

MEDICAL POLICY



MEDICAL POLICY DETAILS	
Medical Policy Title	INTENSITY MODULATED RADIATION THERAPY (IMRT)
Policy Number	6.01.24
Category	Technology Assessment
Effective Date	2/21/02
Revised Date	03/20/03, 03/18/04, 02/17/05, 12/15/05, 12/21/06, 12/20/07, 10/23/08, 01/21/10, 08/19/10, 11/17/11, 12/20/12, 01/16/14, 08/21/14, 11/19/15, 12/15/16, 08/17/17, 08/16/18, 05/16/19
Product Disclaimer	<ul style="list-style-type: none"> • If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply. • If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit. • If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY STATEMENT

IMRT will be approved 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).

POLICY GUIDELINES

- I. Daily IGRT is recommended when IMRT is considered **medically appropriate** for individuals with the following cancers when the following criteria have been met:

A. Adrenal tumors; localized disease; after surgical resection if at high risk for local recurrence (e.g., positive margins, rupture of capsule, large size and high grade).
B. Anal cancer.
C. Brain metastases; <ol style="list-style-type: none"> 1. sole treatment of partial brain therapy in individuals with good prognosis; or 2. as boost therapy.
D. Primary bone cancer; as clinically indicated.
E. Bladder cancer when dose to nearby critical structures may be exceeded
F. Breast cancer; when: <ol style="list-style-type: none"> 1. there has been previous external beam radiation to the chest; or 2. when dose to nearby critical structures may be exceeded.
G. Cervical cancer; <ol style="list-style-type: none"> 1. pre-operative when additional brachytherapy cannot be performed; or 2. definitive treatment when additional brachytherapy cannot be performed and the patient is inoperable; or 3. as post-operative treatment for positive surgical margins, positive pelvic nodes, close vaginal margins less than 0.5 cm, extensive lymphovascular or capillary involvement; or 4. as salvage therapy when normal tissue dose constraints cannot be met with 3D CRT; or 5. in the non-curative setting when symptoms are present and when previous external beam radiation therapy (EBRT) or brachytherapy has been given and normal tissue dose constraints cannot be met with 3D CRT.
H. Colorectal cancer; for recurrent disease when higher doses are required.

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I. Craniospinal tumors; 1. malignant brain tumors- Gliomas; or 2. primary CNS lymphoma; a. younger adults with good performance status and good response to chemotherapy; or b. poor response to chemotherapy; or c. without chemotherapy in patients with a poor performance status, or severely immunocompromised; or d. in patients with ocular disease; or e. in patients with recurrent disease; or 3. benign brain tumors (e.g., pituitary adenomas, acoustic neuromas, schwannomas, craniopharyngiomas, hemangioblastomas, pineocytomas, glomus tumors, and meningiomas).
J. Endometrial cancer; when: 1. dose to nearby critical structures may be exceeded; or 2. postoperative pelvic radiation is performed as part of a sequential or concurrent treatment plan incorporating the para-aortic lymph node treatment.
K. Esophageal cancer in the curative setting when normal tissue dose constraints cannot be met with 3D CRT and: 1. in the neoadjuvant setting in Stage T1b node-positive or any T2-T4a for tumors; or 2. as adjuvant treatment for squamous cell carcinoma and adenocarcinoma, if the clinical and/or pathologic features warrant; or 3. as definitive treatment for tumors in the cervical esophagus.
L. Gastric cancer; when dose to small bowel, liver, heart, lung, kidneys and spinal cord may be exceeded
M. Head and neck cancer; when clinically meaningful reduction in doses to critical organs can only be achieved with IMRT and: 1. as definitive therapy in select T1N1, T2 N0 cases; monotherapy; or 2. as definitive therapy with concurrent chemotherapy in T2-4a, N0-3 cases; or 3. post-operatively when there are high risk factors (e.g., pT3 or pT4 primary tumors, N2 or N3 nodal disease, positive nodes in levels IV or V, perineural invasion, vascular tumor embolism, or positive surgical margins or residual gross disease; or 4. as palliative therapy in a previously un-irradiated individual with symptomatic local disease; or 5. as salvage therapy after prior radiation in cases of recurrent or persistent disease, or for in-field new primary tumors, in cases in which there are no known distant metastases.
N. Hodgkin Lymphoma; when clinically meaningful reduction in doses to critical organs can only be achieved with IMRT and: 1. when used as sole therapy selected cases of stage I-IIA lymphocyte predominant Hodgkin's lymphoma; or 2. as adjuvant radiation therapy (combined modality treatment) after chemotherapy; or 3. as salvage radiation therapy after chemotherapy to areas of relapsed bulky involvement; or 4. as salvage therapy in an individual who relapses after solo chemotherapy for initial stage I/IIA disease 5. as palliative therapy in an individual with advanced or recurrent symptomatic local disease that is not curative.
O. Liver, primary (hepatocellular (HCC), cholangiocarcinoma): 1. as definitive management of medically or technically unresectable localized disease; or 2. as palliative management of localized disease or local disease with minimal extrahepatic disease; or 3. as palliative management of unresectable localized intrahepatic biliary duct cancer.
P. Lung Cancer (Small Cell and Non-Small Cell) when: 1. dose to nearby critical structures may be exceeded; and

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2. in cases with bilateral mediastinal disease, or bilateral hilar regions, or paraspinous or superior sulcus tumors.
O. NonHodgkin Lymphoma; when clinically meaningful reduction in doses to critical organs can only be achieved with IMRT (e.g., high neck involvement where the extent of disease allows preferential sparing of salivary glands) and: 1. when used as sole therapy for selected cases in an individual with stage I-IIA low grade non-Hodgkin's lymphoma NHL with supradiaphragmatic presentation or extranodal NK/T-cell lymphoma, or nasal lymphoma; or 2. as adjuvant radiation therapy after in an individual with stage I-IIB disease to areas of initial involvement and supradiaphragmatic disease; or 3. as palliative therapy an individual with local advanced or recurrent supradiaphragmatic symptomatic disease that is not curative.
P. Pancreatic cancer when dose to small bowel, liver, heart, lung, kidneys and spinal cord may be exceeded.
Q. Prostate cancer; clinically localized disease: 1. low, intermediate and high-risk ; or 2. as adjuvant or salvage therapy after radical prostatectomy in men with adverse pathological features or detectable PSA with no evidence of disseminated disease; or 3. combined with brachytherapy for intermediate and high risk disease and negative bone scan within the last 6 months.
Q. Sarcomas of retroperitoneum.
R. Spinal Cord primary inoperable tumors with compression or intractable pain where tolerance may be exceeded by conventional treatment.
S. Urethral cancer

II. Based on our criteria and review of the peer-reviewed literature intensity modulated radiation therapy (IMRT) has not been medically proven to be more effective than 3D CRT and is considered **not medically necessary** for all other indications including, but not limited to:

A. <i>Bone metastasis</i> unless there has been previous irradiation to the site.
B. <i>Pancreatic cancers</i> when used for palliation.
C. <i>Renal cell cancer</i> as definitive or adjuvant treatment.

III. Based on our criteria and review of the peer-reviewed literature, the use of the SpaceOAR[®] system (Augmenix, Inc) in men prior to IMRT treatment for prostate cancer is considered **not medically necessary**.

Refer to Corporate Medical Policy #6.01.16 regarding Brachytherapy or Radioactive Seed Implantation for Prostate Cancer.

Refer to Corporate Medical Policy #6.01.30 regarding Brachytherapy for Breast Cancer (Balloon or Electronic).

POLICY GUIDELINES

- I. Radiation therapy may be delivered by many different techniques depending on the type of cancer being treated, tumor size, location, and dose to be delivered. Therefore the clinical rationale for use of IMRT must be clearly documented by the treating Radiation Oncologist. The documentation must reflect the condition of the individual patient, and indicate the medical necessity for which the service was performed. The documentation submitted for review must include:
 - A. A statement by the treating physician documenting the special need for performing IMRT on the specific patient, rather than performing conventional or 3-dimensional treatment planning and delivery.

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- B. A clear, concrete explanation, not theoretical, as to why 3D CRT would not meet the patient's needs. Comparative 3D CRT and IMRT treatment plans with Dose Volume Histograms (DVH) that support this position are required. The prescription must define the goals and requirements of the treatment plan, including the specific dose constraints for the target(s) and nearby critical structures.
- II. In prostate cancer, adverse pathological features include:
 - A. Positive surgical margins; and/or
 - B. Extracapsular extension; and/or
 - C. Seminal vesicle involvement; and/or
 - D. Positive lymph nodes; and/or
 - E. Gleason score 8 to 10; and/or
 - F. Detectable or rising postoperative PSA level.
- III. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION

The ACR –ASTRO Practice Guideline for IMRT (2011) states that a major goal of radiation therapy is the delivery of the desired dose distribution of ionizing radiation to target tissue while limiting the radiation dose to the surrounding normal tissues to an acceptable level. Thus achieving optimal patient care outcomes,. This can be accomplished using IMRT.

The process of care for IMRT consists of multiple steps for treatment planning and delivery of radiation. Compared to 3D conformal radiation therapy, IMRT combines inverse treatment planning and computer controlled intensity modulation of the photon radiation beam. Delineation of both the target volume and the surrounding tissues at risk is required to decrease the dose to volumes of non-target structures while achieving prescription doses to the target volume. An optimized treatment plan is developed that respects the target dose requirements as well as the dose constraints of the surrounding dose-limiting structures.

IMRT treatment delivery demands careful, day-by-day reproduction of the treatment plan within the patient as well as, levels of precision and accuracy that surpass the requirements of conventional radiotherapy treatment planning and delivery techniques. The IMRT process requires a coordinated team effort between the radiation oncologist, the medical physicist, the medical dosimetrist, and the radiation therapist.

In summary, the ability of IMRT to deliver the radiation dose preferentially to target structures in close proximity to organs at risk (OAR) and other non-target tissues while minimizing dose to these normal tissues makes it an alternative to conventional 3D conformational radiation therapy.

IGRT is the use of imaging at the time of treatment delivery to ensure that the location of the target relative to the treatment beams based on a pre-determined plan is reproduced. At the time of treatment delivery, an IGRT modality is employed to determine the location of the target (and often the surrounding normal organs) at some frequency, most often at the beginning, to as often as nearly continuously throughout delivery. The target location may be determined by a range of methods from soft tissue volumetric imaging (e.g., kV or MV CT, ultrasound, magnetic resonance imaging) to localization of surrogates such as implanted fiducial markers or external surface markers or features (eg, by planar imaging or fluoroscopy, electromagnetic localization or optical surface imaging). The match or discrepancy between the simulated location and the “live” IGRT measurement at the time of treatment may be determined manually, or in some cases using automated image analysis software. If a discrepancy is found, a correction is applied. Corrections may include repositioning the patient, either through rigid corrections (shift and/or rotation) or readjustment of anatomic relationship (eg, neck and shoulder manipulations for head/neck treatments), or movement or reshaping of the radiation beam to match the target position, or holding the beam until the target falls in the correct location (eg, respiratory gating). In this manner, the treatment will be delivered precisely and accurately according to the treatment plan approved by the radiation oncologist.

Due to its close proximity to the prostate, the rectum may receive low doses of radiation which can cause gastrointestinal toxicities. To potentially reduce toxicities to the rectum, the SpaceOAR[®] system (Augmenix, Inc, Waltham, MA) has been

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developed. The SpaceOAR[®] system (Spacing Organs At Risk (OAR)) is a hydrogel that is injected between the prostate and rectum, creating a space between the rectum and prostate which moves the rectum further away from the radiation field during IMRT treatment. The hydrogel remains in place for 3 months during radiation treatment, and is then absorbed and leaves the body in the patient's urine. The SpaceOAR[®] system received FDA approval in 2015.

RATIONALE

Clinical evidence supports that IMRT improves health outcomes by allowing adequate radiation therapy while minimizing damage to surrounding structures for adrenal tumors, primary brain tumors, brain metastasis, head and neck cancer, lung cancer, pancreatic cancer and other upper abdominal sites, pituitary tumors, prostate cancer and spinal cord tumors.

Breast cancer. There is interest in the use of IMRT as compared to 3D-CRT for patients with breast cancer, as a technique of accelerated partial breast irradiation, and as a technique of accelerated whole-breast irradiation with concomitant boost as an alternative to whole breast irradiation therapy after breast conserving surgery. It is proposed that IMRT may reduce the effects of radiation therapy to the lung and to the heart. However, lacking data with adequate follow-up from randomized controlled trials, available clinical evidence is insufficient to determine whether IMRT is superior to 3D-CRT for improving health outcomes for patients with breast cancer. The National Comprehensive Cancer Network (NCCN) guidelines for breast cancer (2015) indicate that target delineation includes the majority of breast tissue, and is best done by both clinical assessment and CT-based treatment planning. A uniform dose distribution is the objective, using compensators such as wedges, forward planning using segments, intensity modulated radiation therapy, respiratory gating, or prone positioning. The American Society for Radiation Oncology (ASTRO) consensus statement recommends that women who are over 60 years partial breast irradiation (PBI) should be performed only as part of a prospective trial. PBI can be delivered with brachytherapy or external beam radiation using 3-D conformal radiation or IMRT. If not trial eligible, PBI should be reserved for patients with a low risk of recurrence.

Prostate cancer. The most recent National Comprehensive Cancer Network (NCCN) guidelines for principles of radiation therapy for prostate cancer (2017) indicate that for external-beam radiotherapy, 3D-conformal or IMRT are techniques which allows the volume receiving high radiation doses to conform more closely to the prostate shape. IMRT is used increasingly in practice because compared to 3D-CRT, it significantly reduces the risk of gastrointestinal toxicities and rates of salvage therapy in some, but not all studies, although treatment cost is increased. Results from randomized trials suggest that dose escalation is associated with improved biochemical outcomes. Evidence from randomized trials has emerged that supports the use of adjuvant/salvage radiation therapy after radical prostatectomy in men with adverse laboratory or pathological features or detectable PSA. Adverse pathological features include positive surgical margin(s), seminal vesicle invasion and/or extracapsular extension place a patient at risk for biochemical failure after prostatectomy. Biochemical failure after radical prostatectomy is defined in the National Comprehensive Cancer Network (NCCN) guidelines for principles of radiation therapy for prostate cancer (2017) as either the persistence of a detectable PSA postoperatively, or the elevation of PSA to a detectable from a previously undetectable postoperative level.

The NCCN Guidelines Panel (2017) recommends active surveillance for men with very-low-risk prostate cancer and an estimated life expectancy less than 20 years or for men with low-risk prostate cancer and estimated life expectancy of less than 10 years. The active surveillance recommendation must be based on careful individualized weighing of a number of factors: life expectancy, disease characteristics, general health condition, potential side effects of treatment, and patient preference. Older age and poorer health status should favor active surveillance. Patients and physicians involved in active surveillance must be aware that the PSA is likely to rise and that the tumor may grow with time and patients must be prepared to reevaluate the decision to defer treatment. The NCCN Guideline Panel recommends treatment in most men who demonstrate a Gleason grade of 4 or 5 on repeat biopsy, have cancer in greater number or greater extent of prostate biopsies, or have a PSA doubling time of less than three years.

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Clinically localized prostate cancer has been categorized by the risk of recurrence as follows:

Recurrence Risk	Stage	Gleason Score	PSA(ng/ml)	PSADensity (ng/ml/g)	Other
Very Low	T1c	Less than or equal to 6	Less than 10	Less than 0.15	Less than 3 prostate biopsy cores positive or less than or equal to 50% cancer in any core
Low	T1-T2a	Less than or equal to 6	Less than 10		
Intermediate	T2b-T2c	7	10-20		
High	T3a	8-10	Greater than 20		

The SpaceOAR® system is a modality that is used to reduce rectal toxicities in men receiving IMRT for treatment of prostate cancer. Preliminary studies evaluating the effectiveness of the SpaceOAR system in reducing adverse gastrointestinal events with IMRT show a greater than 25% reduction in rectal volume receiving at least 70 Gy in the majority of men due to spacer placement but no difference in acute adverse events between men using the spacer and in controls who did not receive the spacer. A reduction in late rectal toxicity (three-15 months after RT) has been observed and no patients treated with the spacer experienced greater than grade 1 toxicity. These preliminary results are encouraging and more trials are needed to continue to evaluate the use of the SpaceOAR System especially in dose escalation, hypofractionation, stereotactic radiotherapy or re-irradiation.

Life Expectancy can be estimated using the Social Security Administration tables. Life expectancy can then be adjusted using the clinician’s assessment of overall health.

There are various other cancers where NCCN recommends the use of IMRT in special circumstances (e.g. anal cancer, esophageal cancer, and small cell lung cancer).

There are numerous clinical trials in progress regarding IMRT. These include comparative trials of IMRT for carcinoma of the breast, cervix, non-small cell lung carcinoma, pancreas, prostate cancer and head and/or neck.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.*
- ***CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.***
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*

CPT Codes

Code	Description
31626	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed with placement of fiducial markers, single or multiple
31627	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed with computer-assisted, image-guided navigation (List separately in addition to code for primary procedure(s))
32553	Placement of interstitial device(s) for radiation therapy guidance (e.g., fiducial markers, dosimeter), percutaneous, intra-thoracic, single or multiple
49411	Placement of interstitial device(s) for radiation therapy guidance (eg, fiducial markers, dosimeter), percutaneous, intra-abdominal, intra-pelvic (except prostate), and/or retroperitoneum, single or multiple
55874 (NMN)	Transperineal placement of biodegradable material, peri-prostateic, single or multiple injection(s), including image guidance, when performed

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Code	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
77387	Guidance for localization of target volume for delivery of radiation treatment delivery, includes intrafraction tracking, when performed

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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
G6017	Intra-fraction localization and tracking of target or patient motion during delivery of radiation therapy (e.g., 3D positional tracking, gating, 3d surface tracking), each fraction of treatment

ICD10 Codes

Code	Description
Numerous	

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*Key Article

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KEY WORDS

IMRT, Intensity modulated radiotherapy, Intensity modulated radiation therapy, SpaceOAR®.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for Intensity Modulated Radiation Therapy (IMRT).

There is currently a Local Coverage Determination (LCD) for Prostate Rectal Spacers. Please refer to the following LCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=37485&ver=8&CtrctrSelected=298*1&Ctrctr=298&s=41&DocType=Active&bc=AAgAAAQBA AAA&