Corporate Medical Policy

Real-Time Intra-Fraction Target Tracking During Radiation Therapy

File Name:	real_time_intra_fraction_target_tracking_during_radiation_therapy
Origination:	2/2009
Last CAP Review:	8/2011
Next CAP Review:	8/2012
Last Review:	8/2011

Description of Procedure or Service

This policy discusses 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 will also not address technologies using respiratory gating.

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 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, 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.

As noted above, 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." 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.

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

Related Policies:
Charged Particle Radiotherapy, Proton or Helium Ion

Radiosurgery, Stereotactic Approach

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

Real –time intra-fraction target tracking during radiation therapy is considered not medically necessary. BCBSNC does not provide coverage for services that are not medically necessary.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Real-Time Intra-Faction Target Tracking During Radiation Therapy is covered

Not applicable

When Real-Time Intra-Fraction Target Tracking During Radiation Therapy is not covered

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 **not medically necessary** in the treatment of cancer in any site, including but not limited to prostate, lung, and breast**.**

Policy Guidelines

No relevant outcome studies have been published in the literature for any site including, but not limited to, prostate, lung, and breast. Additionally, there are few registered clinical trials of these techniques at this time, and none of a randomized design focused on showing how these additional procedures may improve clinical outcomes, including a decrease in toxicity to surrounding tissue.

Because real-time intra-fraction target tracking generally uses IMRT to deliver radiation therapy, the use of real-time tracking is unlikely to produce outcomes that are inferior to IMRT treatment. Thus, on this basis, the real-time tracking approach is not considered to be investigational. However, there are no data that indicate that 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. In summary, because this technology is more costly than alternative services that

produce equivalent therapeutic results, this is considered not medically necessary.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: *0197T*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

U.S. Food and Drug Administration (FDA), Center for Devices and Radiologic Health (CDRH). Calypso 4D Localization System. Summary of Safety and Effectiveness. 510(k) No. K060906. July 28, 2006. Retrieved 2/25/09 from http://www.fda.gov/cdrh/pdf8/K060906.pdf

U.S. Food and Drug Administration (FDA), Center for Devices and Radiologic Health (CDRH). Calypso 4D Localization System. Summary of Safety and Effectiveness. 510(k) No. K080726. May14, 2008. Retrieved 2/25/09 from http://www.fda.gov/cdrh/pdf8/K080726.pdf

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.10, 12/11/08

BCBSA-Medical Policy Reference Manual [Electronic Version]. 2.03.10, 10/6/09

Specialty Matched Consultant Advisory Panel 5/2010

National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology. Prostate Cancer (V.3.2010). Available online at: ttp:/www.nccn.org/professionals/physician_gls/PDF/prostate.pdf.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.10, 1/13/11

Specialty Matched Consultant Advisory Panel 8/2011.

Policy Implementation/Update Information

For Policy Named: Image-Guided Radiation Therapy for Prostate Cancer

6/8/09 New Policy issued. BCBSNC does not provide coverage for image-guided radiation therapy for prostate cancer. It is considered Not Medically Necessary. (adn)

8/31/09 Added the following statement to the Not Covered section, "All other uses for image-guided radiation therapy are considered investigational." (adn)

6/22/10 Specialty Matched Consultant Advisory Panel review 5/24/10. No criteria changes. Description section extensively revised for consistency with BCBSA Medical Policy. Reference added.(lr)

For Policy Renamed: Real-Time Intra-Fraction Target Tracking During Radiation Therapy

8/17/10 Policy name changed from Image Guided Radiation for Prostate Cancer to Real-Time Intra-Fraction Target Tracking During Radiation Therapy for consistency with BCBSA policy. No

changes to policy statement. Reviewed with Senior Medical Director. (lpr)

10/26/10 Added diagnoses codes to the "Billing/Coding" section. Under "When Not Covered" section added "in the treatment of prostate cancer" to 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 **not medically necessary** in the treatment of prostate cancer**.** (lpr)

9/30/11 Specialty Matched Consultant Advisory Panel review 8/31/2011. Description section updated for consistency with BCBSA. Policy references updated. No changes to policy statement. Removed diagnoses codes 185 and 233.4 from the Billing/Coding section due to no smart suspend in place. (lpr)