



**Kaiser Foundation Health Plan
of Washington**

**Clinical Review Criteria
Advanced Radiation Therapy Policy**

- Intensity Modulation Therapy (IMRT)
- Stereotactic Radiation (SRS/Radiosurgery/Focused Beam/Gamma Knife)
- Stereotactic Body Radiotherapy (SBRT)

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**Criteria
For Medicare Members**

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	<p>Intensity Modulated Radiation Therapy (IMRT) (L34080) – RETIRED</p> <p>08/01/2020 Noridian retired Intensity Modulated Radiation Therapy (IMRT) (L34080). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L34080 for determining medical necessity.</p> <p>01/15/2021 Noridian retired Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (L34151). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L34151 for determining medical necessity.</p>
Local Coverage Article	<p>Billing and Coding: Intensity Modulated Radiation Therapy (IMRT) (A58245) RETIRED</p> <p>11/01/2023 Noridian retired Billing and Coding: Intensity Modulated Radiation Therapy (IMRT) (A58245). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the</p>

	material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. Therefore, continue to use LCD L34080 and A58245 for determining medical necessity.
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For Non-Medicare Members

Service	Criteria
Intensity Modulation Therapy (IMRT)	<p>Effective until July 1, 2026 Kaiser Permanente has elected to use the Intensity Modulated Radiation Therapy (IMRT) (KP-0455 06012023) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.</p> <p><i>Qty limit for simulation and planning: no more than 2 episodes each</i></p> <p>Effective July 1, 2026 Kaiser Permanente has elected to use the Intensity Modulated Radiation Therapy (IMRT) (KP-0455 07012026) MCG* for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.</p> <p><i>Qty limit for simulation and planning: no more than 2 episodes each</i></p>
Stereotactic Radiation (Radiosurgery/Focused Beam/Gamma Knife) <ul style="list-style-type: none"> • CyberKnife Robotic Radiosurgery System • Fractionated Stereotactic Radiotherapy • Stereotactic Body Radiation Therapy for Prostate Cancer 	<p>Kaiser Permanente has elected to use the Stereotactic Radiosurgery (KP-0423 06012023) MCG* for medical necessity determinations for the following indications*: trigeminal neuralgia, arteriovenous malformation, essential tremor, glomus jugulare tumor, intracranial meningioma, pituitary adenoma, vestibular schwannoma, and tumors of the prostate. This list does not include all indications covered in the criteria. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.</p>
	<p>Multiple Brain Metastatic Lesions (5 or more brain metastatic lesions) 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.</p>
	<p>For solitary lung metastases (from any primary) Send all cases to MD review and possible further radiation oncology consultation</p>

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from oncologist and radiation oncologist

***MCG manuals 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 or access the MCG Guideline Index using the link provided above.

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.

Evidence and Source Documents

[Intensity-Modulated Radiation Therapy \(IMRT\) for Head and Neck Cancer](#)

[Intensity Modulated Radiation Therapy \(IMRT\) for Prostate Cancer](#)

[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](#)

Background

Intensity-Modulated Radiation Therapy (IMRT)

The aim of radical radiotherapy is to deliver a homogenous radiation dose to a tumor target with a minimal dose to surrounding normal tissue. Conventional external beam irradiation (EBRT) has been used to treat prostate cancer for more than thirty years. It partly achieves its goal but leads to irradiation of unnecessarily large volumes of normal tissue. The proximity to the rectum and the bladder has limited the ability to deliver doses > 70Gy to the prostate. This dose may be sufficient for many, but not all prostate cancer cases. The frequent persistence of local residual tumor after EBRT has been a matter of concern. The inability to eradicate some prostate cancers may be related to the lack of tumoricidal doses of radiotherapy on certain resistant clones of tumor cells.

Conformal radiotherapy (CRT) aims at minimizing the volume of normal tissue irradiated by shaping the dose distribution to conform tightly to the shape of the tumor, thus reducing the dose to the normal tissue surrounding it. The three-dimension conformal radiotherapy (3D-CRT) is a further advancement to the 2D dose planning system. It entails direction of multiple beams conformed to the shape of the target from each beam's eye view (BEV). It thus enables a higher degree of certainty of target localization and permits the use of narrow margins around it. Its ultimate goal is to escalate the radiation dose to the target, while maximally excluding the adjacent normal tissue. However, there are situations in which 3D-CRT cannot produce a satisfactory treatment plan because of complex target volume shapes, or close proximity of sensitive normal tissue.

Most recently, an advanced form of 3D-CRT, called intensity modulated radiation therapy (IMRT) was developed to overcome these limitations by adding modulation of beam intensity to beam shaping. In this method intensity modulators, such as multiple leaf collimators (MLC), or beam modifiers are used to divide the treatment beam into a set of small beamlets, the intensity of which vary from 0-100%, independent of all other beamlets. IMRT can achieve any dose distribution, notably an abrupt decrease in the dose at the limit between the tumor volume and the adjacent normal tissue.

The benefits of IMRT will be greatest for patients with tumor targets that are concave, and where normal tissues around it are clinically important. Examples of these are the larynx, pharynx, and thyroid. The main focus for IMRT in the United States has been the prostate, which forms the largest single tumor site treated with IMRT. It is hoped that it will reduce the rectal and bladder doses of irradiation, allow further dose escalation and increase the cure rates.

Special software and computer control systems are necessary to implement IMRT. The planner has to define the anatomical contour of the target volume, the desired dose and the degree of inhomogeneity in the tumor volume. Several target volumes can be distinguished e.g. primary tumor and lymph nodes. The total dose or the dose per session to each target volume can be modulated. IMRT could be used for the whole duration of a radiotherapy treatment, or simply as a boost after more conventional treatment.

Stereotactic Radiation Therapy

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.

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, it 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).

Medical Technology Assessment Committee (MTAC)

Intensity-Modulated Radiation Therapy (IMRT) for Head and Neck Cancer

BACKGROUND

Intensity-modulated radiation therapy (IMRT) is a type of external beam radiation therapy that permits complex three-dimensional shaping of the radiation beams to precisely target the tumor. This allows for a larger dose of radiation to be applied to the tumor site, while minimizing exposure of the surrounding healthy tissue. Instead of a single, uniform beam as in traditional external beam radiation, IMRT involves the delivery of many small beams of varying intensity. Computer algorithms are used to coordinate the beams and plan the delivery of the radiation dose. Compared to other types of external beam radiation, IMRT is best able to generate concave dose distributions. Head and neck cancers may be particularly suited to treatment with IMRT because these tumors often have concave volumes and because head and neck tumors generally require relatively high doses (i.e. 60-70 Gy) of radiation and are in close proximity to critical tissues and organs that are radiation-sensitive (such as the salivary glands, inner and middle ears, temporomandibular joints, temporal brain and optic nerve). Head and neck cancers may also be good candidates for IMRT because of the relative lack of organ motion compared to other areas of the body. Due to the highly focused radiation dose, lack of motion is important. The most prevalent long-term adverse effect with radiation therapy for head and neck cancers is xerostomia (dry mouth) caused by damage to the salivary glands. This adverse effect may be reduced with IMRT. To date, several thousand patients worldwide have received IMRT treatment; so far, most of this has been for the treatment of prostate cancer. Several centers in the U.S. have been providing IMRT for head and neck cancer, most notably Washington University in St. Louis, the University of California, San Francisco (UCSF) and the University of Michigan (Cozzi & Fogliata, 2002). IMRT is a rapidly evolving technology that experienced clinicians believe will continue to evolve in the near future (Eisbruch, 2002).

04/09/2003: MTAC REVIEW**Intensity-Modulated Radiation Therapy (IMRT) for Head and Neck Cancer**

Evidence Conclusion: There is insufficient evidence to determine the effect of IMRT on health outcomes in patients with head and neck cancer compared to other types of radiation therapy. There is only one published comparative study with clinical outcomes, a retrospective cohort study. This study is limited because only 26 patients received IMRT (14 had post-operative IMRT and 12 had definitive IMRT). Although the findings suggest that there is a higher survival rate and lower rate toxicity rate with IMRT compared to other forms of radiation therapy, the statistics are unreliable due to the small number in the IMRT group. (Percentages are generally considered unstable when the sample size is less than 100). In the Lee case series, actuarial 4-year survival estimates were 98% for local-regional progression-free survival and 66% for distant metastasis-free survival. Two years after IMRT, 32% of patients had Grade I xerostomia and only 1 patient had Grade 2 xerostomia. In the Chao case series, the 2-year actuarial survival estimates was 85% for loco-regional control, (89% after salvage surgery). The case series were limited by lack of comparison groups, variable length of follow-up and inconsistent interventions (e.g. three different IMRT techniques were used over time in the Lee study, and in both case series, some patients had chemotherapy). In addition, each included a heterogeneous patient population in terms of cancer location and stage.

Articles: The search yielded 120 articles, many of which were reviews, opinion pieces, dealt with technical aspects of the procedure or addressed treatment planning only. There were no randomized controlled trials comparing clinical outcomes after IMRT versus other forms of radiation therapy. There was one non-randomized comparative clinical study, a retrospective cohort study. The other empirical studies were all case series. The most recent case series from the three major institutions performing IMRT for head and neck cancer (Washington University, UCSF and the University of Michigan) were identified. Two of these institutions had published series of over 50 patients with head and neck cancer who had received IMRT. The comparative study and the two largest case series were critically appraised: Chao KSC, Majhail N, Huang C et al. Intensity-modulated radiation therapy reduces late salivary toxicity without compromising tumor control in patients with oropharyngeal carcinoma: A comparison with conventional techniques. *Radiother Oncol* 2001; 61: 275-280. See [Evidence Table](#)

The use of IMRT in the treatment of head and neck cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

06/01/2004: MTAC REVIEW**Intensity-Modulated Radiation Therapy (IMRT) for Head and Neck Cancer**

Evidence Conclusion: No new randomized or non-randomized comparative studies were identified. There were updates of earlier case series from two of the major institutions performing IMRT for head and neck cancer, UCSF and Washington University. There were also several new small case series. The new literature does not substantially change the conclusions of the April 2003 MTAC review.

Articles: Medline was searched from 2003 to May 2004 using the terms, "intensity-modulated radiation therapy", "IMRT", and "head and neck cancer", with variations. The search was limited to English language publication and human populations. No new randomized or non-randomized comparative studies were identified. There were updates of earlier case series from two of the major institutions performing IMRT for head and neck cancer, UCSF and Washington University. There were also several new small case series. Lee N, Xia P, Quivey JM. Intensity-modulated radiotherapy in the treatment of nasopharyngeal carcinoma: An update of the UCSF experience. *Int J Radiation Oncology Biol Phys* 2002; 53: 12-22. See [Evidence Table](#) Chao KSC, Ozyigit G, Tran BN et al. Patterns of failure in patients receiving definitive and postoperative IMRT for head-and-neck cancer. *Int J Radiation Oncology Biol Phys* 2003; 55: 312-321. See [Evidence Table](#)

The use of IMRT in the treatment of head and neck cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Intensity Modulated Radiation Therapy (IMRT) for Prostate Cancer**BACKGROUND**

The aim of radical radiotherapy is to deliver a homogenous radiation dose to a tumor target with a minimal dose to surrounding normal tissue. Conventional external beam irradiation (EBRT) has been used to treat prostate cancer for more than thirty years. It partly achieves this goal but may lead to irradiation of unnecessarily large volumes of normal tissue. The proximity to the rectum and the bladder has limited the ability to deliver doses > 70 Gy to the prostate. This dose may be sufficient for many but not all prostate cancer cases. The frequent persistence of local residual tumor after EBRT has been a matter of concern. The inability to eradicate some prostate cancers may be related to the lack of tumoricidal doses of radiotherapy on certain resistant clones of tumor cells. Conformal radiotherapy (CRT) aims at minimizing the volume of normal tissue irradiated by shaping the dose distribution to conform tightly to the shape of the tumor, thus reducing the dose to the normal tissue surrounding it. The three-

dimension conformal radiotherapy (3D-CRT), is a further advancement to the 2D dose planning system. It entails direction of multiple beams conformed to the shape of the target from each beam's eye view (BEV). It thus enables a higher degree of certainty of target localization and permits the use of narrow margins around it. Its ultimate goal is to escalate the radiation dose to the target, while maximally excluding the adjacent normal tissue. However, there are situations in which 3D-CRT cannot produce a satisfactory treatment plan because of complex target volume shapes, or close proximity of sensitive normal tissue. Most recently, an advanced form of 3D-CRT, called intensity modulated radiation therapy (IMRT) was developed to overcome these limitations by adding modulation of beam intensity to beam shaping. In this method intensity modulators, such as multiple leaf collimators (MLC), or beam modifiers are used to divide the treatment beam into a set of small beamlets, the intensity of which vary from 0-100%, independent of all other beamlets. IMRT can achieve any dose distribution, notably an abrupt decrease in the dose at the limit between the tumor volume and the adjacent normal tissue. The benefits of IMRT will be greatest for patients with tumor targets that are concave, and where normal tissues around it are clinically important. Examples of these are the larynx, pharynx, and thyroid. The main focus for IMRT in the United States has been the prostate, which forms the largest single tumor site treated with IMRT. It is hoped that it will reduce the rectal and bladder doses of irradiation, allow further dose escalation and increase the cure rates. Special software and computer control systems are necessary to implement IMRT. The planner has to define the anatomical contour of the target volume, the desired dose and the degree of homogeneity in the tumor volume. Several target volumes can be distinguished e.g. primary tumor and lymph nodes. The total dose or the dose per session to each target volume can be modulated. IMRT could be used for the whole duration of a radiotherapy treatment, or simply as a boost after more conventional treatment. IMRT for prostate cancer was previously reviewed by MTAC in April, 2002. At that time, the evidence consisted of case series on the toxicity of IMRT and the item failed MTAC evaluation criteria.

4/10/02: MTAC REVIEW

Intensity Modulated Radiation Therapy (IMRT) for Prostate Cancer

Evidence Conclusion: The studies reviewed aimed at determining the toxicity of the high-dose radiation delivered by IMRT. In both studies IMRT was not compared to a low dose conventional treatment, instead it was compared to 3D-CRT, which also uses a high dose irradiation, yet not modulated. Compared to 3D-CRT, IMRT was found to cause significantly lower acute, and late rectal toxicity in Zelefsky's study, and significantly higher acute rectal toxicity in the Shu study. In the two studies reviewed, there was no significant difference between the two treatments in the acute or late bladder toxicity. Both studies were not randomized and non-blinded, there were some variations in the base-line characteristics in the treatment groups, and no adjustments were made for confounding factors. Randomized controlled studies with long-term follow-up are needed to study the effect of IMRT on the outcome of the cancer, as well as the morbidity from the radiation.

Articles: The search yielded 55 articles most of which were reviews, case reports, editorials, and letters. The literature did not reveal any randomized controlled studies or meta-analyses.

It also did not reveal any study on the effect of IMRT on the outcome of the prostate cancer. There were 2 articles on studies made to determine the toxicity of IMRT, and compare it to 3D-CRT. *The following articles were critically appraised:* Zelefsky MJ, et al. Clinical experience with intensity modulated radiation therapy (IMRT) in prostate cancer. *Radiotherapy and Oncology* 2000;55:241-9. See [Evidence Table](#) Shu H G, et al. Toxicity following high-dose three-dimensional conformal and intensity modulated radiation therapy for clinically localized prostate cancer. *Urology* 2001;57:102-7. See [Evidence Table](#)

The use of intensity modulated radiation in the treatment of prostate cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

2/11/04: MTAC REVIEW

Intensity Modulated Radiation Therapy (IMRT) for Prostate Cancer

Evidence Conclusion: The evidence is limited by the lack of randomized controlled trials, comparison only to 3D-CRT rather than lower-dose standard radiotherapy, inconsistent length of follow-up, lack of actual survival data and potential confounding by androgen deprivation therapy in a substantial proportion of patients. Both studies reported on biochemical survival rates. Three-year actuarial PSA relapse-free survival varied from 81-92% in the Zelefsky study and thirty-month actuarial PSA relapse-free survival was 94% for IMRT and 88% for 3D-CRT (non-significant difference) in the Kuplian study. Change in PSA level is an intermediate outcome and may not be an accurate measure of prognosis. There appeared to be relatively low rates of serious late toxicity, but many patients were not followed up long enough to contribute to this analysis. In the Zelefsky study, 9 of the patients followed for a sufficiently long time (1%) developed grade 3 late toxicity. In the Kuplian study, actuarial grade 3 late rectal toxicity at 30 months was 2% in the IMRT group and 8% in the 3D-CRT group. The evidence is limited by the lack of randomized controlled trials, comparison only to 3D-CRT rather than lower-dose standard radiotherapy, inconsistent length of follow-up, lack of actual survival data and potential confounding by androgen deprivation therapy in a substantial proportion of patients. Both studies reported on biochemical survival rates.

Three-year actuarial PSA relapse-free survival varied from 81-92% in the Zelefsky study and thirty-month actuarial PSA relapse-free survival was 94% for IMRT and 88% for 3D-CRT (non-significant difference) in the Kuplian study. Change in PSA level is an intermediate outcome and may not be an accurate measure of prognosis. There appeared to be relatively low rates of serious late toxicity, but many patients were not followed up long enough to contribute to this analysis. In the Zelefsky study, 9 of the patients followed for a sufficiently long time (1%) developed grade 3 late toxicity. In the Kuplian study, actuarial grade 3 late rectal toxicity at 30 months was 2% in the IMRT group and 8% in the 3D-CRT group.

Articles: The search yielded 102 articles, many of which were reviews, opinion pieces, dealt with technical aspects of the procedures or were on related procedures. There were no randomized controlled trials. There were three new case series publications by the Memorial Sloan-Kettering Cancer Center research group (led by Zelefsky). The patients included in the three publications overlapped. Two of the articles also included patients who were treated with 3D-CRT, but IMRT and 3D-CRT were not compared in analysis. The Zelefsky case series with the largest number of IMRT cases was critically appraised. In addition, there was a study conducted at the Cleveland Clinic which compared series of patients treated with short-course IMRT and 3D-CRT. There were no studies comparing IMRT to lower dose conventional radiotherapy. *The studies reviewed were:* Zelefsky MJ, Fuks Z, Hunt M et al. High-dose intensity modulated radiation therapy for prostate cancer: Early toxicity and biochemical outcome in 772 patients. *Int J Radiation Oncology Biol Phys* 2002; 53: 1111-1116. See [Evidence Table](#) Kuplian PA, Reddy CA, Carlson TP. et al. Preliminary observations on biochemical relapse-free survival rates after short-course intensity-modulated radiotherapy (70Gy at 2.5Gy/Fraction) for localized prostate cancer. *Int J Radiation Oncology Biol Phys* 2002; 53: 904-912. See [Evidence Table](#).

The use of intensity modulated radiation in the treatment of prostate cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

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. Gamma knife 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.

Articles: The search yielded 71 articles. There were no meta-analyses or randomized control trials on CyberKnife robotic surgery. There were several small case reports and series that dealt with the technology for the treatment of several lesions in different parts of the body including pituitary tumors, extracranial lesions, metastatic brain tumors, acoustic neuromas, trigeminal neuralgia, spinal lesions, lung, renal, and prostate cancer. Gerstzen et al, published two articles on the same series of patients. The largest and most comprehensive case series, and/or the series with long-term follow-up were selected for critical appraisal. Chang SD, Gibbs IC, Sakamoto GT. Staged stereotactic irradiation for acoustic neuromas. *Neurosurgery*. 2005; 56:1245-1263. See [Evidence Table](#). Gerszten PC, Ozhasoglu C, Burton SA, et al. Evaluation of CyberKnife frameless real-time image-guided stereotactic radiosurgery for spinal lesions. *Stereotact Funct Neurosurg*. 2003; 81:84-89. See [Evidence Table](#). Gerszten PC, Ozhasoglu C, Burton SA, et al. CyberKnife frameless stereotactic radiosurgery for spinal lesions: Clinical experience in 125 cases. *Neurosurgery*. 2004; 55:89-99. See [Evidence Table](#).

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: 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 (JLKG0901): 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 1999, Freeman 2011, McBride 2012, Bolzicco 2013, Cabrera 2013, Katz 2013, Oliai 2013, Mangoni 2014, Tan 2014). Hypofractionation may be defined as moderate (2.4-4 Gy per fraction) or extreme (6.5-10 Gy per fraction). Extreme hypofractionation with high-dose-rate brachytherapy (HDR-BT) has been used in some centers for the treatment of prostate cancer, either as a monotherapy or in combination with EBRT. HDR-BT therapy, however, is not widely adopted due to its relatively invasive nature, need for hospitalization, anesthesia, resources, and technical expertise for the planning and delivery of therapy. It also requires prolonged bed rest that increases the risk of infection and thromboembolism (Jabbari 2012, Fukudo 2014, Koh 2014). Stereotactic radiation therapy refers to non-surgical techniques that deliver precisely-targeted (within a few millimeters) external beam photon radiotherapy. Stereotactic techniques are often used to deliver much higher doses per treatment (in only a single or few treatments), compared to traditional radiation therapy. Stereotactic radiosurgery (SRS) was initially developed to treat small brain tumors and functional abnormalities of the brain. Stereotactic body radiotherapy (SBRT) has recently emerged, and is highly marketed, as a non-invasive alternative to HDR-BT for delivering hypofractionated radiotherapy to the prostate. The term 'stereotactic' means precise positioning of the target within three-dimensional space, and the term 'body' is used to distinguish the technique from the current terminology of SRS used for brain tumors. SRS and SBRT rely on several technologies: 1. Three-dimensional imaging and localization techniques that determine the exact coordinates of the target within the body, 2. Systems to immobilize and carefully position the patient and maintain it during therapy, 3. Highly focused gamma-ray or x-ray beams that converge on a tumor or abnormality, and 4. Image-guided radiation therapy to improve the precision and accuracy of the treatment (Freeman 2011, Radiology Info.org, Aneja 2014, Tan 2014). SBRT for prostate cancer delivers the entire course of therapy in 4-5 visits over 2-2.5 weeks, compared with up to 45 fractions over 9 weeks with conventional fractionation. Thus, it may be more convenient to patients, potentially improve their adherence to therapy, reduce staff and machine burden, and according to a number of analyses (based on modeling), may be less costly than EBRT. However, the use of SBRT for prostate cancer is an area of controversy in the radiation oncology community and is still regarded by many as an experimental treatment. The mechanism of cell kill with large hypofractionated doses is not fully understood in vivo, and many radiation oncologists have concerns over the potential toxicity of the very high ablative doses delivered per fraction, as well as the risk of disease recurrence (Hodges 2012, Parthan 2012, Cabrera 2013, Seison 2013, Tan 2014). CyberKnife® (Accuray Incorporated, Sunnyvale, CA) is one of the devices used for delivering SBRT. It is a non-gantry-based frameless robotic stereotactic radiation delivery system that consists of a 6MV linear accelerator mounted on a robotic arm, with two orthogonal X-ray imagers to track the inserted gold fiducial markers (GFM) and perform real-time corrections for target repositioning during treatment. CyberKnife delivers hundreds of individualized circular beams with a targeting error of less than 1 mm, allowing the safe delivery of highly conformal treatment plans. To date, CyberKnife has been used to treat tumors of the head and neck, lung, kidney, liver, pancreas, and prostate. The CyberKnife SBRT treatment protocol has two principal phases; treatment planning and treatment delivery. The treatment planning phase involves the implanting of three to four gold fiducial markers (GFMs) in the apex, intermediate lateral zone, and base of the prostate using TRUS for image guided positioning and motion tracking, followed by treatment planning using CT to differentiate the prostate and proximal seminal vesicles from the surrounding tissue. Treatment is then delivered to the prostate by the CyberKnife system in four or five fractions to a total of 34 -39 Gy, given on consecutive or alternating days, according to the study protocol (Freeman 2011, Chen 2013, Seisen 2013). CyberKnife was previously reviewed by MTAC in 2006 for the treatment of lesions or tumors in any anatomical site and did not meet MTAC evaluation criteria. The current review is limited to the use of CyberKnife SBRT for the treatment of prostate cancer, based on a request for coverage of the technology.

10/20/2014: MTAC REVIEW**Stereotactic Body Radiation Therapy (SBRT)**

Evidence 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](#)

Katz AJ, Santoro M, Diblasio F, et al. Stereotactic body radiotherapy for localized prostate cancer: disease control and quality of life at 6 years. *Radiat Oncol.* 2013;8: 118.doi: 10.1186/1748-717X-8-118. See [Evidence Table 2](#). Oliari C, Lanciano R, Sprandio B et al. Stereotactic body radiation therapy for the primary treatment of localized prostate cancer. *J Radiat Oncol.* 2013; 2:63-70. 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*.

Applicable Codes**Intensity Modulation Therapy (IMRT)**

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
77301	Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications
77338	Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan
77385	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple
77386	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex

77387	Guidance for localization of target volume for delivery of radiation treatment, includes intrafraction tracking, when performed
HCPC Codes	Description
G6015	Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session
G6016	Compensator-based beam modulation treatment delivery of inverse planned treatment using three or more high resolution (milled or cast) compensator, convergent beam modulated fields, per treatment session
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

Stereotactic Radiosurgery

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
61796	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 simple cranial lesion
61797	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional cranial lesion, simple (List separately in addition to code for primary procedure)
61798	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 complex cranial lesion
61799	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional cranial lesion, complex (List separately in addition to code for primary procedure)
61800	Application of stereotactic headframe for stereotactic radiosurgery (List separately in addition to code for primary procedure)
61781	Stereotactic computer-assisted (navigational) procedure; cranial, intradural (List separately in addition to code for primary procedure)
61782	Stereotactic computer-assisted (navigational) procedure; cranial, extradural (List separately in addition to code for primary procedure)
61783	Stereotactic computer-assisted (navigational) procedure; spinal (List separately in addition to code for primary procedure)
63620	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 spinal lesion
63621	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional spinal lesion (List separately in addition to code for primary procedure)
32701	Thoracic target(s) delineation for stereotactic body radiation therapy (SRS/SBRT), (photon or particle beam), entire course of treatment
77301	Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications
77371	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source Cobalt 60 based
77372	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based
77373	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions
77432	Stereotactic radiation treatment management of cranial lesion(s) (complete course of treatment consisting of 1 session)
77435	Stereotactic body radiation therapy, treatment management, per treatment course, to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions
G0339	Image guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment
G0340	Image guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course 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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Date Created	Date Reviewed	Date Last Revised
05/22/2003	07/02/2013 ^{MPC} , 05/06/2014 ^{MPC} , 03/03/2015 ^{MPC} , 07/07/2015 ^{MPC} , 01/05/2016 ^{MPC} , 11/01/2016 ^{MPC} , 09/05/2017 ^{MPC} , 07/10/2018 ^{MPC} , 07/09/2019 ^{MPC} , 07/07/2020 ^{MPC} , 07/06/2021 ^{MPC} , 07/05/2022 ^{MPC} , 07/11/2023 ^{MPC} , 04/02/2024 ^{MPC} , 04/01/2025 ^{MPC}	02/03/2026

Revision History	Description
4/28/2020	Added list of covered indications from KP-0423 criteria as clarification for searching
07/07/2020	Added Medicare LCA (A57231); removed deleted CPT code 77418
03/02/2021	MPC approved to expand coverage to the IMRT criteria by including additional indications for coverage which include Cholangiocarcinoma, Gallbladder carcinoma, Gastric cancer, Hepatocellular carcinoma, Liver metastases, Lymphoma with mediastinal involvement, in proximity to lung and heart, Pancreatic cancer; Breast Cancer will still require MD review. Requires 60-day notice, effective date 08/01/2021.
03/09/2021	Updated criteria to include clarifying language: <i>For cognitive sparing, an alternative consideration could be whole brain radiation therapy with hippocampal sparing and memantine.</i>
01/10/2023	MPC approved to adopt the revised changes the IMRT criteria to include indications for Breast Cancer (APBI). Requires 60-day notice effective 06/01/2023.
01/10/2023	MPC approved to adopt the revised changes to the SRS criteria to include indications for brain metastasis. Requires 60-day notice effective 06/01/2023.
04/03/2023	Updated applicable codes
02/03/2026	MPC approved the proposed update to the IMRT medical policy which includes adoption of the MCG 29th edition. 60-day notice required, effective 07/01/2026.
02/03/2026	Merged policies: IMRT, SRS and SBRT