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OVERVIEW

Intensity-modulated radiation therapy (IMRT), for treatment of cancers of the abdomen and pelvis, breast and lung, head, neck and thyroid, and prostate cancer, is a method of radiation therapy that allows adequate radiation therapy to a tumor while minimizing the radiation dose to surrounding normal tissues and critical structures

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. The Calypso 4D localization system, is considered equivalent to existing devices such as implanted fiducials.

PRIOR AUTHORIZATION

Not Applicable.

POLICY STATEMENT

BlueCHiP for Medicare and Commercial

IMRT utilizing 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. Claims for the Calypso 4D localization system, requires submission of the procedure/clinical notes and the invoice to ensure correct claims processing and pricing of this item

MEDICAL CRITERIA

Not Applicable

BACKGROUND

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 multileaf collimator (MLC), situated between the beam source and the patient to modulate the intensity of the 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 dose 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.² 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.

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

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

Note: To ensure correct pricing of HCPC code **A4648** for the Calypso 4D localization system, the procedure/clinical notes and the invoice must be submitted.

The following codes are covered for BlueCHiP for Medicare and Commercial:

Intensity-modulated radiation therapy

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

77418 Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session

0073T 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

Fiducial and Intra-fraction Tracking

0197T 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

Note: When reporting this service (0197T), other guidance/localization services should not be reported in the same session.

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 (e.g., fiducial markers, dosimeter), percutaneous, intra-abdominal, intra-pelvic (except prostate), and/or retroperitoneum, single or multiple
- 55876** Placement of interstitial device(s) for radiation therapy guidance (e.g., fiducial markers, dosimeter), prostate (via needle, any approach), single or multiple
- A4650** Implantable radiation dosimeter, each (payment requires submission of invoice)

RELATED POLICIES

None

PUBLISHED

Provider Update	Aug 2014
Provider Update	Apr 2012
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