Clinical Review Criteria
Stereotactic Radiation (Radiosurgery/Focused Beam/Gamma Knife)

- CyberKnife Robotic Radiosurgery System
- Fractionated Stereotactic Radiotherapy
- Multiple Brain Metastatic Lesions (5 or more brain metastatic lesions)
- Stereotactic Body Radiation Therapy for Prostate Cancer

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Criteria
For Medicare Members

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<td>National Coverage Determinations (NCD)</td>
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<td>Local Coverage Determinations (LCD)</td>
<td>Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (L34151)</td>
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For Non-Medicare Members
Kaiser Permanente has elected to use the Stereotactic Radiosurgery (KP-0423) MCG* for medical necessity determinations.

MCG* are proprietary and cannot be published and/or distributed. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

If requesting this service, please send the following documentation to support medical necessity:
- Most recent medical oncology notes
- Most recent radiation oncology notes
- Most recent imaging (i.e. CT/MRI)

<table>
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<td>Multiple Brain Metastatic Lesions (5 or more brain metastatic lesions)</td>
<td>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.</td>
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<tr>
<td>Stereotactic Body Radiation Therapy (SBRT) for Prostate Cancer</td>
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The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background
Radiosurgery can be defined as the stereotactic (precision) delivery of multiple cross-fired radiation beams to a point or volume within a configured space (Chang 2003). Stereotactic radiosurgery may also be described as a
method to destroy targets using single high doses of focused ionizing radiation, administered using stereotactic guidance (Niranjan 2001). It is a combination of minimally invasive technologies administered by a multidisciplinary team consisting of surgeons, oncologists, medical physicists, and engineers.

Stereotactic radiosurgery (SRS) was originally designed to produce functional lesions in the brain. It then evolved to target benign tumors and vascular malformations in surgically inaccessible locations. These indications are continuously expanding with the rapidly evolving technology of radiosurgical systems. Currently it has become an alternative to microsurgery and conventional radiation therapy in the treatment of many lesions in the base of the skull. It is used for vascular, tumor, and functional brain surgery, including arteriovenous malformations, pituitary adenomas, acoustic neuromas, and meningiomas, as well as brain metastases. Radiosurgery was initially limited to the brain because of the requirement of a stereotactic frame attached to the skull to provide a coordinate system for tumor localization. Recent advances however, allow radiosurgical treatment throughout the body without such frames.

A variety of methods have been developed to provide a reference system for the localization study to determine the target coordinates, including fixed frame and frameless systems, removable frame systems, and rigid masks.

Treatment can be repeated any number of times with equal precision as the target is calculated from the position of gold markers. Regardless of the number of sessions, these procedures consist of the following components:

- Head position stabilization (attachment of a frame or frameless)
- Imaging for localization (CT, MRI, or angiography, etc)
- Computer assisted tumor localization
- Treatment planning – number of isocenters, number, placement and length of arcs, beam size and weight, etc.
- Isodose distributions, dosage prescription and calculation
- Setup and quality assurance testing
- Simulation of prescribed arcs or fixed portals
- Stereotactic intervention or treatment itself

Gamma knife, the prototype of stereotactic radiosurgery was first clinically used in 1967. It developed rapidly from the earlier A-units to B units, and in 1999 to Model C that has a robotic engineering. With the gamma knife, the patient's head is placed within a large metal collimator consisting of a dome-shaped shell with holes that transmit the radiation to the center point. A stereotactic frame is anchored to the skull with four screws that penetrate the outer table to position the head so that the desired target is at the center of the collimator. The use of the frame limited the use of the gamma knife to head lesions, and to patients who could tolerate the rigid frame fixation. Moreover, the use of fractionated treatments that extended for several days was impractical with the frame fixation (Giller 2005).

The CyberKnife is a recently developed frameless stereotactic system that consists of a modified linear accelerator mounted on a robotic arm that moves slowly around the patient. It delivers several beams of radiation at each of many stopping points while minimizing radiation exposure of surrounding tissue (Quinn 2001). Stereotactic precision is achieved without a rigid frame by means of two diagnostic x-ray cameras mounted in the CyberKnife vault and are used to acquire real-time images of the patient's internal anatomy during treatment. Any patient motion is detected by these images, and the information is used by the robot to compensate and keep the linear acceleration on target. Treatment time ranges from 45-60 minutes and can be given in one fraction, or several fractions with smaller doses given over several days, depending on the condition being treated and the size of the affected area.

The use of the CyberKnife for radiosurgery of organs other than the brain is more challenging and requires several technical refinements. When used for spinal lesions for example, it requires the placement of internal small 2-mm stainless steel screws in the spinal lamina adjacent to the target site as “fiducial markers” (Giller 2005).

Radiosurgery has its advantages as well as risks. It is non-invasive, and can treat poor surgical candidates, and tumors inaccessible to surgery. Moreover, it can safely deliver higher doses of radiation than those used in conventional radiotherapy, while sparing the surrounding tissues from the high levels of radiation. It can thus be more effective in treating radioresistant and recurrent tumors and may be used as a boost to conventional radiotherapy. On the other hand, its was reported that its efficacy is lower and risk of complications higher in larger tumors, or those that were previously treated with radiation. Another limitation is the sensitivity of the optic nerve and chiasma to radiosurgical doses. There is also the risk of radionecrosis which is a combination of cytotoxic and microvascular tissue injury within the treated field due to radiation. This may be delayed for months, asymptomatic, severe, and/or persistent (Giller 2005).
The CyberKnife was cleared by the FDA in October 2001 for radiosurgery for lesions, tumors, and other conditions in any anatomical site.

Trigeminal neuralgia (tic douloureux) is a disorder of the fifth cranial (trigeminal) nerve that causes episodes of intense, stabbing pain (separated by pain-free periods) in the areas of the face where the branches of the nerve are distributed.

The general approach to treating this disorder is to begin treatment with pharmacological agents and to initiate surgical treatment if medical treatment fails. There are 3 categories of surgical options: 1) Percutaneous procedures (glycerol injection commonly used at GHC); 2) Microvascular decompression; 3) Focused beam radiosurgery (gamma knife, LINAC). According to the MRU, GHC patients currently referred for radiosurgery on a case-by-case basis).

In gamma knife radiosurgery, magnetic resonance imaging (MRI) is used to identify the trigeminal nerve root. Subsequently, a single 4-mm isocenter of radiation is delivered to the trigeminal nerve root (just posterior to the pons). The radiation dose is 70-90 Gy. No surgical incisions are made.

Evidence and Source Documents

Gamma Knife in the treatment of Trigeminal Neuralgia
CyberKnife Robotic Radiosurgery System
Gamma Knife in the treatment of five or more brain metastatic lesions
Stereotactic Body Radiation Therapy (SBRT) for Prostate Cancer

Medical Technology Assessment Committee (MTAC)

Gamma Knife in the treatment of Trigeminal Neuralgia
04/12/2000: MTAC REVIEW

Evidence Conclusion: Since this topic was last reviewed in 1997, there have been two moderately sized case series articles published examining gamma knife radiosurgery on trigeminal neuralgia. A substantial proportion of patients improved after treatment with low rates of adverse outcomes. Case series have numerous threats to validity and provide weak evidence. If patients with trigeminal neuralgia are known to uniformly experience unrelenting pain, however, the improvement reported in these papers is more suggestive of efficacy. Even in this situation, it is not known whether alternate treatments might be as or more effective than gamma knife radiosurgery. If pain episodes tend to occur infrequently, case series results are less impressive because many patients would likely have been in remission during the initial follow-up period.

Articles: Articles were selected based on study type. For gamma knife therapy, there were no randomized control trials or meta-analyses. Several case series were sub-sets of subsequent case series. The largest and most comprehensive case series that had not been previously reviewed for the 1997 CPC evaluation were selected for critical appraisal and evidence tables were created (Kondziolka, D, Perez, B, Flickinger, JC, Habeck, M, Lunsford, D. Gamma knife radiosurgery for trigeminal neuralgia. Arch Neurol 1998; 55: 1524-1528. Young, RF, Vermeulen, S, Posewitz, A. Gamma knife radiosurgery for the treatment of trigeminal neuralgia. Stereotact Funct Neurosurg 1998; 70 (suppl 1): 192-199). The search on LINAC did not yield any additional articles. One book chapter on LINAC was located. This reported on a case series with 10 patients and was not included in this review due to the small sample size.Young, RF, Vermeulen, S, Posewitz, A. Gamma knife radiosurgery for the treatment of trigeminal neuralgia. Stereotact Funct Neurosurg 1998; 70 (suppl 1): 192-199. See Evidence Table. Kondziolka, D, Perez, B, Flickinger, JC, Habeck, M, Lunsford, D. Gammaknife radiosurgery for trigeminal neuralgia. Arch Neurol 1998; 55: 1524-1528. See Evidence Table.

The use of Gamma Knife in the treatment of Trigeminal Neuralgia does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

CyberKnife Robotic Radiosurgery System
06/05/2006: MTAC REVIEW

Evidence Conclusion: CyberKnife; There were no published meta-analyses or randomized controlled trials on the CyberKnife radiosurgery system. There were only case reports and small case series with no control or comparison groups. Case series have numerous threats to validity and provide the weakest grade of evidence, Chang, et al reported on their experience with radiosurgical treatment with the CyberKnife among 61 patients treated in their center at Stanford University over 3 years, and who had at least 36 months of follow-up. The treatment was not compared to an alternative therapy. Data were collected both prospectively and retrospectively,
and the main outcome was the tumor response and hearing preservation. The authors did not discuss any inclusion/exclusion criteria, included a heterogeneous group of patients, and two fractionation regimens for the therapy were used. After 36 months of observation, the tumor size decreased among 48% of the patients, was stable among 50%, and increased in size in 2%. Ninety percent of those with those with measurable hearing maintained their hearing level after treatment. Gerszten and colleagues reported their experience with CyberKnife radiosurgery for spinal lesions among 115 patients with several variations in their baseline characteristics and indications for the treatment. It was also a case series with no control or comparison group and potential selection and observation biases. The median follow-up duration was 18 months, and the outcome was improvement in pain, and tumor control. The results of the series indicate that 94% of the patients presenting with significant pain described an improvement in their pain using a 10-point scale after one month of the treatment. The condition did not progress among those who received the therapy as the primary treatment modality or those who had undergone previous surgery. In conclusion the published literature to date does not provide sufficient evidence to determine the efficacy of Cyberknife for stereotactic radiosurgery for lesions or tumors in various anatomical sites.


The use of CyberKnife Robotic Radiosurgery System in the treatment of lesions, tumors, and other conditions in any anatomical site does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

Gamma Knife in the treatment of five or more brain metastatic lesions
02/09/2015: MTAC REVIEW

Evidence Conclusion: To date, there is no direct evidence from randomized controlled trials to determine that stereotactic radiosurgery alone or in combination with WBRT for patients with more than 4 brain metastases leads to better or equivalent outcomes to those of WBRT as regards overall survival, local recurrence, need for salvage therapy, neurological functioning, quality of life, or other outcomes. The best published evidence consists of a recent large prospective observational study of patients with one to 10 brain metastases (Yamamato et al, 2014), two case-matched studies conducted by the same principal author and colleagues, that compared SRS treatment results for patients with 1-4 versus ≥ 5 tumors and 2-9 vs. >10 brain metastases (Yamamato et al, 2013 & 2014 respectively), and a number of retrospective analyses of patients for multiple brain metastases treated with SRS used alone or in conjunction with surgical excision or WBRT. The prospective study conducted by Yamamato and colleagues (2014, Evidence table 1) included 1,194 patients with 1-10 newly diagnosed brain metastasis, with a maximum lesion volume <15 mL, and a Karnofsky performance status (KPS) score of ≥70. All patients received standard stereotactic radiosurgery and the primary outcome was overall survival for which the non-inferiority margin for the comparison of outcomes in patients with two to four brain metastases with those of patients with five to ten brain metastases was set as the value of the upper 95% CI for a hazard ratio (HR) of 1.30. The results of the analysis showed a median overall survival after stereotactic radiosurgery of 13.9 months in the patients with one brain metastasis, 10.8 months for those with 2-4 metastases, and 10.8 months among those with 5-10 lesions). Overall survival did not differ between the patients with two to four vs. those with 5-10 lesions (HR 0.97, 95% CI 0.81-1.18). This was less than the value of non-inferiority margin set by the authors a prior. The same group of investigators performed two retrospective case matched-studies to examine whether treatment results of SRS alone for patient with five or more brain metastases differ from those for patients with 1-4 metastases in one study, and for patients with 2-9 versus 10 or more lesions in the other study (Yamamato et al 2013, 2014). Overall the analysis comparing outcomes of SRS in patients with more than 5 metastases versus 1-4 showed a minimal, but statistically significant higher survival in patients with 1-4 versus ≥ 5 metastases. There were no significant differences between the subgroups in other outcomes including death due to progression of brain disease, need for salvage WBRT, salvage surgery, repeat SRS for new tumors, neurological deterioration, or SRS-related complications. Generally similar results were observed with the comparison of outcomes among patients with 2-9 versus 10 or more brain metastases. The studies had their shortcomings including the inherent limitations of retrospective studies, as well as limitations in analyses performed. The great majority of published observational retrospective studies suggest that the number of brain metastases (exceeding one lesion) had no statistically
significant impact on overall survival among patients treated with SRS given alone or in combination with WBRT. These retrospective studies include the largest series (Karlsson et al 2009) with data for 1,885 patients with 1-8 metastases treated over 30 years. The results of the analysis indicate that the median overall survival did not differ significantly between those with 2, 3-4, 5-8 or >8 brain metastatic lesions; but patients with one brain metastasis survived longer than those with multiple brain metastases. Prospective randomized controlled trials are needed to determine the efficacy of SRS with or without surgery for multiple brain metastases compared to WBRT alone or following surgical excision of the lesions. A randomized controlled study of neurocognitive outcomes in patients with five or more brain metastases treated with radiosurgery or whole-brain radiotherapy is underway. The primary aim of this study is to compare the change in neurocognitive function outcome between baseline and 6 months in WBRT versus SRS treatment groups. Conclusion: There is insufficient evidence to determine that SRS with or without whole brain radiation therapy (WBRT) has non-inferior, equivalent, or superior outcomes to WBRT in the management of patients with five or more brain metastases. There is insufficient direct evidence to determine that the outcomes of SRS in patients with five or more brain metastases are non-inferior or equivalent to those in patients with 1-4 brain metastases.

**Articles:** The literature search revealed over 400 articles on the use of SRS for brain metastases. The majority of published articles were studies evaluating the use of the technology for one to four brain lesions, studies comparing different radiation doses, and articles on the technical aspects of the technology. The search did not identify any randomized controlled trial (RCT) that compared SRS with or without WBRT versus WBRT. Almost all the studies that examined the efficacy of SRS in patients with five or more brain lesions were retrospective, observational studies with no comparison groups. There was one recently published prospective, observational study conducted in Japan (Yamamoto, et al, 2014) among patients with up to 10 brain metastases, and two case-matched retrospective studies conducted by the same group of principal authors comparing the SRS results for patients with 1-4 versus ≥ 5 tumors in one study, and 2-9 versus 10 or more lesions in the other. The Prospective study and the case matched study comparing outcomes of SRS for 1-4 versus ≥ 5 brain metastases were critically appraised. The results of the retrospective studies published in the last 8 years were summarized and presented in Table 3. Yamamoto M, Serizawa T, Shuto T, et al. Stereotactic radiosurgery for patients with multiple brain metastases (JLGK0901): A multi-institutional prospective observational study. Lancet Oncol. 2014 April; 15(4):387–395. Evidence tables 1 and 2. Yamamoto M, Kawabe T, Sato Y, et al. A case-matched study of stereotactic radiosurgery for patients with multiple brain metastases: comparing treatment results for 1-4 vs ≥ 5 tumors: clinical article. J Neurosurg. 2013 Jun; 118(6):1258-1268. Evidence tables 1 and 2.

The use of Gamma Knife in the treatment of five or more brain metastatic lesions does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

**Stereotactic Body Radiation Therapy (SBRT) for Prostate Cancer**

**BACKGROUND**

Prostate cancer is one of the most common cancers, and the second leading cause of cancer death in men in the US. There are many treatment options for a localized disease, and each has its advantages and side effects. The choice of intervention should be considered carefully, balancing the benefits and harms as they relate to the patient’s age, overall health, and personal preferences. External beam radiation therapy (EBRT) is one of the standard treatment options for localized prostate cancer and research shows that there is a dose response for biochemical relapse-free survival. However, the increase in radiation dose to the prostate also results in an increase in exposure to the adjacent organs at risk (namely the bladder, urethra, and rectum). The National Comprehensive Cancer Network (NCCN) Prostate Cancer Guideline (2014) states that doses of 75.6–79.2 Gy in conventional fractions to the prostate are appropriate for patients with low-risk cancers, and that patients with intermediate- or high-risk disease should receive doses up to 81.0 Gy. Several advanced techniques have been developed within the last two decades to deliver these high doses of radiation to the prostate while sparing the surrounding normal tissues. Currently intensity-modulated radiation therapy (IMRT) is the most common EBRT modality used for the treatment of localized prostate cancer. IMRT involves the external delivery of multiple beams of radiation that conform to the shape of the tumor, and where the intensity of each beam can be modulated in order to spare the surrounding healthy tissue. IMRT is typically delivered in 38-45 fractions (treatment sessions) and requires 7-9 weeks of treatment (Parthan 2012, Yamazaki 2014, NCCN 2014). Slowly proliferating prostate cancer cells are thought to have a unique radiobiology that is characterized by a low α/β ratio (around 1.5 Gy as opposed to about 10 Gy for other cancers). This assumption was first promoted in 1999 by Brenner and Hall, based on their observation of 367 patients from two centers. They noted that this low α/β ratio of prostate cancer is comparable or lower than that for late-responding normal tissue (experiments on rodents suggest that α/β ratio for the rectum is 4-6 Gy). This suggests that prostate cancer cells have a high degree of sensitivity to dose per fraction, and that the use of fewer high-dose per fraction radiation treatments (hypofractionation) would improve local tumor control. This theory is controversial, supported by some investigators and questioned by others, yet it provided the biologic rationale in favor of hypofractionated radiotherapy for localized prostate cancer (Brenner...
10/20/2014: MTAC REVIEW

Stereotactic Body Radiation Therapy (SBRT)

Evidence Conclusion: There is insufficient published evidence to date, to determine the long-term safety and effectiveness of SBRT compared to other conventional radiation therapy regimens used for the treatment of localized prostate cancer. The published literature includes a number of phase I and phase II feasibility trials conducted in several centers in the US (Virginia Mason Medical Center, Stanford University, Naples Florida, Georgetown University, Philadelphia CyberKnife Center, and Winthrop University). The population sizes varied between studies from 40 patients in the Stanford trial to 304 in the Winthrop trial. The longest median follow-up duration reported to date was 5 years, and data were collected prospectively or retrospectively. Patients included in the studies were newly diagnosed with biopsy-proven prostate cancer with no evidence of metastases. The majority of participants were low risk, a lower proportion at intermediate risk, and a few at high risk based on NCCN or D’Amico risk stratification criteria. Most studies described a protocol using five fractions of 7-7.25 Gy, for a total dose of 35-36.25 Gy. In one study (Oliai et al, 2013) the dose was 37.5 Gy in two thirds of the participants. The treatment was delivered either in consecutive days or every other day. In the majority of studies, androgen deprivation therapy was administered at the discretion of the treating urologist. The main endpoints of these observational studies were the PSA response, biochemical relapse free survival (bRFS), and the toxicity associated with SBRT. Conclusion: Overall the results of the published small observational phase I and II trials
indicate that SBRT has favorable outcomes in terms of short-term biochemical control, and with acceptable toxicity. However, the literature does not provide sufficient evidence to determine the comparative effectiveness of SBRT to other conventional radiotherapy techniques, or the durability of the observed biochemical control and low toxicity associated with the treatment beyond 3-5 years. The published studies did not examine the long-term safety of SBRT or its clinical effects in terms of disease-free survival, metastases-free survival, or overall survival. Larger trials with longer follow-up duration are required to evaluate the long-term safety and effects of SBRT, especially that late toxicity could be worse with extreme hypofractionation compared to the conventional hypofractionation. A number of RCTs involving extreme hypofractionation are underway and may provide more evidence on the safety and efficacy of SBRT compared to conventional therapies for the treatment of localized prostate cancer. However, it will be several years before the results of these trials are published. These ongoing studies are: PACE (Prostate Advances in Comparative Evidence) is an ongoing international randomized phase III study comparing SBRT using Cyberknife, radical prostatectomy, and IMRT (78 Gy in 39 fractions) for low and intermediate risk prostate cancer. HYPO-RT-PC (Hypofractionated radiotherapy of intermediate risk localized prostate cancer) is a Swedish phase III trial that will compare 78Gy in 39 fractions delivered with IMRT over 8 weeks vs. SBRT 42.7 Gy in 7 fractions of 6.1 Gy over 2.5 weeks. RTOG 0938 is a randomised phase II trial that compares the health related side effects of 2 hypofractionation regimens (36.25 Gy delivered twice weekly for a total of 5 treatment sessions (7.25Gy/session) over 15-17 days versus 51.6 Gy delivered in 12 daily treatment sessions (4.3Gy per session) over 16-18 days) for low-risk patients.

**Articles:** The literature search revealed over 200 articles, the majority of which were reviews, description of hypofractionation radiation therapy, or studies that were unrelated to the current review. No randomized controlled trials (RCTs) comparing SBRT to conventional EBRT regimens or low dose brachytherapy for low-risk prostate cancer were identified. The published empirical studies on the use of the technology for prostate cancer were only phase I and phase II feasibility trials conducted in a number of centers in US and overseas. The search also revealed a pooled analysis (King et al, 2013) of the results of the phase II trials conducted in 8 institutions participating in a consortium for prostate SBRT, as well as a number of published systematic reviews (with no meta-analyses) for hypofractionation therapy in general, or SBRT for the treatment of localized prostate cancer. The pooled analysis by King and colleagues, and the larger phase II trials with the longest follow-up duration were selected for critical appraisal: King CR, Brooks JD, Gill H, et al. Long-term outcomes from a prospective trial of stereotactic body radiotherapy for low-risk prostate cancer. Int J Radiat Oncol Biol Phys. 2012; 82:877-882. See Evidence Table 1. King CR, Freeman D, Kaplan I, et al. Stereotactic body radiotherapy for localized prostate cancer: pooled analysis from a multi-institutional consortium of prospective phase II trials. Radiother Oncol. 2013;109:217-221. See Evidence Table 1. King CR, Collins S, Fuller D, et al. Health-related quality of life after stereotactic body radiation therapy for localized prostate cancer: results from a multi-institutional consortium of prospective trials. Int J Radiat Oncol Biol Phys. 2013;87(5):939-45. See Evidence Table 1. Chen LN, Suy S, Uhm S, et al. Stereotactic body radiation therapy (SBRT) for clinically localized prostate cancer: the Georgetown University experience. Radiat Oncol. 2013;8:58.doi: 10.1186/1748-717X-8-58. See Evidence Table 2.


The use of Stereotactic body radiation therapy (SBRT) for Prostate Cancer does not meet the Kaiser Permanente Medical Technology Assessment Criteria.
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