Protocol

Real-Time Intra-Fraction Motion Management During Radiation Therapy

(20310)

(Formerly Real-Time Intra-Fraction Target Tracking During Radiation Therapy)

Medical Benefit		**Effective Date**: 10/01/14	**Next Review Date**: 07/15
Preauthorization	No	**Review Dates**: 01/10, 01/11, 03/11, 03/12, 03/13, 03/14, 07/14	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary.*** *Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

This Protocol discusses the use of real-time intra-fraction target tracking during radiotherapy ("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 radiotherapy" (IGRT). For this Protocol real-time tracking is defined as frequent or continuous target tracking in the treatment room during radiotherapy, with periodic or continuous adjustment to targeting made on the basis of target motion detected by the tracking system. This Protocol 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, which includes technologies using respiratory gating. This Protocol does not address IGRT used as part of stereotactic (body) radiation therapy.

Background

In general, intra-fraction adjustments can be grouped into two categories: online and off-line. An online correction takes place 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.

During radiotherapy, 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 radiotherapy, such as 3-D conformal treatment (3D-CRT), 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 radiotherapy treatment of prostate cancer. In addition, more sophisticated imaging techniques, including use of implanted fiducial (radio-opaque) markers, has been used to better position the tumor (patient) as part of treatment planning and individual radiation treatment sessions.

Intra-fraction target motion can be caused by many things including breathing, cardiac and bowel motion, swallowing or sneezing. Data also suggest that a strong relationship may exist between obesity and organ shift,

indicating that without some form of target tracking, the target volume may not receive the intended dose for patients who are moderately to severely obese. (1) Respiration affects the position of all thoracic and abdominal organs, primarily the lungs, liver, and breast. (2) The American Association of Physicists in Medicine Task Group 76 recommends motion management for tumor motion that exceeds 5 mm in any direction or if significant normal tissue-sparing can be gained. (3) Measurement of tumor motion commonly uses fluoroscopy or four-dimensional computed tomography (4D-CT), a sequence of 3D-CT images over time, with or without fiducial markers.

Five principal respiratory motion management techniques are commonly used: integration of respiratory movements (i.e., mean tumor position, range of motion) into treatment planning; abdominal compression plates to force shallow breathing; breath-hold, often using spirometry; respiratory gating; and real-time tumor-tracking. (4) Respiratory gating delivers radiation during a particular portion of the breathing cycle. This "gate" is defined by monitoring respiratory motion with external sensors and selecting a constant cycle amplitude or phase (e.g., end-inspiration or end-expiration) for radiation delivery. Respiratory gating assumes a consistent association between the respiratory cycle and tumor position. For patients in whom this association is unreliable, real-time target tracking techniques can be used. These techniques involve fluoroscopic, radiograph, or digital tracking of external respiratory surrogates, e.g., an abdominal belt, or, like other real-time tumor-tracking techniques described here, implanted fiducial markers. (5)

As previously noted, the next step in this evolving process of improved targeting is 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. Some of the devices cleared by the U.S. Food and Drug Administration (FDA) are referred to as "4-D imaging" (not to be confused with 4D-CT, described earlier). One such device is the Calypso® 4D Localization System (Varian Medical Systems; Palo Alto, CA). This system uses a group of three electromagnetic transponders (Beacon®) implanted in or near the tumor to allow continuous localization of a treatment isocenter. Beacon® transponders are 8.5-mm long with a diameter of 1.85 mm. The three transponders have a "field of view" of 14-cm square and a depth of 27 cm.

FDA Status

The Calypso® 4D Localization System obtained FDA clearance for prostate cancer in March 2006 through the 510(k) process (K060906) and for other soft tissue tumors in May 2008 (K080726). This system was considered equivalent to existing devices such as implanted fiducials and other body-positioning technologies.

Respiratory-gating systems by several manufacturers have received FDA-approval, e.g., Real-time Position Management™ (RPM, Varian Medical Systems, Palo Alto, CA; K102024), Active Breathing Coordinator System®, (ABC, Aktina, Congers, NY; K003330), and SDX™ (Dyn'R, Toulouse, France; K092479).

This Protocol does not address IGRT used as part of stereotactic (body) radiation therapy.

Policy (Formerly Corporate Medical Guideline)

Real-time intra-fraction target tracking during radiation therapy to adjust radiation doses or monitor target movement during individual radiation therapy treatment sessions is considered **investigational**.

Respiratory gating techniques for the delivery of radiotherapy are considered **investigational**.

Policy Guidelines

This Protocol only addresses real-time tracking and devices defined as devices that allow for the adjustment of radiation doses during individual radiation treatment sessions.

Benefit Application

If real-time intra-fraction motion management is billed in addition to radiation therapy, because it is investigational, it will be considered incidental to the radiation therapy service.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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