Real-Time Intra-Fraction Target Tracking During Radiation Therapy

Policy Number: MM.05.011
Line(s) of Business: HMO; PPO; QUEST
Section: Radiology
Place(s) of Service: Outpatient

I. Description

Real-time intra-fraction target tracking, as an adjunct to the delivery of radiation therapy is defined as techniques and devices that 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 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.

During radiation therapy, it is important to target the tumor so that radiation treatment is delivered to the tumor, but surrounding tissue is spared. This targeting seems increasingly important as dose-escalation is used in an attempt to improve long-term tumor control and improve patient survival. Over time, a number of approaches have evolved to improve targeting of the radiation dose. Better targeting has been achieved through various approaches to radiation therapy, such as 3-D conformal treatment and intensity-modulated radiation therapy (IMRT). For prostate cancer, use of a rectal balloon has been reported to improve consistent positioning of the prostate and thus reduce rectal tissue irradiation during radiation therapy treatment of prostate cancer. In addition, more sophisticated imaging techniques, including use of implanted fiducial markers, have been used to better position the tumor (patient) as part of treatment planning and individual radiation treatment sessions.

This policy does not address inter-fraction image guided therapy, defined as techniques and devices that can be used to guide radiation therapy prior to its delivery.
II. Policy Statement:

Real-time intra-fraction target tracking during individual radiation therapy treatment sessions is **not covered** because there is no data indicating that the use of real-time tracking during radiation therapy to adjust the intra-fraction dose of radiation therapy or monitor target motion during radiation treatment improves clinical outcomes over existing techniques.

III. Administrative Guidelines:

Applicable code:

<table>
<thead>
<tr>
<th>CPT code</th>
<th>Description</th>
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<tbody>
<tr>
<td>0197T</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>
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IV. Rationale

Proponents of real time intra-fraction image guidance argue that these techniques improve treatment accuracy, thereby reducing the likelihood of radiation induced complications and potentially improving the effectiveness of radiation therapy. Therefore, validation of the clinical utility of intra-fraction image guidance requires studies comparing this technology to standard radiation delivery using inter-fraction guidance. To date, published studies have suggested favorable outcomes with use of intra-fraction target guidance but have also acknowledged the need for larger controlled trials to clarify the role of this technology in facilitating safer dose escalation while reducing organ motion challenges and toxic effects to improve delivery to the target volume for various sites, such as prostate, lung and breast (1, 2, 3, 4, 5).

A literature search identified two additional studies that address the Calypso System, as an adjunct to prostate cancer radiation. Both of these studies focused on the technical capabilities of the device and did not report clinical outcomes (6, 7). Kindblom published a feasibility study of the RayPilot device in 10 subjects with prostate cancer, but no clinical results were reported (8).

Sandler and colleagues reported on 64 patients treated with IMRT for prostate cancer in the Assessing the Impact of Margin Reduction (AIM) study (9). Patients were implanted with Beacon transponders (Calypso Medical Technologies, Inc., Seattle, WA) and were treated with IMRT to a nominal dose of 81 Gy in 1.8 Gy fractions. Patients in this study were treated with reduced tumor margins, as well as real-time tumor tracking. Patient-reported morbidity associated with radiotherapy was the primary outcome. Study participants were compared to historic controls. Study participants reported fewer treatment-related symptoms and/or worsening of symptoms after treatment than the comparison group. For example, the percentage of patients in the historic comparison group reporting rectal urgency increased from 3% pre-treatment to 22% post-treatment, no increase was observed in the current experimental group.
**Practice Guidelines and Position Statements**

The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines for Prostate Cancer state, "The accuracy of treatment should be improved by attention to daily prostate localization with techniques, such as image guided radiation therapy (IGRT) using computed tomography (CT), ultrasound implanted fiducials, electromagnetic targeting/tracking, or an endorectal balloon to improve oncologic cure rates and reduce side effects." This NCCN guideline for prostate cancer says, "IGRT is required for doses greater than or equal to 78 Gy." (10). These guidelines do not mention the use of real-time intra-fraction target tracking or the specific use of the Calypso 4D Localization System.

**Summary**

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 health outcome (fewer adverse effects and/or improved survival). There is also no data supporting the use of real-time tracking during radiation therapy to adjust the intra-fraction dose or monitor target motion during radiation treatment improves clinical outcomes over existing techniques.

**V. Important Reminder**

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

**VI. References**