



Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Localization System for External Beam Radiation

- Calypso 4D Localization
- Electromagnetic Localization System
- GPS for the Body
- Tracking with Beacon Transponders during External Beam Radiation Therapy (Calypso Medical)

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "Localization System for External Beam Radiation" for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Prostate cancer is the most commonly diagnosed cancer and second leading cause of death in men in the United States. The treatment options for early-stage prostate cancer include radical prostatectomy, high dose brachytherapy, and high dose external beam radiation therapy (EBRT). Several studies showed improvement in biochemical progression free survival with radiation dose escalation. However, this comes at the cost of higher bladder and bowel toxicity. Investigators found that toxicity due to radiation therapy can be reduced by the use of intensity modulated radiotherapy (IMRT) techniques that focus a high dose radiation to the prostate while decreasing the dose to the bladder and rectum. With the higher doses being delivered with increased conformity,

it is critical that the isocenter of the prostate treatment volume be placed with precision (Kuban 2008, Quigley 2009, Rajendran 2010).

The prostate gland is known to have some movement during the day as the bladder and rectum are filled at different volumes. Two types of motion have been described and may be an issue for treatment planning: 1. Interfraction motion from day-to-day, and 2. Intrafraction movement that is motion occurring while the patient is on the treatment table during radiation delivery. This is thought to be caused by breathing or other biological factors as contraction/relaxation of the pelvic floor and by rectal gas. Target localization during radiation therapy for prostate cancer has two aspects: the initial setup before delivering the radiation, and the subsequent real-time target position monitoring during the actual delivery of radiation. The interfraction position has been addressed by various techniques including ultrasound, infrared cameras, diagnostic CT imaging, and x-ray imaging. The use of implanted markers as gold is accepted as an accurate, reliable, and reproducible method to establish the position of the prostate gland during EBRT treatment. Other techniques used to estimate the motion of prostate during delivery of radiation include transabdominal ultrasound, X-rays, MRI, CT, and fluoroscopy. The use of these technologies may be limited as they may not be available in the treatment room or usable during radiation delivery, provide only a snapshot of the prostate position, result into additional radiation dose, are labor intensive and /or require user skill for image acquisition or interpretation (Kupelian 2006, Rajendran 2010).

In the last few years, the use of an implantable radiofrequency emitting device has been proposed as an alternative to radiopaque fiducial markers and radiographic localization to provide an objective, accurate real-time method of localizing and monitoring prostate position. The Calypso 4D Localization System is based on electromagnetic detection of implanted Beacon transponders that allows the three-dimensional position of the implanted transponders and target isocenter to be tracked at a frequency of 10Hz. This provides continuous real-time localization and monitoring of the prostate. The Calypso System (Calypso Medical, Seattle, WA) consists of three implantable wireless Beacon transponders approximately 8 mm in length and 2mm in diameter, an electromagnetic array, an infrared camera system, and a tracking station. Typically, three transponders are implanted in the right and left base and the apex of the prostate gland under transrectal ultrasound guidance in a manner similar to needle biopsy. The coordinates of the Beacons and the isocenter are identified on the treatment planning CT and entered into the calypso tracking station. Similar to ultrasound localization, the initial localization with the Calypso System is performed using skin marks to align with room lasers. Calypso is used to localize the prostate and the system calculates the initial offset. The couch is shifted until the three offsets are zero. During treatment Calypso monitors and reports the offset between the actual and planned isocenter position (Santanam 2009, Foster 2010, Rajendran 2010).

Potential benefits of the Calypso system include its ability to continuously monitor target position during treatment, with no exposure to ionizing radiation to perform the localization, and without using complicated procedures of acquiring X-ray images. Potential disadvantages on the other hand, are the need for implantation, transponders stability within the implanted tissues, and the absence of any associated image of the targeted areas. The Calypso System has received 510 (K) clearance from the FDA in 2006.

Medical Technology Assessment Committee (MTAC)

Calypso 4D Localization System

12/20/2010: MTAC REVIEW

Evidence Conclusion: The published literature on the Calypso system is very limited and do not provide sufficient evidence to determine the safety of the technology or its effect on patients with localized prostate cancer treated with radiation therapy. The published studies were small case series the majority of which were conducted by the same group of authors many of whom had financial interest with the manufacturer of the technology. The safety of the Calypso system and its effect on improving health outcomes were not examined in randomized controlled trials. Assessing the Impact of Margin Reduction (AIM) study was the largest case series on the Calypso System published to date, and the first with clinical outcomes. However, it was not randomized and used a historical comparison group. It had several other limitations including the significant baseline differences between study participants and the comparison groups, difference in the time of treatment, and variations in the radiation therapy received by the two groups, as well as the absence of long-term follow-up to determine the effect of the technology on the incidence of late complications. Moreover only 83% of the participants were included in the analysis, and the study was funded by the manufacturer.

Articles: The published literature on the Calypso 4D localization system for the prostate is very limited. There are no published randomized controlled trials that compared the effect of the Calypso system versus other localization technologies on reducing radiation toxicity or improving quality of life (QoL) in patients with prostate cancer. The

literature search identified the ‘Assessing the Impact of Margin Reduction (AIM)’ study that assessed the effect of reducing the planning target volume margins while using real-time tumor tracking on the quality of life of patients with prostate cancer treated with radiation therapy. It did not include a comparison or control group. No trials on the safety of the technology were identified.

The AIM study was selected for critical appraisal: Sandler M, Liu P-Y, Dunn RL, et al. Reduction in patient-reported acute morbidity in prostate cancer patients treated with 81-Gy Intensity-modulated radiotherapy using reduced planning target volume margins and electromagnetic tracking: assessing the impact of margin reduction study. *Urology*. 2010 May;75(5):1004-8. Epub 2010 Feb 13. See [Evidence Table](#)

The use of Calypso 4D localization system (Calypso 4D localization and Tracking with Beacon transponders during external beam radiation therapy [Calypso Medical], GPS for the Body, electromagnetic localization system) does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Not Medically Necessary:

CPT® / HCPC Codes	Description
77387	Guidance for localization of target volume for delivery of radiation treatment, includes intrafraction tracking, when performed
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

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

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Creation Date	Review Dates	Date Last Revised
12/20/2010	02/10/2011 ^{MDCRPC} , 12/06/2011 ^{MDCRPC} , 10/02/2012 ^{MDCRPC} , 08/06/2013 ^{MPC} , 06/03/2014 ^{MPC} , 04/07/2015 ^{MPC} , 02/02/2016 ^{MPC} , 12/06/2016 ^{MPC} , 10/03/2017 ^{MPC} , 09/04/2018 ^{MPC} , 09/03/2019 ^{MPC} , 09/01/2020 ^{MPC} , 09/07/2021 ^{MPC} , 09/06/2022 ^{MPC} , 09/05/2023 ^{MPC}	09/16/2020

^{MDCRPC} Medical Director Clinical Review and Policy Committee

^{MPC} Medical Policy Committee

Revision History	Description
09/01/2020	Added KPWA Medical Policy statement under Medicare section
09/16/2020	Added HCPC code G6017