



POLICY NUMBER UM XRT_2003	SUBJECT Intensity-Modulated Radiation Therapy (IMRT)		DEPT/ UM De _l	PROGRAM ot	PAGE 1 OF 7
DATES COMMITTEE REVIEWED 09/07/16, 09/06/17, 11/14/18, 12/11/19	APPROVAL DATE December 11, 2019	EFFECTIVE DATE December 11, 2019	COMMITTEE APPROVAL DATES (latest version listed last) 09/07/16, 09/06/17, 11/14/18, 12/11/19		
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		COMMITTEE/BOARD APPROVAL Utilization Management Committee			
URAC STANDARDS HUM 1		NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS All		

I. PURPOSE

The purpose of this policy is to provide general information applicable to the review and appropriateness of IMRT services. Although a service, supply or procedure may be medically necessary, it may be subject to limitations and/or exclusions under a member's benefit plan. If a service, supply or procedure is not covered and the member proceeds to obtain the service, supply or procedure, the member may be responsible for the cost. Decisions regarding treatment and treatment plans are the responsibility of the physician. This policy is not intended to direct the course of clinical care a physician provides to a member, and it does not replace a physician's independent professional clinical judgment or duty to exercise special knowledge and skill in the treatment of members. NCH is not responsible for, does not provide, and does not hold itself out as a provider of medical care. The physician remains responsible for the quality and type of health care services provided to a member.

II. BACKGROUND

Intensity – modulated radiation therapy (IMRT) is an advanced mode of high–precision radiotherapy that utilizes computer – controlled x–ray accelerators to deliver precise radiation doses to a malignant tumor or specific areas within the tumor. IMRT allows for the radiation dose to conform more precisely to the three – dimensional (3D) shape of the tumor by modulating or controlling the intensity of the radiation beam. IMRT also allows higher radiation doses to be focused to regions within the tumor while minimizing the dose to surrounding normal critical structures. Treatment is planned by using 3D computed tomography (CT) images of the patient in conjunction with computerized dose calculations to determine the dose intensity pattern that will best conform to the tumor shape. IMRT treatment may be delivered using several delivery methods, including, for example multiple static segment treatment (Step–and–shoot), dynamic segment treatment (sliding window), binary–collimator tomotherapy and volumetric modulated arc techniques (VMAT).

Other names used to report intensity modulated radiation therapy (IMRT):

Compensatory – Based IMRT Helical Tomotherapy IMRT Tomotherapy Inverse Treatment Planning Segment Radiation Therapy (RT) Sliding Window Technique Step – and – Shoot Inverse IMRT Volumetric ARC therapy (VMAT)

III. DEFINITIONS

Intensity-modulated radiation therapy (IMRT) - is complex requiring precision and accuracy and involves multiple radiation specialists (e.g., radiation oncologist, medical physicist, radiation therapists, and dosimetrist). IMRT requires multiple or fractionated treatment sessions and different radiation doses. Several factors determine the number of treatment sessions and radiation dose; the type, location and size of the tumor, doses to the critical normal structures and the individual's health. An IMRT schedule may consist of



five days a week for five to ten weeks. At the beginning of each treatment, the individual is positioned on the treatment table guided by the marks on the skin, implanted fiducial markers, or through the use of cone beam CT scans (CBCT) defining the treatment area; the individual may be repositioned during the IMRT treatment.

Imaging systems on the IMRT treatment delivery systems may be used to check positioning and marker location, molded devices may be used to help the individual maintain proper position. IMRT treatment may take between 3 to 20 minutes.

IV. POLICY

Medicare- for Medicare and Medicare Advantage enrollees, the coverage policies of CMS (Centers for Medicare and Medicaid Services) may take precedence over Company's guidelines.

- 1. IMRT **meets the definition of medical necessity** for the following indications:
 - a. IMRT is considered **medically necessary** in individuals with Central Nervous System (CNS) lesions (that are either primary or metastatic lesions) with close proximity to critical structures such as the Optic Nerve, Lens, Retina, Optic Chiasm, Cochlea, or Brain Stem.
 - b. IMRT is considered **medically necessary** in the treatment of individuals with Head and Neck cancer with the exception of individuals with early stage Glottic cancer (stage I and II).
- 2. IMRT is considered **medically necessary** in the treatment of individuals with Thyroid cancer.
- 3. IMRT is considered **medically necessary** for the treatment of Breast cancer when the following criteria are met:
 - a. Treatment of left-sided Breast cancer:
 - IMRT may be indicated when dose to critical organs, such as the heart, and lung, is
 of concern
 - ii. When comparative 3D and IMRT plans demonstrate that a 3D plan does not meet the "Acceptable" normal tissue constraints using standard metrics published by the Radiation Therapy Oncology Group (RTOG)/National Comprehensive Cancer Network (NCCN) OR
 - b. In individuals with large Breasts when the treatment planning with 3D-CRT results in hot spots (focal regions with dose variation greater than 10% of target) and the hot spots are able to be avoided with IMRT; *OR*
 - c. In individuals who are to receive internal mammary node irradiation based on *any* of the following:
 - i. Pathologically enlarged (as reported based on imaging technique utilized) internal mammary lymph node(s)by CT, MRI, PET/CT, or CXR OR
 - ii. Pathologically involved internal mammary lymph node(s) (based on aspiration cytology or tissue biopsy pathology); OR
 - iii. High risk of internal mammary lymph node involvement based on:
 - Greater than or equal to 4 positive axillary lymph nodes; or
 - Medial quadrant tumor with 1 or more positive axillary lymph nodes; or
 - Medial quadrant T3 tumor.
- 4. IMRT is considered **medically necessary** for the treatment of Lung cancer when ALL of the following criteria are met:
 - a. Disease in the bilateral mediastinum or bilateral Hilar regions
 - b. Disease in the Para-Spinal region



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- c. Superior Sulcus tumors
- d. IMRT may be indicated when dose to critical organs, such as the, liver, heart, lung, and spinal cord is of concern When comparative 3D and IMRT plans demonstrate that a 3D plan does not meet the "Acceptable" normal tissue constraints using standard metrics published by the Radiation Therapy Oncology Group (RTOG)/National Comprehensive Cancer Network (NCCN)
- 5. IMRT is considered **medically necessary** for the treatment of the following abdominal cancers: Gastric, Gastroesophageal junction, Pancreas, and Hepatobiliary cancer when ALL of the following criteria are met:
 - a. The disease is primary and non-metastatic, that is, confined regionally to the primary organ (including regional lymph nodes); AND
 - b. IMRT may be indicated when dose to critical organs, such as the small bowel, liver, heart, lung, kidneys, and spinal cord is of concern When comparative 3D and IMRT plans demonstrate that a 3D plan does not meet the "Acceptable" normal tissue constraints using standard metrics published by the Radiation Therapy Oncology Group (RTOG)/National Comprehensive Cancer Network (NCCN)
- 6. IMRT is considered **medically necessary** for Esophageal cancer.
 - a. The disease is primary and non-metastatic, that is, confined regionally to the primary organ (including regional lymph nodes); AND
 - b. IMRT may be indicated when dose to critical organs, such as the small bowel, liver, heart, lung, kidneys, and spinal cord is of concern When comparative 3D and IMRT plans demonstrate that a 3D plan does not meet the "Acceptable" normal tissue constraints using standard metrics published by the Radiation Therapy Oncology Group (RTOG)/National Comprehensive Cancer Network (NCCN)
- 7. IMRT of the Prostate is considered **medically necessary** in individuals who meet either of the following:
 - a. Definitive treatment for localized prostate cancer; **OR**
 - b. Post-Prostatectomy:
 - PSA remains detectable after surgery; **OR**
 - PSA is detectable and increases on two or more lab determinations; OR
 - The individual has post-operative stage T3 to T4; **OR**
 - Post-operative pathology reveals positive surgical margins.
- 8. IMRT is considered **medically necessary** in individuals with cancer of the Anus or Anal canal, certain malignant gynecologic tumors (Uterus, Cervix, Ovary, and Fallopian tube), primary pelvic Sarcomas. Bladder carcinoma.
- 9. IMRT is considered **medically necessary** in individuals with Lymphoma when the disease involves the aortic/periaortic lymph nodes.
- 10. IMRT is considered **medically necessary** in individuals with Retroperitoneal Sarcomas located within the abdominal cavity.
- 11. IMRT is considered **medically necessary** in individuals who require repeat irradiation of a field that has received *prior* irradiation.
- 12. All other indications not listed above may be considered experimental or investigational, as there may be insufficient evidence to support conclusions regarding the effect of on health outcomes. Indications not listed will be evaluated on a case by case basis at the clinical reviewer level.

V. PROCEDURE



The following documentation is necessary for reviewing an IMRT Request:

- a. Physician history and physical including prior radiographic reports IE: MRI, CT and prior PET/CT scan if applicable.
- b. Attending Radiation Oncologist Consult or Progress note.
- c. Treatment; in certain circumstances a comparison dose volume histogram (DVH) comparing IMRT to 3D conformal therapy.

VI. APPROVAL AUTHORITY

- 1. Review Utilization Management Department
- 2. Final Approval Utilization Management Committee

VII. ATTACHMENTS

None

VIII. REFERENCES

- 1. Abdel-Wahab M, Mahmoud O, Merrick G, et al. Expert Panel on Radiation Oncology-Prostate. ACR Appropriateness Criteria® External Beam Radiation Therapy Treatment Planning for Clinically Localized Prostate Cancer. [Online publication]. Reston (VA): American College of Radiology (ACR); 2011.
- 2. American College of Radiology (ACR). ACR Practice Guideline for Intensity Modulated Radiation Therapy. 2002 (Res. 17). ACR Practice Guideline. Reston, VA: ACR; effective January 1, 2003. Revised 2014. Available at: http://www.acr.org/~/media/ACR/Documents/PGTS/guidelines/IMRT.pdf
- 3. American Society for Therapeutic Radiation and Oncology (ASTRO). Model Policy on Intensity Modulated Radiation Therapy (IMRT). Revised December 9, 2015.
- 4. Bentzen SM, Constine LS, Deasy JO, et al. Quantitative analyses of normal tissue effects in the clinic QUANTEC: An introduction to the scientific issues. Introductory paper. Int J Radiat Oncol Biol Phys. 2010; 76(3):S3-S9.
- 5. Blue Cross Blue Shield Association. Special Report: Intensity Modulation Radiation Therapy for Cancer of the Breast or Lung. TEC Assessment, 2005; 20(13).
- 6. Blue Cross Blue Shield Association. Technology Evaluation Center (TEC). Accelerated Partial Breast Irradiation as Sole Radiotherapy After Breast-Conserving Surgery for Early Stage Breast Cancer Assessment Program. TEC Assessment 2007; 22(4).
- 7. Clark EE, Thielke A, Kriz H, et al. Intensity modulated radiation therapy. Final Evidence Report. Prepared by the Oregon Health & Science University, Center for Evidence-based Policy for the Washington State Health Care Authority, Health Technology Assessment Program. Olympia, WA: Washington State Health Care Authority, Health Technology Assessment Program; August 20, 2012. Available at: http://www.hca.wa.gov/hta/Documents/081712 imrt summary table final.pdf
- 8. Dawson LA, Kavanagh BD, Paulino AC, et al. Radiation-associated kidney injury. QUANTEC: organ-specific paper. Int J Radiat Oncol Biol Phys. 2010; 76(3):S108-S115.
- 9. European Organization for Research and Treatment of Cancer EORTC. Lymph node radiation therapy in patients with stage I, stage II, or stage III breast cancer that has been surgically removed. NLM Identifier NCT00002851. Last updated on January 28, 2010. Available at: http://clinicaltrials.gov/ct2/show/NCT00002851?term=NCT00002851.&rank=1
- 10. European Organization for Research and Treatment of Cancer EORTC. Radiation Therapy, Surgery, and Chemotherapy in Treating Patients with Rectal Cancer That Can Be Surgically Removed. NCT00002523. Last updated July 20, 2011. Available at: http://clinicaltrials.gov/show/NCT00002523
- 11. Freedland SJ, Rumble RB, Finelli A, et al. Adjuvant and salvage radiotherapy after prostatectomy: American Society of Clinical Oncology (ASCO) clinical practice guideline endorsement. J Clin Oncol. 2014; 32(34):3892-3898.



New Century Health

POLICY#UM XRT_2003 PROPRIETARY & CONFIDENTIAL

- 12. Gagliardi G, Constine LS, Moiseenko V, et al. Radiation dose-volume effects in the heart. QUANTEC: organ-specific paper. Int J Radiat Oncol Biol Phys. 2010; 76(3):S77-S85.
- 13. Galvin JM, Ezzell G, Eisbrauch A, et al.; American Society for Therapeutic Radiology and Oncology; American Association of Physicists in Medicine. Implementing IMRT in clinical practice: a joint document of the American Society for Therapeutic Radiology and Oncology and the American Association of Physicists in Medicine. Int J Radiat Oncol Biol Phys. 2004; 58(5):1616-1634.
- 14. Hartford AC, Galvin JM, Beyer JC, et al.; American College of Radiology (ACR) and American Society for Therapeutic Radiology and Oncology (ASTRO) Practice Guideline for Intensity-Modulated Radiation Therapy (IMRT). Am J Clin Oncol. 2012; 35:612–617.
- 15. Hartford AC, Palisca MG, Eichler TJ, et al.; American Society for Therapeutic Radiology and Oncology, American College of Radiology. American Society for Therapeutic Radiology and Oncology (ASTRO) and American College of Radiology (ACR) Practice Guidelines for Intensity-Modulated Radiation Therapy (IMRT). Int J Radiat Oncol Biol Phys. 2009; 73(1):9-14.
- 16. Hong TS, Pretz JL, et al. American College of Radiology (ACR) Appropriateness Criteria® Anal Cancer. Expert Panel on Radiation Oncology-Rectal/Anal Cancer. Gastrointest Cancer Res. 2014; 7(1):4-14.
- 17. Hummel S, Simpson EL, Hemingway P, Stevenson MD, Rees A. Intensity-modulated radiotherapy for the treatment of prostate cancer: A systematic review and economic evaluation. Health Technol Assess. 2010; 14(47):1-108, iii-iv.
- 18. Institute of Cancer Research, United Kingdom. Intensity-Modulated Radiation Therapy in Treating Patients with Localized Prostate Cancer. NCT00392535. Last updated May 19, 2011. Available at: http://clinicaltrials.gov/ct2/show/NCT00392535?term=imrt&recr=Open&type=Intr&phase=12&rank=28
- 19. Jackson A, Marks LB, Bentzen SM, et al. The lessons of QUANTEC: Recommendations for reporting and gathering data on dose-volume dependencies of treatment outcome. Int J Radiat Oncol Biol Phys. 2010: 76(3):S155-S160.
- 20. Kavanagh BD, Pan CC, Dawson LA, et al. Radiation dose-volume effects in the stomach and small bowel. QUANTEC: organ-specific paper. Int J Radiat Oncol Biol Phys. 2010; 76(3 Suppl):S101-S107.
- 21. Kirkpatrick JP, van der Kogel AJ, Schultheiss TE. Radiation dose-volume effects in the spinal cord. QUANTEC organ-specific paper. Int J Radiat Oncol Biol Phys. 2010; 76(3):S42-S49.
- 22. Michalski JM, Gay H, Jackson A, et al. Radiation dose-volume effects in radiation-induced rectal injury. QUANTEC organ-specific paper. Int J Radiat Oncol Biol Phys. 2010; 76(3):S123-S129.
- 23. Michalski JM, Lawton C, El Naqa I, et al. Development of RTOG consensus guidelines for the definition of the clinical target volume for postoperative conformal radiation therapy for prostate cancer. Int J Radiat Oncol Biol Phys. 2010; 76(2):361-368.
- 24. Michalski JM, Yan Y, Watkins-Bruner D, et al. Preliminary toxicity analysis of 3-dimensional conformal radiation therapy versus intensity modulated radiation therapy on the high-dose arm of the Radiation Therapy Oncology Group 0126 prostate cancer trial. Int J Radiat Oncol Biol Phys. 2013; 87(5):932-938.
- 25. National Cancer Institute (NCI). Intensity-modulated radiotherapy: current status and issues of interest. Intensity Modulated Radiation Therapy Collaborative Working Group. Advanced Technologies for Breast Cancer. ASTRO Presentation. 2006. Available at: http://rrp.cancer.gov/content/docs/workshop-2006/McCormick.ppt
- 26. NCCN Clinical Practice Guidelines in Oncology™. © 2019. National Comprehensive Cancer Network, Inc. For additional information: http://www.nccn.org/index.asp.
- 27. Anal Carcinoma (V2.2019). Revised August 28, 2019.
- 28. Breast Cancer (V3.2019). Revised September 6, 2019.
- 29. Bladder Cancer (V4.2019), Revised July 10, 2019.
- 30. Head and Neck Cancers (V3.2019). Revised September 16, 2019.
- 31. Thymomas and Thymic Carcinomas (V1.2019). Revised March 11, 2019.
- 32. Melanoma (V3.2019). Revised October 22, 2019.
- 33. Non-Hodgkin's Lymphomas (V5.2019). Revised September 23,2019.



New Century Health

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- 34. Hodgkin Lymphoma (V2.2019). Revised July 15, 2019.
- 35. Esophageal and Esophagogastric Junction Cancers (V2.2019). Revised May 29, 2019.
- 36. Non-small cell Lung Cancer (V7.2019). Revised August 30, 2019.
- 37. Pancreatic Adenocarcinoma (V3.2019). Revised July 2, 2019.
- 38. Hepatobiliary Cancers (V3.2019). Revised August 1, 2019.
- 39. Gastric Cancer (V2.2019). Revised June 3, 2019.
- 40. Colon Cancer (V3.2019). Revised September 26, 2019.
- 41. Rectal Cancer (V3.2019). Revised September 26, 2019.
- 42. Prostate Cancer (V4.2019). Revised August 19, 2019.
- 43. Thyroid Carcinoma (V1.2019). Revised September 16, 2019.
- 44. Nguyen PL, Aizer A, Assimos DG, et al. American College of Radiology (ACR) Appropriateness Criteria® Definitive External-Beam Irradiation in stage T1 and T2 prostate cancer. Am J Clin Oncol. 2014; 37(3):278-288.
- 45. Oliver RJ, Clarkson JE, Conway D, Glenny AM, Macluskey M, Pavitt S, Sloan P, The CSROC Expert Panel, Worthington HV. Interventions for the treatment of oral cancer: radiotherapy. (Protocol) Cochrane Database Syst Rev. 2007; (1):CD006387.
- 46. Pan CC, Kavanagh BD, Dawson LA, et al. Radiation-associated liver injury. QUANTEC: organ-specific paper. Int J Radiat Oncol Biol Phys. 2010; 76(3):S94-S100.
- 47. Ratko TA, Douglas GW, de Souza JA, et al. Radiotherapy Treatments for Head and Neck Cancer Update. Comparative Effectiveness Review No. 144. (Prepared by Blue Cross and Blue Shield Association Evidence-based Practice Center under Contract No. 290-2007-10058.) AHRQ Publication No. 15-EHC001-EF. Rockville, MD: Agency for Healthcare Research and Quality (AHRQ); December 2014. Available at: http://www.effectivehealthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=2019
- 48. Roach M, 3rd, Hanks G, Thames H, Jr., et al. Defining biochemical failure following radiotherapy with or without hormonal therapy in men with clinically localized prostate cancer: Recommendations of the RTOG-ASTRO Phoenix Consensus Conference. Int J Radiat Oncol Biol Phys. 2006; 65(4):965-974.
- 49. Roeske JC, Lujan AE, Krishnamachari U, et al. Dose volume histogram analysis of acute gastrointestinal toxicity for gynecologic patients receiving intensity modulated whole pelvis radiotherapy. ASTRO Abstract 1086. 43rd Annual Meeting. 2001.
- 50. Samson DM, Ratko TA, Rothenberg BM et al. Comparative effectiveness and safety of radiotherapy treatments for head and neck cancer. Comparative Effectiveness Review No. 20. (Prepared by Blue Cross and Blue Shield Association Technology Evaluation Center Evidence-based Practice Center under Contract from the Agency for Healthcare Research and Quality. May 2010. Available online at: http://www.effectivehealthcare.ahrq.gov/ehc/products/19/448/Head-Neck%20Cancer_exec%20summary.pdf
- 51. Sun F, Yesanmi O, Fontanarosa J, et al. Therapies for Clinically Localized Prostate Cancer: Update of a 2008 Systematic Review. Comparative Effectiveness Review No. 146. (Prepared by the ECRI Institute– Penn Medicine Evidence-based Practice Center under Contract No. 290-2007-10063.) AHRQ Publication No. 15-EHC004-EF. Rockville, MD: Agency for Healthcare Research and Quality; December 2014. Available at:
 - http://www.effectivehealthcare.ahrq.gov/ehc/products/521/2023/prostate-cancer-therapies-update-report-141216.pdf.
- 52. Thompson IM, Valicenti RK, Albertsen P, et al. Adjuvant and salvage radiotherapy after prostatectomy: AUA/ASTRO Guideline. J Urol. 2013; 190(2):441-449.
- 53. Vanderbilt University. Comparative Effectiveness Analysis of Surgery and Radiation (CEASAR) for Localized Prostate Cancer. NCT01326286. Last updated October 6, 2014. Available at: http://www.clinicaltrials.gov/ct2/show/NCT01326286?term=proton+prostate+cancer&rank=19
- 54. Werner-Wasik M, Yorke E, Deasy J, et al. Radiation dose-volume effects in the esophagus.
- 55. QUANTEC organ-specific paper. Int J Radiat Oncol Biol Phys. 2010; 76(3):S86-S93.
- 56. Whelan TJ, Olivotto I, Ackerman I, et al: NCIC-CTG MA.20: An intergroup trial of regional nodal irradiation in early breast cancer. 2011 ASCO Annual Meeting. Abstract LBA1003. Presented June 6,



2011. (N.B. Includes link to Buchholz T. Expert Point of View: Patients with Early Breast Cancer Benefit from Regional Nodal Irradiation. The ASCO® Post. November 15, 2011).