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Subject: Image-Guided Radiation Therapy

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DESCRIPTION:

Image-guided radiation therapy (IGRT) is the use of frequent imaging during the course of radiation therapy to improve the precision and accuracy of the delivery of external beam radiation treatment. In IGRT, equipment that delivers radiation (e.g., linear accelerator) is equipped with imaging technology, which enables imaging of the tumor immediately before and during radiation treatment delivery. Using specialized computer software, these images are compared to the images taken during [simulation](#). Adjustments are made to the patient's position and/or radiation beams in order to more precisely target radiation at the tumor and avoid healthy surrounding tissue. IGRT is used in the treatment of tumors in areas of the body that are prone to movement (e.g., lungs, prostate gland, tumors located close to critical organs and tissues).

The process of IGRT begins with the construction of digitally reconstructed radiographs (DRRs) from the approved computer treatment plan computed tomography (CT) data set. These images are compared to the "live" IGRT images obtained before and/or during radiation treatment delivery. The patient is positioned based on the congruence of the images data sets to align the images within predetermined localization criteria. The treatment is delivered precisely and accurately according to the treatment plan approved by the radiation oncologist.

IGRT can be performed to enhance either 3-dimensional conformal radiation therapy (3DCRT) (e.g., intensity modulated radiation therapy (IMRT), stereotactic body radiation therapy (SBRT)). There are several types of imaging modalities that may be used for IGRT; computed tomography (CT), magnetic resonance imaging (MRI), positron emission tomography (PET), ultrasound (US) and x-ray imaging. When the target is not clearly visible and bony anatomy is not sufficient for adequate target alignment, fiducial markers may be needed. Fiducial markers are used as aids in simulation and radiation treatment.

IGRT may be performed in real time, during the course of a radiation therapy session. This localization procedure is called intra-fraction. An example of intra-fraction technology includes, but is not limited to the Calypso® 4D Localization System.

Several systems, devices, and components for IGRT and intra-fraction systems have received U.S. Food and Drug Administration (FDA) 510(k) clearance (e.g., Calypso® 4D localization System). The Calypso® 4D Localization System is intended for use as an adjunct in treatment planning and radiation therapy, to align and monitor the patient's position relative to the isocenter of a linear accelerator. The Calypso System provides accurate, precise, and continuous localization of a treatment isocenter by using two or more Beacon® transponders. Beacon transponders are indicated for permanent implantation in the prostate only. The Calypso® 4D localization System is considered equivalent to existing devices such as implanted fiducials.

Several systems, devices, and accessories for respiratory gating for tracking respiratory pattern for respiratory synchronized image acquisition during radiation therapy treatment have received U.S. Food and Drug Administration (FDA) 510(k) clearance (e.g., RPM Respiratory Gating System, SDX-SpiroDyrn'X Radiotherapy Breathing Control).

POSITION STATEMENT:

Image-guided radiation therapy (IGRT) (any modality) **meets the definition of medical necessity** when any of the following indications are met:

- Intensity modulated radiation therapy (IMRT) is being utilized
- Proton beam therapy is being utilized
- Use of IGRT will allow significant reduction of radiation dose to sensitive normal structures, for example:
 - Left-sided breast cancer treatment with deep inspiration breath hold technique (DIBH) for cardiac sparing is being utilized.
- Implanted fiducial markers have been placed
- Bony anatomy fails to accurately delineate a tumor location and fiducial markers or intensity modulated radiation therapy (IMRT) are not indicated (for example: head and neck cancer or prone breast radiotherapy)
- The treatment field abuts a previously irradiated field
- There is significant setup variation affecting the treatment target, for example:
 - Member is morbidly obese (BMI>35) and receiving treatment of tumors in the mediastinum, abdomen or pelvis
 - There is significant organ movement due to respiration and a 4D planning CT scan was performed with documentation demonstrating that the treatment plan addresses tumor motion that is both accounted for and managed.

Image guidance should be performed at the minimum frequency needed to assure proper member positioning.

Image-guided radiation therapy for all other indications not meeting any of the above criteria **does not meet the definition of medical necessity**.

BILLING/CODING INFORMATION:

CPT Coding:

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| 77014 | Computed tomography guidance for placement of radiation therapy fields |
| 77387 | Guidance for localization of target volume for delivery of radiation treatment, includes intrafraction tracking, when performed |

HCPCS Coding:

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|-------|---|
| G6001 | Ultrasonic guidance for placement of radiation therapy fields |
| G6002 | Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy |
| 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 |

LOINC Codes:

The following information may be required documentation to support medical necessity: physician history and physical, physician progress notes, plan of treatment and reason for imaged-guided radiation therapy (IGRT).

| Documentation Table | LOINC Codes | LOINC Time Frame Modifier Code | LOINC Time Frame Modifier Codes Narrative |
|-----------------------------------|--------------------|---------------------------------------|---|
| Physician history and physical | 28626-0 | 18805-2 | Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim |
| Attending physician progress note | 18741-9 | 18805-2 | Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim |
| Plan of treatment | 18776-5 | 18805-2 | Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim |

REIMBURSEMENT INFORMATION:

Refer to section entitled [**POSITION STATEMENT**](#).

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

DEFINITIONS:

Fraction: a single session of radiation treatment delivered to a specific area of interest at one setting.

Linear accelerator: the device most commonly used for external beam radiation treatments for patients with cancer. It delivers a uniform dose of high-energy x-ray to the region of the patient's tumor. These x-rays can destroy the cancer cells while sparing the surrounding normal tissue.

Simulation: the process of establishing and documenting the appropriate volume to be treated and identifying the normal structures within or adjacent to this volume.

RELATED GUIDELINES:

None applicable.

OTHER:

Other names used to report image-guided radiation therapy (IGRT):

Dynamic Targeting IGRT
Electromagnetic Transponders
Intra-fraction Image Guidance
On-Board Imager
Real-Time Intra-Fraction

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15. U.S. Food Drug Administration (FDA) 510(k) Premarket Notification-RPM Respiratory Gating (K107024).
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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 01/25/18.

GUIDELINE UPDATE INFORMATION:

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| 02/15/10 | New Medical Coverage Guideline. |
| 01/01/11 | Annual HCPCS update; revised 55876 code descriptor. |
| 02/15/11 | Annual review. Maintain position statement. Updated references. |
| 10/01/11 | Revision; formatting changes. |
| 05/15/14 | Annual review. Maintain position statement. Added heading for "intra-fraction, description section. Revised FDA statement for Calypso 4D Localization System, description section. Added Medicare Advantage products program exception. Updated references. |
| 01/01/15 | Annual HCPCS code update. Deleted 0197T, 76050 and 77421. Added 77387, G6001, G6002 and G6017. |
| 05/15/15 | Annual review; position statement unchanged. Updated description and references. |
| 05/01/16 | Revision; deleted "for Treatment Planning and Delivery" from MCG name; deleted position statement for intra-fraction localization and tracking of target and imaging modalities; added position statement for image-guided radiation therapy; deleted 32553, 49411 and 55876; added LOINC codes; updated program exception; updated references. |
| 11/15/16 | Revision; revised position statement. Updated references. |
| 10/15/17 | Revision; revised position statement. Updated references. |
| 02/15/18 | Revision; updated position statement and definitions. |
| 01/01/19 | Annual HCPCS code update. Revised 77387 code descriptor. |
| 02/15/22 | Updated program exceptions. |