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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Intensity Modulated Radiation Therapy (IMRT)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Intensity Modulated Radiation Therapy (IMRT) (L34080) – **RETIRED** 08/01/2020 Noridian 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.
Local Coverage Article	Billing and Coding: Intensity Modulated Radiation Therapy (IMRT) (A58245)

For Non-Medicare Members

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.

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.

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Evidence and Source Documents

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

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

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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

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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
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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.*

Applicable Codes

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

***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]	01/10/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
07/07/2015	MPC approved to reinstate IMRT criteria for medical necessity review. New criteria effective date 11/2015.
09/08/2015	Revised LCD Intensity Modulated Radiation Therapy (IMRT) L34251 and L34080
03/01/2016	Added indication to policy
11/01/2016	MPC approved revised indication for lung cancer
12/05/2017	MPC approved new indication for esophageal cancer
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.
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.

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