Clinical Policy: Intensity-Modulated Radiotherapy

Reference Number: CP.MP.69
Date of Last Revision: 08/23

Coding Implications
Revision Log

See Important Reminder 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.[1] 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.

Note: For criteria applicable to Medicare plans, please see MC.CP.MP.69 Intensity-Modulated Radiotherapy.

Policy/Criteria

I. It is the policy of non-Medicare health plans affiliated with Centene Corporation® that IMRT is **medically necessary** for any of the following indications:

A. Age ≤ 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, demonstrated by any of the following:
   i. A maximum dose of greater than 110% is given to a volume of at least 0.3 cc;
   ii. The volume of breast tissue receiving 105% of the prescribed dose exceeds 10% (or 20% for a large volume breast defined as greater than 800 cc);
   iii. Hot spots in the inframammary fold are 105% or greater;
b. The volume of lung tissue receiving 20 Gy exceeds 20%;
c. The volume of heart tissue receiving 25 Gy exceeds 2%

9. Uterine neoplasms;
10. Pancreatic cancer;
11. Stage III non-small cell lung cancer.

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.[1]

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.[2-3]

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.[4-8]

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 2022, 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. 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.

CPT® Codes	Description
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	Revision Date	Approval Date
Policy Developed and reviewed by Radiation Oncologist.	02/14	03/14
Added thyroid and tonsils as subtypes to head and neck cancer list; added cervical, vulvar, perianal cancer indications per NCCN. Updated background. Removed option for CNS, spinal, and head and neck tumors to be metastatic. Replaced descriptive breast cancer indication criteria with specific radiation parameters. Removed deleted CPT code 0073T and added HCPCS G6016. Specialist reviewed.	02/19	02/19
Coding updates: Removed deleted CPT 77418; updated ICD-10-CM codes per 02/19 criteria updates.	04/19	
References reviewed and updated. ICD codes updated C00.0-C14.8 now C14.9 and description correction for C30.	01/20	01/20
References reviewed and updated. Replaced “members” with “members/enrollees’ in all instances.	12/20	12/20
Annual review. References reviewed and updated. Reviewed by specialist. Changed "Last Review Date" in the header to "Date of Last Revision" and "Date" in revision log to "Revision Date".	12/21	12/21
Annual review completed. Background updated. ICD-10 code table removed. References reviewed and updated.	12/22	12/22
Annual review. Added Criteria I.G.9. uterine neoplasms. Added Criteria 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.	08/23	08/23

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Added note to policy to refer to MC.CP.MP.69 for Medicare criteria. Added "non-Medicare" to health plans in Policy/Criteria I.	11/23	

References

1. Local coverage determination (L36711). Centers for Medicare and Medicaid Services Web site. http://www.cms.hhs.gov/mcd/search.asp. Published December 1, 2016 (revised January 01, 2021). Accessed June 26, 2023.
2. Koyfman SA. General principles of radiation therapy for head and neck cancer. UpToDate. www.uptodate.com. Updated October 10, 2022. Accessed June 26, 2023.
3. Mitin T. Radiation therapy techniques in cancer treatment. UpToDate. www.uptodate.com. Updated March 16, 2023. Accessed June 26, 2023.
4. National Comprehensive Cancer Network®. NCCN Guidelines Version 2.2023 Uterine Neoplasms. https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf. Updated April 28, 2023. Accessed June 27, 2023.
5. National Comprehensive Cancer Network®. NCCN Guidelines Version 1.2023 Vulvar Cancer. https://www.nccn.org/professionals/physician_gls/pdf/vulvar.pdf. Updated December 22, 2022. Accessed June 27, 2023.
6. National Cancer Institute (NCI). ATC guidelines for use of IMRT (including intra-thoracic treatments). May 2006. Accessed June 27, 2023.
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. www.uptodate.com. Updated February 16, 2023. Accessed June 26, 2023.
10. National Comprehensive Cancer Network®. NCCN Guidelines Version 4.2023 Breast cancer. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Updated March 23, 2023. Accessed June 26, 2023.
11. National Comprehensive Cancer Network®. NCCN Guidelines Version 1.2023 Cervical Cancer. https://www.nccn.org/professionals/physician_gls/pdf/cervical.pdf. Updated April 28, 2023. Accessed June 27, 2023.
12. National Comprehensive Cancer Network®. NCCN Guidelines Version 1.2023 Prostate Cancer. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Updated September 16, 2022. Accessed June 27, 2023.
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. www.uptodate.com. Updated April 13, 2023. Accessed June 23, 2023.
16. Synderman C. Chordoma and chondrosarcoma of the skull base. UpToDate. www.uptodate.com. Updated April 13, 2022. Accessed June 23, 2023.
17. National Comprehensive Cancer Network®. NCCN Guidelines Version 1.2023 Central Nervous System Cancers. https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Updated March 24, 2023. Accessed June 27, 2023.
18. National Comprehensive Cancer Network®. NCCN Guidelines Version 2.2023 Anal Carcinoma. https://www.nccn.org/professionals/physician_gls/pdf/anal.pdf. Updated April 28, 2023. Accessed June 26, 2023.
19. National Comprehensive Cancer Network®. NCCN Guidelines Version 1.2023 Gastric Cancer. https://www.nccn.org/professionals/physician_gls/pdf/gastric.pdf. Updated March 10, 2023. Accessed June 27, 2023.
20. National Comprehensive Cancer Network®. NCCN Guidelines Version 2.2023 Head and Neck Cancers (Version 2.2022). https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf. Updated May 15, 2023. Accessed June 26, 2023.
21. National Comprehensive Cancer Network®. NCCN Guidelines Version 2.2023 Thyroid Carcinoma. https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Updated May 18, 2023. Accessed June 27, 2023.
22. DiBiase SJ, Roach M. External beam radiation therapy for localized prostate cancer. UpToDate. www.uptodate.com. Updated October 19, 2022. Accessed June 27, 2023.
23. Galloway T, Amdur RJ. Management and prevention of complications during initial treatment of head and neck cancer. UpToDate. www.uptodate.com. Updated January 05, 2023. Accessed June 26, 2023.
24. Gray HJ. Adjuvant treatment of intermediate-risk endometrial cancer. UpToDate. www.uptodate.com. Updated June 20, 2022. Accessed June 26, 2023.
25. Karajannis MA, Marcus KJ. Focal brainstem glioma. UpToDate. www.uptodate.com. Updated March 20, 2023. Accessed June 26, 2023.
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. http://www.cms.hhs.gov/mcd/search.asp. Published November 07, 2016. (revised July 31, 2019). Accessed June 26, 2023.
30. Dagan R, Amdur RJ, Yeung AR, Dziegielewski PT. Tumors of the nasal cavity. UpToDate. www.uptodate.com. Updated March 14, 2023. Accessed June 27, 2023

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. www.uptodate.com. Updated January 11, 2023. Accessed June 23, 2023.
33. Ryan DP, Willett CG. Treatment of anal cancer. UpToDate. www.uptodate.com. Updated June 26, 2023. Accessed June 27, 2023.
34. Loeffler JS. Overview of the treatment of brain metastases. UpToDate. www.uptodate.com. Updated March 17, 2023. Accessed June 23, 2023.
35. Peikert T, Owen D. Radiation-induced lung injury. UpToDate. www.uptodate.com. Updated March 23, 2023. Accessed June 23, 2023.
36. Marks LB, Constine LS, Adams MJ. Cardiotoxicity of radiation therapy for breast cancer and other malignancies. UpToDate. www.uptodate.com. Updated June 16, 2023. Accessed June 27, 2023.
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. https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf. Updated June 19, 2023. Accessed June 27, 2023.
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®. NCCN Guidelines Version 3.2023. Non-Small Cell Lung Cancer. https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Updated April 13, 2023. Accessed June 30, 2023.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs and LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.