POLICY STATEMENT:
Based upon our criteria and assessment of the peer-reviewed literature, real-time image guided intra-fraction target tracking (IGRT) during radiation therapy to adjust radiation doses or monitor target movement during individual radiation therapy treatment sessions has not been proven to improve patient outcomes over existing techniques and is considered **not medically necessary**.

POLICY GUIDELINES:

I. This policy addresses the use of real-time image guided intra-fraction target tracking during radiation therapy (“real-time tracking”). These techniques enable adjustment of the target radiation while it is being delivered (e.g., intra-fraction adjustments) to compensate for movement of the organ inside the body.

II. 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 (e.g., ultrasound, cone beam CT, and megavolt CT). It deals with approaches to monitor organ movement within a single treatment session.

III. This policy applies to image-guided therapy irrespective of the method for localizing the tumor target (e.g. radiographic image or electromagnetic localization).

IV. 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.

Refer to Corporate Medical Policy #6.01.12 regarding Stereotactic Radiosurgery and Stereotactic Radiotherapy.

Refer to Corporate Medical Policy #6.01.24 regarding Intensity Modulated Radiation Therapy (IMRT).

DESCRIPTION:
During radiation therapy it is important to target the tumor so that radiation treatment is delivered to the tumor but surrounding tissue is spared, especially during dose escalation. One type of image-guided radiation therapy (IGRT) for prostate cancer has been proposed as a technique to adjust the targeting of radiation while it is being delivered in real-time (e.g. intra-fraction adjustments) to compensate for movement of the organ inside the body. It is defined as a device to track the tumor (e.g. organ motion) via frequent or continuous imaging in the treatment room during radiation treatment sessions to allow adjustment of the radiation dose during a session based on tumor movement detected by the image.

In general, image guided adjustments can be grouped into two categories: on-line and off-line. An off-line approach refers to imaging without immediate intervention. An on-line correction occurs when corrections or actions occur at the time of radiation delivery on the basis of pre-defined thresholds. Intra-fraction (e.g. during a treatment session) adjustments are done through on-line corrections.

The Calypso® 4D Localization System is a target localization platform based on detection of electromagnetic markers called Beacon® Electromagnetic Transponders. Beacon® transponders, smaller than a grain of rice, are implanted in the prostate. When coupled with the 4D Localization system, the transponders send signals that generate location instructions to the radiation therapist to register the target to isocenter prior to treatment. The proposed result is simpler
location of the true treatment target and objective, and efficient management of patient alignment continuously without extra non-therapeutic x-ray doses.

RATIONALE:
The Calypso® 4D Localization System, using Beacon® transponders, obtained U.S. Food and Drug Association (FDA) clearance for use in prostate cancer in 2006 through the 510(k) process.

With no randomized trials that compare IMRT with real-time intra-fraction target tracking to IMRT alone, it is not known whether the addition of real-time intra-fraction target tracking improves net heath outcome (fewer adverse effects and/or improved survival). Specifically for prostate cancer studies are needed to show the impact on clinical outcomes of these image-guided devices that adjust radiation therapy or monitor the tumor-target during individual treatment sessions during. Current studies focus on movement of the prostate during radiation therapy sessions. This is considered an initial step in evaluating this technology, but is not sufficient to determine if patient outcomes are improved. There is limited clinical evidence regarding use of the Calypso® 4D Localization System or the Cyberknife® Robotic Radiosurgery System for prostate cancer.

CODES:

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>55876</td>
<td>Placement of interstitial device(s) for radiation therapy guidance (e.g., fiducial markers, dosimeter), percutaneous prostate, single or multiple</td>
</tr>
<tr>
<td>0197T (NMN)</td>
<td>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</td>
</tr>
</tbody>
</table>

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.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

There are no codes specific to the Beacon transponders or use of the Calypso localization system.

CPT: 55876

HCPCS: No specific code.

ICD9: NMN for all codes.

ICD10: NMN for all codes

REFERENCES:


**KEY WORDS:**

Beacon, Beacon Care Package, Calypso, Calypso System, electromagnetic transponders, IGRT, 4D localization.

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**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

There is currently no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for Image-Guided Radiation Therapy.