

**Effective Date:** 01/01/2024 **Revision Date:** 01/01/2024

Review Date: Click or tap to enter a date.
Policy Number: WI.UM-1138-000
Line of Business: Medicare

### **Medicare Advantage Medical Coverage Policy**

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#### **Disclaimer**

**Change Summary** 

The Coverage Summaries are reviewed by the iCare Medicare Utilization Management Committee. Policies in this document may be modified by a member's coverage document. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. References to CPT® codes or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee of claims payment. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from iCare.

## **Related Medicare Advantage Medical/Pharmacy Coverage Policies**

None

#### **Related Documents**

Please refer to <a href="CMS website">CMS website</a> for the most current applicable National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

Type Title	ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
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			JH - Novitas Solutions, Inc. (Part A/B MAC)	AR, CO, NM, OK, TX, LA, MS
LCD LCA	Intensity Modulated Radiation Therapy (IMRT)	L36711 A56725	JL - Novitas Solutions, Inc. (Part A/B MAC)	DE, D.C., MD, NJ, PA
LCD LCA	Intensity Modulated Radiation Therapy (IMRT)	<u>L36773</u> <u>A56746</u>	JN - First Coast Service Options, Inc. (Part A/B MAC)	FL, PR, U.S. VI
LCD LCA	Prostate Rectal Spacers	L37485 A56539	J6 - National Government Services, Inc. (Part A/B MAC)	IL, MN, WI
			JK - National Government Services, Inc. (Part A/B MAC	CT, NY, ME, MA, NH, RI, VT

## **Description**

Intensity modulated radiation therapy (IMRT) is an advanced form of external beam radiotherapy that uses computer-controlled linear accelerators to deliver precise radiation doses to specific areas within a tumor. This therapy allows for increased precision by conforming radiation to the planned target site while significantly reducing the amount of radiation to surrounding healthy tissues. Image-guidance in the form of computed tomography (CT), magnetic resonance imaging (MRI), ultrasound (US) or X-rays may be utilized to direct delivery of the radiation beams.

Different techniques are utilized to control the radiation amount given during IMRT. The most common approach is the use of multileaf collimators (MLCs). These devices are attached to the linear accelerator. The MLCs are composed of computer-controlled tungsten leaves or panels that move while the radiation beam is directed toward the target. The leaves function as filters that block out certain areas. This modifies the beam's intensity so that the radiation is distributed according to the treatment plan.

Another delivery approach is compensator based IMRT. This approach utilizes custom made (based on three dimensional (3D) images and the treatment plan) high-density blocks to control the administration of the radiation. The blocks are placed into position according to the treatment plan and the radiation is delivered.

Tomotherapy and volumetric modulated arc therapy (VMAT) are types of IMRT. In these forms of treatment, the machines combine the linear accelerator with MLCs and CT scanners in an effort to provide IMRT with increased precision to select tumors. The frame that houses the treatment and scanning devices rotates in a 360-degree fashion around the individual to deliver a focused beam of radiation to the tumor. Tomotherapy involves obtaining a CT scan prior to each treatment session to identify any changes to tumor shape or position so that adjustments can be made. The radiation is delivered in smaller beams (beamlets) which deliver varying doses of radiation to the target. In VMAT, one or more beams of radiation are delivered in an uninterrupted arc delivered as the housing rotates. The radiation beams may be modified according to the shape of the tumor.<sup>32</sup>

The placement of a **transperineal biodegradable spacer** also known as **prostate rectal spacers** (**eg, Barrigel, SpaceOAR, SpaceOAR Vue**) positions the anterior (frontal) section of the rectal wall away from the prostate during external beam radiotherapy treatments for prostate cancer with the goal of limiting the radiation exposure to the anterior rectum. Because this material is biodegradable, it is absorbed over time by the individual's body. SpaceOAR is comprised of a synthetic, absorbable polyethylene glycol-based hydrogel. SpaceOAR Vue contains PEGylated iodine, which is designed to enhance visibility via CT scan. Barrigel injectable gel is similar to the SpaceOAR product; however, it is made of stabilized hyaluronic acid.

### **Coverage Determination**

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the criteria contained in the following:

**IMRT** will be considered medically reasonably and necessary when all the following requirements are met:

- An immediately adjacent area has been previously irradiated and abutting portals must be established with high precision<sup>59</sup>; **OR**
- Dose escalation is planned to deliver radiation doses in excess of those commonly utilized for similar tumors with conventional treatment<sup>59</sup>; **OR**
- The target volume is concave or convex, and the critical normal tissues are within or around that convexity or concavity<sup>59</sup>; **OR**
- The target volume is in close proximity to critical structures that must be protected<sup>59</sup>; **OR**
- The volume of interest must be covered with narrow margins to adequately protect immediately adjacent structures<sup>59</sup>

Based on the above conditions demonstrating medical necessity, **IMRT** may be considered reasonable and necessary for the following indications:

- Abdominal malignancies when dose constraints to small bowel or other normal abdominal tissue are exceeded and present administration of a therapeutic dose<sup>59</sup>; OR
- Lymphoma for the following indications:
  - Eye (primary monocular)<sup>71</sup>; OR
  - Head and neck (eg, nasal cavity, paranasal sinuses, parotid or other salivary gland)<sup>98</sup>; OR
  - o Lung<sup>98</sup>; **OR**
  - Mediastinum, in proximity to lung and heart<sup>98</sup>; OR
  - o Thyroid<sup>71</sup>; **OR**
  - o Stomach<sup>98</sup>; **OR**
- Other pelvic or retroperitoneal malignancies<sup>59</sup>; OR
- Pelvic malignancies (eg, prostatic, gynecological, anal carcinoma)<sup>59</sup>; OR
- Primary, metastatic, benign or recurrent head and neck malignancies (eg, orbits, sinuses, skull base, aero-digestive tract, salivary glands)<sup>59</sup>; **OR**
- Primary, metastatic or benign tumors of the central nervous system including the brain, the brain stem, and spinal cord<sup>59</sup>; OR
- Primary or metastatic tumors of the spine where the spinal cord tolerance may be exceeded with conventional treatment or where the spinal cord has previously been irradiated<sup>59</sup>; **OR**
- Thoracic malignancies<sup>59</sup>

Other malignancies not delineated in the above can be supported with submission of documentation for medical necessity should a denial occur. The determination of appropriateness and medical necessity for IMRT for any site shall be found in the documentation from the radiation oncologist and must be available when requested or submitted in the appeals process.<sup>59</sup>

**Transperineal biodegradable spacer** also known as **prostate rectal spacers** (eg, Barrigel, SpaceOar, SpaceOAR Vue) will be considered medically reasonable and necessary for use during prostate cancer radiation therapy.<sup>61</sup>

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

## **Coverage Limitations**

<u>US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage</u>

IMRT is not considered reasonable and necessary when at least 1 of the criteria listed above and 1 of the applicable ICD-10-CM diagnosis codes are not present.<sup>59</sup>

- Where IMRT does not offer an advantage over conventional or three-dimensional conformal radiation therapy techniques that deliver good clinical outcomes and low toxicity;<sup>32,59</sup> OR
- Clinical urgency, such as spinal cord compression, superior vena cava syndrome or airway obstruction<sup>32,59</sup>; OR
- Palliative treatment of metastatic disease where the prescribed dose does not approach normal tissue tolerances<sup>32,59</sup>; **OR**
- Inability to accommodate for organ motion, such as for a mobile lung tumor<sup>32,59</sup>; **OR**
- Inability of the patient to cooperate and tolerate immobilization to permit accurate and reproducible dose delivery<sup>32,59</sup>; **OR**

There must be documented rationale of the advantage of IMRT versus the use of other radiation therapy methods in the medical record of each patient for whom IMRT is provided.<sup>59</sup>

A review of the current medical literature shows that the <u>evidence is insufficient</u> to determine that these services are standard medical treatments. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

## **Coding Information**

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
31626	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of fiducial markers, single or multiple	

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HCPCS Code(s)	Description	Comments
No code(s) id	entified I	
CPT® Category III Code(s)	Description	Comments
77386	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex	
77385	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple	
77338	Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan	
77301	Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications	
55876	Placement of interstitial device(s) for radiation therapy guidance (eg, fiducial markers, dosimeter), prostate (via needle, any approach), single or multiple	
55874	Transperineal placement of biodegradable material, peri- prostatic, single or multiple injection(s), including image guidance, when performed	
49412	Placement of interstitial device(s) for radiation therapy guidance (eg, fiducial markers, dosimeter), open, intra-abdominal, intrapelvic, and/or retroperitoneum, including image guidance, if performed, single or multiple (List separately in addition to code for primary procedure)	
49411	Placement of interstitial device(s) for radiation therapy guidance (eg, fiducial markers, dosimeter), percutaneous, intraabdominal, intra-pelvic (except prostate), and/or retroperitoneum, single or multiple	
49327	Laparoscopy, surgical; with placement of interstitial device(s) for radiation therapy guidance (eg, fiducial markers, dosimeter), intra-abdominal, intrapelvic, and/or retroperitoneum, including imaging guidance, if performed, single or multiple (List separately in addition to code for primary procedure)	
32553	Placement of interstitial device(s) for radiation therapy guidance (eg, fiducial markers, dosimeter), percutaneous, intra-thoracic, single or multiple	

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C9728	Placement of interstitial device(s) for radiation therapy/surgery guidance (e.g., fiducial markers, dosimeter), for other than the following sites (any approach): abdomen, pelvis, prostate, retroperitoneum, thorax, single or multiple	
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	

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# **Appendix**

## Appendix A – Tumor staging for prostate cancer 98

T category	T criteria
T2	Organ confined
T3	Extraprostatic extension
T3a	Extraprostatic extension (unilateral or bilateral) or microscopic
	invasion of bladder neck
T3b	Tumor invades seminal vesicle(s)
T4	Tumor is fixed or invades adjacent structures other than seminal
	vesicles such as external sphincter, rectum, bladder, levator
	muscles, and/or pelvic wall

## **Change Summary**

- Click or tap to enter a date. New Policy.

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