

# Medical Coverage Policy



**Blue Cross  
Blue Shield**  
of Rhode Island

## Intensity Modulated Radiation Therapy (IMRT), including Intra-Fraction Tracking

Device/Equipment    Drug    Medical    Surgery    Test    Other

<b>Effective Date:</b>	<b>11/17/2009</b>	<b>Policy Last Updated:</b>	<b>3/6/2012</b>
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**Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.**

**Prospective review is not required.**

### Description:

Intensity-modulated radiation therapy (IMRT), also known as tomotherapy, is radiosurgery which delivers a highly conformal, three-dimensional (3D) distribution of radiation doses. IMRT uses inverse planning, computer controlled radiation deposition, and normal tissue avoidance. There are several methods of delivery: multi-leaf collimator (MLC), tomotherapy, and compensator-based beam modulation.

Treatment with multi-leaf collimation uses a device, the multi-leaf collimator (MLC), situated between the beam source and the patient to modulate the intensity of then beams of radiation. The MLC moves along an arc around the patient. As it moves, a computer varies aperture size independently and continuously for each leaf. Thus, MLCs divide beams into narrow "beamlets," with intensities that range from zero to 100% of the incident beam.

In an alternative method, termed tomotherapy, a small radiation portal emitting a single narrow beam moves spirally around the patient, with intensity varying as it moves.

Compensator-based beam modulation therapy uses IMRT does delivery and beam modulation using a physical absorber to modulate the radiation beam with placement of compensator between the accelerator target and the patient. The multi-leaf collimator is not used in compensator based IMRT.

Each method is coupled to a computer algorithm for "inverse" treatment planning. The planner/radiotherapist delineates the target on each slice of a CT scan, and specifies the target's prescribed radiation dose, acceptable limits of dose heterogeneity within the target volume, adjacent normal tissue volumes to avoid, and acceptable dose limits within the normal tissues. Based on these parameters and a digitally-reconstructed radiographic image of the tumor and surrounding tissues and organs at risk, computer software optimizes the location and shape of beam ports, and beam and beamlet intensities, to achieve the treatment plan's goals.

According to ASTRO/ACR Guide to Radiation Oncology Coding (2007), IMRT is clinically indicated when one or more of the following condition are present:

- the target volume is in close proximity to critical structures that must be protected; or
- the volume of interest must be covered with narrow margins to adequately protect immediately adjacent structures; or
- an immediately adjacent areas has been previously irradiated and abutting portals must be established with high precision; or
- the target volume in concave or convex, and the critical normal tissues are within or around that convexity or concavity; or

- does escalation is planned to deliver radiation doses in excess of those commonly utilized for similar tumors with conventional treatment.

The ASTRO/ACR guide indicates that IMRT is indicated as standard treatment options for:

- primary, metastatic or benign tumors of the central nervous system, including the brain, brain stem, and spinal cord;
- primary metastatic tumors of the spine where spinal cord tolerance may be exceeded by conventional treatment;
- primary, metastatic or benign lesions to the head and neck area, including the orbits, sinuses, skull base, aerodigestive tract, salivary glands;
- carcinoma of the prostate;
- selected cases of thoracic and abdominal malignancies;
- selected cases of breast cancers with close proximity to critical structures;
- other pelvic and retroperitoneal tumors;
- reirradiation that meets the requirements of medical necessity.

IMRT often uses image guidance to assure the intended target area receives the radiation. Various techniques exist. These include the use of real-time intra-fraction target tracking during radiation therapy (“real-time tracking”). These techniques enable adjustment of the target radiation while it is being delivered (i.e., intra-fraction adjustments) to compensate for movement of the organ inside the body. Real-time tracking, which may or may not use radiographic images, is one of many techniques referred to as “image-guided radiation therapy” (IGRT). For this policy real-time tracking is defined as frequent or continuous target tracking in the treatment room during radiation therapy, with periodic or continuous adjustment to targeting made on the basis of target motion detected by the tracking system. This policy does not address approaches used to optimize consistency of patient positioning in setting up either the overall treatment plan or individual treatment sessions (i.e., inter-fraction adjustments), instead it deals with approaches to monitor target movement within a single treatment session. This policy does not address technologies using respiratory gating.

In general, intra-fraction adjustments can be grouped into two categories: online and off-line. An online correction occurs when corrections or actions occur at the time of radiation delivery on the basis of predefined thresholds. An off-line approach refers to target tracking without immediate intervention.

This evolving process of improved targeting includes the use of devices to track the target (tumor motion) during radiation treatment sessions and allow adjustment of the radiation dose during a session based on tumor movement. While not an exhaustive list, examples of some U.S. Food and Drug Administration (FDA) cleared devices are listed in the following section. Some of the devices are referred to as “4-D imaging.” One such device is the Calypso® 4D Localization System. This system uses a group of 3 electromagnetic transponders (Beacon®) implanted in the prostate to allow continuous localization of a treatment isocenter. The transponders are 8.5 mm long and have a diameter of 1.85 mm. The 3 transponders have a “field of view” of 14-cm square with a depth of 27 cm.

The Calypso 4D localization system obtained FDA clearance for prostate cancer in March 2006 through the 510(k) process (K060906). This system was considered equivalent to existing devices such as implanted fiducials.

Another system, the Cyberknife® Robotic Radiosurgery System, is a computer-controlled medical system for planning and performing image-guided stereotactic radiosurgery and precision radiotherapy. This system uses gold fiducials implanted in the prostate first to determine the absolute position of the target location, then to track 3-dimensional translation and rotation deviation from that location during treatment.<sup>2</sup> During treatment, the computer automatically adjusts the incident beam to compensate for target deviation. While the system can compensate for deviations of 10 mm, the larger the deviation, the greater is the uncertainty in the computer correction.

The Cyberknife Robotic Radiosurgery System obtained FDA clearance in September 2007 through the 510(k) process (K072504) for any location in the body when radiation therapy is indicated. This system was considered equivalent to existing devices.

**Medical Criteria:**

Not applicable.

**Policy:**

IMRT that utilizes multi-leaf collimator (MLC), tomotherapy delivery methods and compensator-based beam modulation are covered. Intrafraction tracking is covered, including the use of transponders as fiducials.

**Coverage:**

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement, or Benefit Booklet for radiology benefit/coverage.

**Coding:**

**Intensity-modulated radiation therapy**

**77301**

**77418**

**0073T**

**Fiducial and Intra-fraction Tracking**

**0197T**

**32553**

**49411**

**55876**

**A4648** Tissue marker, implantable, any type, each (Note: This code is not separately reimbursed for institutional providers.)

**Note:** To ensure correct pricing of A4648, the procedure/clinical notes and the invoice must be submitted.

**A4650**

**Also known as:**

Calypso® 4D Localization System

4-D imaging

**Related to:**

Not applicable

**Published:**

*Provider Update, January 2010*

*Provider Update, September 2011*

*Provider Update, April 2012*

**References:**

Center for Medicare & Medicaid Services. MLN Matters. Published August 6, 2010 with an effective date of November 6, 2010. Payment for Implantable Tissue Markers (Healthcare Common Procedure Coding System (HCPCS) Code A4648) and Implantable Radiation Dosimeters (HCPCS Code A4650). Accessed on 4/12/11: <http://www.cms.gov/MLNMattersArticles/Downloads/MM6968.pdf>.

Chaiken LM, Steinberg ML . Targeting For Cure: Intensity Modulated Radiation Therapy Current Status and Future Directions in the Treatment of Prostate Cancer. Reprinted from PCRI Insights August 2004;7(3).

<sup>2</sup>Dawson LA, Jaffray DA. Advances in image-guided radiation therapy. Journal of Clinical Oncology; 2007; 25(8):938-46.

Kindblom J, Ekelund-Olvenmark AM, Syren H et al. High precision transponder localization using a novel electromagnetic positioning system in patients with localized prostate cancer. Radiotherapy Oncology; 2009; 90(3):307-11.

<sup>1</sup>Wong JR, Gao Z, Merrick S , Wilson P, Uematsu M, Woo K, AND Cheng CW. Potential for higher treatment failure in obese patients: correlation of elevated body mass index and increased daily prostate deviations from the radiation beam isocenters in an analysis of 1,465 computed tomographic images. International Journal of Radiation Oncology \* Biology\* Physics\*; 2009; 75(1):49-55.

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