls/pdf/rectal.pdf</a>. Updated January 29, 2024. Accessed March 28, 2024.
- 47. National Comprehensive Cancer Network®. NCCN Guidelines Version 3.2023 Soft Tissue Sarcoma. <a href="https://www.nccn.org/professionals/physician\_gls/pdf/sarcoma.pdf">https://www.nccn.org/professionals/physician\_gls/pdf/sarcoma.pdf</a>. Updated December 12, 2023. Accessed March 28, 2024.

#### **Important Reminder**

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