Title: Intensity Modulated Radiotherapy (IMRT)

See also: Stereotactic Radiosurgery and Stereotactic Radiotherapy Body

PRE-DETERMINATION of services for FEP is required effective January 1, 2010.


State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member’s benefits, contact Blue Cross and Blue Shield of Kansas Customer Service.

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The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

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DESCRIPTION
Radiotherapy (RT) is an integral component in the treatment of many cancers. Intensity-modulated radiotherapy (IMRT) has been proposed as a method of external beam radiotherapy that delivers adequate radiation to the tumor while minimizing the radiation dose to surrounding normal tissues and critical structures.
OBJECTIVE
The objective of this policy is to determine whether the use of intensity-modulated radiotherapy improves the net health outcome when used to treat certain cancers.

BACKGROUND
For certain stages of many cancers, randomized controlled trials have shown that postoperative RT improves outcomes for operable patients. Adding radiation to chemotherapy also improves outcomes for those with inoperable tumors that have not metastasized beyond regional lymph nodes.

Radiotherapy Techniques
Conventional External-Beam Radiation Therapy
Methods to plan and deliver radiation therapy have evolved in ways that permit more precise targeting of tumors with complex geometries. Most early trials used 2-dimensional treatment planning, based on flat images and radiation beams with cross-sections of uniform intensity that were sequentially aimed at the tumor along 2 or 3 intersecting axes. Collectively, these methods are termed conventional external beam radiation therapy.

Three-Dimensional Conformal Radiotherapy
Treatment planning evolved by using 3-dimensional images, usually from computed tomography (CT) scans, to delineate the boundaries of the tumor and discriminate tumor tissue from adjacent normal tissue and nearby organs at risk for radiation damage. Computer algorithms were developed to estimate cumulative radiation dose delivered to each volume of interest by summing the contribution from each shaped beam. Methods also were developed to position the patient and the radiation portal reproducibly for each fraction and immobilize the patient, thus maintaining consistent beam axes across treatment sessions. Collectively, these methods are termed 3-dimensional conformal radiation therapy (3D-CRT).

Intensity-Modulated Radiotherapy
Intensity-modulated radiotherapy (IMRT), which uses computer software, CT images, and magnetic resonance imaging (MRI), offers better conformality than 3D-CRT as it is able to modulate the intensity of the overlapping radiation beams projected on the target and to use multiple-shaped treatment fields. Treatment planning and delivery are more complex, time-consuming, and labor intensive for IMRT than for 3D-CRT. The technique uses a multileaf collimator (MLC), which, when coupled with a computer algorithm, allows for “inverse” treatment planning. The radiation oncologist delineates the target on each slice of a CT scan and specifies the target’s prescribed radiation dose, acceptable limits of dose heterogeneity within the target volume, adjacent normal tissue volumes to avoid, and acceptable dose limits within the normal tissues. Based on these parameters and a digitally reconstructed radiographic image of the tumor, surrounding tissues, and organs at risk, computer software optimizes the location, shape, and intensities of the beams ports to achieve the treatment plan’s goals.
Increased conformality may permit escalated tumor doses without increasing normal tissue toxicity and thus may improve local tumor control, with decreased exposure to surrounding normal tissues, potentially reducing acute and late radiation toxicities. Better dose homogeneity within the target may also improve local tumor control by avoiding underdosing within the tumor and may decrease toxicity by avoiding overdosing.

Technologic development has produced advanced techniques that may further improve RT treatment by improving dose distribution. These techniques are considered variations of IMRT. Volumetric modulated arc therapy (VMAT) delivers radiation from a continuous rotation of the radiation source. The principal advantage of VMAT is greater efficiency in treatment delivery time, reducing radiation exposure and improving target radiation delivery due to less patient motion. Image-guided RT involves the incorporation of imaging before and/or during treatment to more precisely deliver RT to the target volume.

IMRT methods to plan and deliver RT are not uniform. IMRT may use beams that remain on as MLCs move around the patient (dynamic MLC) or that are off during movement and turn on once the MLC reaches prespecified positions (“step and shoot” technique). A third alternative uses a very narrow single beam that moves spirally around the patient (tomotherapy). Each method uses different computer algorithms to plan treatment and yields somewhat different dose distributions in and outside the target. Patient position can alter target shape and thus affect treatment plans. Treatment plans are usually based on 1 imaging scan, a static 3D-CT image. Current methods seek to reduce positional uncertainty for tumors and adjacent normal tissues by various techniques. Patient immobilization cradles and skin or bony markers are used to minimize day-to-day variability in patient positioning. In addition, many tumors have irregular edges that preclude drawing tight margins on CT scan slices when radiation oncologists contour the tumor volume. It is unknown whether omitting some tumor cells or including some normal cells in the resulting target affects outcomes of IMRT.

Investigators are exploring an active breathing control device combined with moderately deep inspiration breath-holding techniques to improve conformality and dose distributions during IMRT for breast cancer.¹ Techniques presently being studied with other tumors (eg, lung cancer)² either gate beam delivery to the patient’s respiratory movement or continuously monitor tumor (by in-room imaging) or marker (internal or surface) positions to aim radiation more accurately at the target. The impact of these techniques on outcomes of 3D-CRT or IMRT for breast cancer is unknown. However, it appears likely that respiratory motion alters the dose distributions actually delivered while treating patients from those predicted by plans based on static CT scans, or measured by dosimetry using stationary (nonbreathing) targets.
Note the evidence for the following abdominal and pelvic cancers has not yet been reviewed and is beyond the scope of this document: bladder, kidney, ureter, and esophageal cancer and sarcoma.

**REGULATORY STATUS**

In general, IMRT systems include intensity modulators, which control, block, or filter the intensity of radiation; and RT planning systems, which plan the radiation dose to be delivered.

A number of intensity modulators have received marketing clearance through the U.S. Food and Drug Administration (FDA) 510(k) process. Intensity modulators include the Innocure Intensity Modulating Radiation Therapy Compensators (Innocure) and decimal tissue compensator (Southeastern Radiation Products) cleared in 2006. FDA product code: IXI. Intensity modulators may be added to standard linear accelerators to deliver IMRT when used with proper treatment planning systems.

RT planning systems have also been cleared for marketing by FDA through the 510(k) process. These include the Prowess Panther™ (Prowess) in 2003, TiGRT (LinaTech) in 2009, the RayDose (RaySearch Laboratories) in 2008, and the eIMRT Calculator (Standard Imaging). FDA product code: MUJ.

Fully integrated IMRT systems are also available. These devices are customizable and support all stages of IMRT delivery, including planning, treatment delivery, and health record management. One such device to receive FDA 510(k) clearance is the Varian IMRT system (Varian Medical Systems). FDA product code: IYE.
POLICY

I. IMRT is considered **medically necessary** for the following indications:

A. **Prostate cancer**
   1. As definitive treatment for non-metastatic and appropriate oligometastatic cases of prostate cancer using standard fractionation or equivalent hypofractionated schedules (e.g., 7920 cGy in 44 fractions, 7800 cGy in 39 fractions, 7000 cGy in 28 fractions, 6000 cGy in 20 fractions).
   2. As adjuvant or salvage radiation therapy with curative intent for men who are post-prostatectomy, with biochemical failure, and without distant metastasis when >64 Gy in standard fractionation or equivalent hypofractionation will be given.

B. **Head and neck cancer**, with the exception of patients with early stage laryngeal cancer (stage I and II).

C. **Cancer involving the CNS.**

D. **Carcinoma of the anus or vulva.**

E. **Anaplastic thyroid cancer.**

F. **Carcinoma of the cervix.**

G. **Whole pelvic radiotherapy for gynecologic malignancies.**

H. **Pediatric tumors** (e.g., Ewing’s sarcoma, Wilms’ tumor).

I. **Breast cancer**, when at least one of the following is met:
   1. Heart—3D results in ≥25 % of heart receiving ≥ 30Gy; OR
   2. Lung—3D results in ≥30% of ipsilateral lung receiving ≥20 Gy, OR 3D results in ≥20% of combined lung volume receiving ≥20Gy; OR
   3. Skin / Soft Tissue—3D results in ≥5% of intended breast receiving ≥7% of prescribed dose OR Medial lesion where 3D results in ≥10% of contralateral breast receiving ≥10Gy.

J. **Esophagus, Stomach, Pancreas, Hepatobiliary Tract, Rectum, Colon, Small Bowel**, when at least one of the following is met:
   1. Heart—3D result in ≥50% of heart receiving ≥30 Gy, OR
2. Lung—3D results in ≥30% of combined lung volume receiving ≥20 Gy,
   OR
   Mean lung dose ≥20 Gy;
   OR
3. Spinal Cord—3D result in any portion of the spinal cord receiving a dose above 45 Gy;
   OR
4. Liver—3D results in ≥60% of liver volume receiving ≥30 Gy,
   OR
   Mean liver dose ≥32 Gy;
   OR
5. Kidney—3D results in ≥33% of combined kidney volume receiving ≥20 Gy (two functional kidneys are present);
   OR
   For one functioning kidney or kidney transplant, IMRT provides a lower dose than achievable with 3D;
   OR
6. Small Intestine—3D results in ≥195 cc of small intestine receiving ≥45 Gy;
   OR
7. Stomach—3D results in ≥10% of stomach receiving ≥45 Gy
   OR
   5% receiving ≥50 Gy;
   OR
8. Femoral head—3D results in a femoral head receiving ≥45 Gy.

K. Lung, when at least one of the following is met:
   1. Heart—3D results in ≥50% of heart receiving ≥30 Gy;
   OR
   2. Lung—3D result in ≥30% of non-cancerous combined lung volume receiving ≥20 Gy

L. Lymphomas or Sarcomas of Retroperitoneum, Chest Wall and Thorax, when at least one of the following is met:
   1. Heart—3D results in ≥50% of heart receiving ≥30 Gy;
   OR
   2. Lung—3D results in ≥30% of combined lung volume receiving ≥20 Gy
   OR
   Mean lung dose of ≥20 Gy;
   OR
   3. Spinal cord—3D results in any portion of the spinal cord receiving a dose above 45 Gy
   OR
   4. Liver—3D results in 60% of liver volume receiving ≥30 Gy
OR
Mean liver dose ≥32 Gy;

OR
5. Femoral head—3D results in a femoral head receiving ≥45 Gy;

OR
6. Small intestine—3D results in ≥195 cc of small intestine receiving ≥45 Gy;

OR
7. Stomach—3D results in ≥10% of stomach receiving ≥45 Gy

OR 5% receiving ≥50 Gy;

OR
8. Rectosigmoid—3D results in ≥60% of rectosigmoid area receiving ≥30 Gy;

OR
9. Bladder—3D results in ≥35% of bladder receiving ≥45 Gy;

OR
10. Kidney—3D results in 33% of combined kidney volume receiving ≥20 Gy (two functional kidneys are present)

OR
For one functioning kidney or kidney transplant IMRT provides a lower dose than achievable with 3D.

M. Sarcomas of the Extremities, when at least one of the following is met:
1. Head / Neck—IMRT covered if head and neck structures would receive any radiation via 3D;

OR
2. Femur—3D results in ≥50% of contiguous femur cortex receiving ≥50 Gy

N. Individuals who require repeat irradiation of a field that has received prior irradiation.

O. Radiosensitive tumors where critical structures cannot be adequately protected with standard 3D conformal radiotherapy. Medical necessity for the use of IMRT for these other indications will be considered individually and will require supporting records from the treating radiation oncologist including the 3-D dose volume histogram documenting the need for IMRT.

The American Society for Therapeutic Radiology and Oncology (ASTRO) has a model policy which describes the indications for IMRT:

“IMRT is considered reasonable and necessary in instances where sparing the surrounding normal tissue is of added benefit to the patient. Examples of reasons why IMRT might be advantageous include the following:
1. The target volume is in close proximity to one or more critical structures and a steep dose gradient outside the target must be achieved and avoid exceeding the tolerance dose to the critical structure(s).
2. A decrease in the amount of dose inhomogeneity in a large treatment volume is required to avoid an excessive dose "hotspot" within the treated volume to avoid excessive early or late normal tissue toxicity.
3. A non-IMRT technique would substantially increase the probability of clinically meaningful normal tissue toxicity.
4. The same or an immediately adjacent area has been previously irradiated, and the dose distribution within the patient must be sculpted to avoid exceeding the cumulative tolerance dose of nearby normal tissue."

II. Other applications of IMRT are considered not medically necessary.

DOCUMENTATION
A. As recommended by ASTRO, the IMRT treatment record must support:
   1. The reasonable and necessary requirements as outlined in the Policy section.
   2. The prescription which defines the goals and requirements of the treatment plan, including the specific dose constraints to the target and nearby critical structures.
   3. A note of medical necessity for IMRT by the treating physician.
   4. Signed IMRT inverse plan that meets prescribed dose constraints for the planning target volume (PTV) and surrounding normal tissue.
   5. The target verification methodology must include the following:
      a. Documentation of the clinical treatment volume (CTV) and the planning target volume (PTV).
      b. Documentation of immobilization and patient positioning.
   6. Independent basic dose calculations of monitor units have been performed for each beam before the patient's first treatment.
   7. Documentation of fluence distributions (re-computed and measured in a phantom or dosimetry measuring device) is required.
   8. Documentation supporting identification of structures that transverse high- and low-dose regions created by respiration is indicated when billing for respiratory motion management stimulation.

NOTE: Comparison 3D-CRT dose volume histogram (DVH) in color
CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

77300 Basic radiation dosimetry calculation, central axis depth dose calculation, TDF, NSD, gap calculation, off axis factor, tissue inhomogeneity factors, calculation of non-ionizing radiation surface and depth dose, as required during course of treatment, only when prescribed by the treating physician

77301 Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications

77332 Treatment devices, design and construction; simple (simple block, simple bolus)

77333 Treatment devices, design and construction; intermediate (multiple blocks, stents, bite blocks, special bolus)

77334 Treatment devices, design and construction; complex (irregular blocks, special shields, compensators, wedges, molds or casts)

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

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 3 or more high resolution (milled or cast) compensator, convergent beam modulated fields, per treatment session

- The following CPT codes are used for simple and complex IMRT delivery: 77385, 77386.
- The following codes may be used for IMRT: G6015, G6016.
- Code 77301 remains valid.
- The following CPT code may also be used: 77338.

ICD-10 Diagnoses

C00.0 Malignant neoplasm of external upper lip
C00.1 Malignant neoplasm of external lower lip
C00.3 Malignant neoplasm of upper lip, inner aspect
C00.4 Malignant neoplasm of lower lip, inner aspect
C00.8 Malignant neoplasm of overlapping sites of lip
C01 Malignant neoplasm of base of tongue
C02.0 Malignant neoplasm of dorsal surface of tongue
C02.1 Malignant neoplasm of border of tongue
C02.2 Malignant neoplasm of ventral surface of tongue
C02.3 Malignant neoplasm of anterior two-thirds of tongue, part unspecified
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<td>Malignant neoplasm of anterior floor of mouth</td>
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<td>Malignant neoplasm of lateral floor of mouth</td>
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<td>Malignant neoplasm of overlapping sites of floor of mouth</td>
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<td>Malignant neoplasm of soft palate</td>
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<td>Malignant neoplasm of cheek mucosa</td>
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<td>Malignant neoplasm of vestibule of mouth</td>
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<td>C44.212</td>
<td>Basal cell carcinoma of skin of right ear and external auricular canal</td>
</tr>
<tr>
<td>C44.219</td>
<td>Basal cell carcinoma of skin of left ear and external auricular canal</td>
</tr>
<tr>
<td>C44.222</td>
<td>Squamous cell carcinoma of skin of right ear and external auricular canal</td>
</tr>
</tbody>
</table>
C44.229 Squamous cell carcinoma of skin of left ear and external auricular canal
C44.292 Other specified malignant neoplasm of skin of right ear and external auricular canal
C44.299 Other specified malignant neoplasm of skin of left ear and external auricular canal
C44.301 Unspecified malignant neoplasm of skin of nose
C44.309 Unspecified malignant neoplasm of skin of other parts of face
C44.311 Basal cell carcinoma of skin of nose
C44.319 Basal cell carcinoma of skin of other parts of face
C44.321 Squamous cell carcinoma of skin of nose
C44.329 Squamous cell carcinoma of skin of other parts of face
C44.391 Other specified malignant neoplasm of skin of nose
C44.399 Other specified malignant neoplasm of skin of other parts of face
C44.40 Basal cell carcinoma of skin of scalp and neck
C44.41 Squamous cell carcinoma of skin of scalp and neck
C44.42 Other specified malignant neoplasm of skin of scalp and neck
C44.49 Malignant neoplasm of peripheral nerves of head, face and neck
C47.0 Malignant neoplasm of connective and soft tissue of head, face and neck
C51.0 Malignant neoplasm of labium majus
C51.1 Malignant neoplasm of labium minus
C51.2 Malignant neoplasm of clitoris
C51.8 Malignant neoplasm of overlapping sites of vulva
C51.9 Malignant neoplasm of vulva, unspecified
C52 Malignant neoplasm of vagina
C53.0 Malignant neoplasm of endocervix
C53.1 Malignant neoplasm of exocervix
C53.8 Malignant neoplasm of overlapping sites of cervix uteri
C53.9 Malignant neoplasm of cervix uteri, unspecified
C54.0 Malignant neoplasm of isthmus uteri
C54.1 Malignant neoplasm of endometrium
C54.2 Malignant neoplasm of myometrium
C54.3 Malignant neoplasm of fundus uteri
C54.8 Malignant neoplasm of overlapping sites of corpus uteri
C54.9 Malignant neoplasm of corpus uteri, unspecified
C56.1 Malignant neoplasm of right ovary
C56.2 Malignant neoplasm of left ovary
C57.01 Malignant neoplasm of right fallopian tube
C57.02 Malignant neoplasm of left fallopian tube
C57.11 Malignant neoplasm of right broad ligament
C57.12 Malignant neoplasm of left broad ligament
C57.21 Malignant neoplasm of right round ligament
C57.22 Malignant neoplasm of left round ligament
C57.3 Malignant neoplasm of parametrium
C57.4 Malignant neoplasm of uterine adnexa, unspecified
C57.7 Malignant neoplasm of other specified female genital organs
C57.8 Malignant neoplasm of overlapping sites of female genital organs
C58 Malignant neoplasm of placenta
C61 Malignant neoplasm of prostate
C69.01 Malignant neoplasm of right conjunctiva
C69.02  Malignant neoplasm of left conjunctiva
C69.11  Malignant neoplasm of right cornea
C69.12  Malignant neoplasm of left cornea
C69.21  Malignant neoplasm of right retina
C69.22  Malignant neoplasm of left retina
C69.31  Malignant neoplasm of right choroid
C69.32  Malignant neoplasm of left choroid
C69.41  Malignant neoplasm of right ciliary body
C69.42  Malignant neoplasm of left ciliary body
C69.51  Malignant neoplasm of right lacrimal gland and duct
C69.52  Malignant neoplasm of left lacrimal gland and duct
C69.61  Malignant neoplasm of right orbit
C69.62  Malignant neoplasm of left orbit
C69.81  Malignant neoplasm of overlapping sites of right eye and adnexa
C69.82  Malignant neoplasm of overlapping sites of left eye and adnexa
C69.91  Malignant neoplasm of unspecified site of right eye
C69.92  Malignant neoplasm of unspecified site of left eye
C70.0   Malignant neoplasm of cerebral meninges
C70.1   Malignant neoplasm of spinal meninges
C70.9   Malignant neoplasm of meninges, unspecified
C71.0   Malignant neoplasm of cerebrum, except lobes and ventricles
C71.1   Malignant neoplasm of frontal lobe
C71.2   Malignant neoplasm of temporal lobe
C71.3   Malignant neoplasm of parietal lobe
C71.4   Malignant neoplasm of occipital lobe
C71.5   Malignant neoplasm of cerebral ventricle
C71.6   Malignant neoplasm of cerebellum
C71.7   Malignant neoplasm of brain stem
C71.8   Malignant neoplasm of overlapping sites of brain
C72.0   Malignant neoplasm of spinal cord
C72.1   Malignant neoplasm of cauda equina
C72.21  Malignant neoplasm of right olfactory nerve
C72.22  Malignant neoplasm of left olfactory nerve
C72.31  Malignant neoplasm of right optic nerve
C72.32  Malignant neoplasm of left optic nerve
C72.41  Malignant neoplasm of right acoustic nerve
C72.42  Malignant neoplasm of left acoustic nerve
C72.59  Malignant neoplasm of other cranial nerves
C73    Malignant neoplasm of thyroid gland
C75.0  Malignant neoplasm of parathyroid gland
C75.1  Malignant neoplasm of pituitary gland
C75.2  Malignant neoplasm of craniopharyngeal duct
C75.3  Malignant neoplasm of pineal gland
C75.4  Malignant neoplasm of carotid body
C76.0  Malignant neoplasm of head, face and neck
C77.0  Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck
C79.31 Secondary malignant neoplasm of brain
C79.61 Secondary malignant neoplasm of right ovary
C79.62 Secondary malignant neoplasm of left ovary  
C79.82 Secondary malignant neoplasm of genital organs  
C79.89 Secondary malignant neoplasm of other specified sites  
C83.31 Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck  
C83.51 Lymphoblastic (diffuse) lymphoma, lymph nodes of head, face, and neck  
D03.0 Melanoma in situ of lip  
D03.111 Melanoma in situ of right upper eyelid, including canthus  
D03.112 Melanoma in situ of right lower eyelid, including canthus  
D03.121 Melanoma in situ of left upper eyelid, including canthus  
D03.122 Melanoma in situ of left lower eyelid, including canthus  
D03.21 Melanoma in situ of right ear and external auricular canal  
D03.22 Melanoma in situ of left ear and external auricular canal  
D03.39 Melanoma in situ of other parts of face  
D03.4 Melanoma in situ of scalp and neck  
D32.0 Benign neoplasm of cerebral meninges  
D32.1 Benign neoplasm of spinal meninges  
D32.9 Benign neoplasm of meninges, unspecified  
D33.0 Benign neoplasm of brain, supratentorial  
D33.1 Benign neoplasm of brain, infratentorial  
D33.3 Benign neoplasm of cranial nerves  
D33.4 Benign neoplasm of spinal cord  
D33.7 Benign neoplasm of other specified parts of central nervous system  
D35.1 Benign neoplasm of parathyroid gland  
D35.2 Benign neoplasm of pituitary gland  
D35.3 Benign neoplasm of craniopharyngeal duct  
D35.4 Benign neoplasm of pineal gland  
D35.5 Benign neoplasm of carotid body  
D35.6 Benign neoplasm of aortic body and other paraganglia  
D39.11 Neoplasm of uncertain behavior of right ovary  
D39.12 Neoplasm of uncertain behavior of left ovary  
D39.8 Neoplasm of uncertain behavior of other specified female genital organs  
D40.0 Neoplasm of uncertain behavior of prostate  
D42.0 Neoplasm of uncertain behavior of cerebral meninges  
D42.1 Neoplasm of uncertain behavior of spinal meninges  
D43.0 Neoplasm of uncertain behavior of brain, supratentorial  
D43.1 Neoplasm of uncertain behavior of brain, infratentorial  
D43.4 Neoplasm of uncertain behavior of spinal cord  
D44.3 Neoplasm of uncertain behavior of pituitary gland  
D44.4 Neoplasm of uncertain behavior of craniopharyngeal duct  
D44.5 Neoplasm of uncertain behavior of pineal gland
### REVISIONS

**01-30-2009**  
Policy first published on [www.bcbsks.com](http://www.bcbsks.com).

<table>
<thead>
<tr>
<th>In policy section:</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Added the following indications:</td>
</tr>
<tr>
<td>D. IMRT is considered medically necessary for treatment of anal cancers.</td>
</tr>
<tr>
<td>E. IMRT may also be medically necessary for other radiosensitive tumors where critical structures cannot be adequately protected with standard 3D conformal radiotherapy. Medical necessity for the use of IMRT for these other indications will be considered individually and will require supporting records from the treating radiation oncologist including the dose volume histograms documenting the need for IMRT as opposed to conventional radiation therapy.</td>
</tr>
<tr>
<td>The American Society for Therapeutic Radiology and Oncology (ASTRO) has a model policy which describes the indications for IMRT:</td>
</tr>
<tr>
<td>“IMRT is not a replacement therapy for conventional or three-dimensional conformal radiation therapy methods. IMRT is considered reasonable and necessary in instances where sparing the surrounding normal tissue is of added benefit and at least one of the following conditions is met:</td>
</tr>
<tr>
<td>1. The target volume is in close proximity to critical structures that must be protected.</td>
</tr>
<tr>
<td>2. The volume of interest must be covered with narrow margins to adequately protect immediately adjacent structures.</td>
</tr>
<tr>
<td>3. An immediately adjacent area has been previously irradiated and abutting portals must be established with high precision.</td>
</tr>
<tr>
<td>4. The target volume is concave or convex, and critical normal tissues are within or around that convexity or concavity.</td>
</tr>
<tr>
<td>5. Dose escalation is planned to deliver radiation doses in excess of those commonly utilized for similar tumors with conventional treatments.”</td>
</tr>
<tr>
<td>F. Other applications of IMRT are considered not medically necessary.</td>
</tr>
<tr>
<td>▪ Added the following documentation information: DOCUMENTATION</td>
</tr>
<tr>
<td>As recommended by ASTRO, documentation in the patient's medical records must support:</td>
</tr>
<tr>
<td>1. The reasonable and necessary requirements as outlined in the Policy section.</td>
</tr>
<tr>
<td>2. The prescription must define the dose to the target and the dose constraints to the nearby critical structures.</td>
</tr>
<tr>
<td>3. A note of medical necessity for IMRT, by the treating physician.</td>
</tr>
<tr>
<td>4. Signed IMRT inverse plan that meets prescribed dose constraints for the planning target volume (PTV) and surrounding normal tissue.</td>
</tr>
<tr>
<td>5. The target verification methodology must include the following:</td>
</tr>
<tr>
<td>a. Documentation of the clinical treatment volume (CTV) and the planning target volume (PTV).</td>
</tr>
<tr>
<td>b. Documentation of immobilization and patient positioning.</td>
</tr>
<tr>
<td>6. Independent basic dose calculations of monitor units have been performed for each beam before the patient's first treatment.</td>
</tr>
<tr>
<td>7. Documentation of fluence distributions (re-computed and measured in a phantom or dosimetry measuring device) is required.</td>
</tr>
<tr>
<td>8. Identification of structures that transverse high-and low-dose regions created by respiration is indicated. Voluntary breath-holding alone is not a satisfactory solution for accounting for organ motion.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>In Coding section:</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Reflected the applicable CPT codes 77300, 77301, 77332, 77333, 77334, 77418, 0073T</td>
</tr>
</tbody>
</table>

**01-01-2010**  
In Coding Section:  
▪ Added CPT Code: 77388
In the Policy section:
- Item D, removed “anal cancers” and added “squamous cell carcinoma of the anus.”
- Added Item “E. IMRT is considered medically necessary in the treatment of individuals with anaplastic thyroid cancer.”
- Added Item “F. IMRT is considered medically necessary in individuals with pediatric tumors (e.g., Ewing Sarcoma, Wilms’ Tumor).”
- Added Item “G. IMRT is considered medically necessary in individuals who require repeat irradiation of a field that has received prior irradiation.”

Updated the Reference section.

07-13-2012
Updated the Description section.

In the Policy section:
- Added the following indication: "F. Carcinoma of the cervix."
- Added the following indication: "G. Whole pelvic radiotherapy for gynecologic malignancies."
- In Item J, inserted "3-D" to read "radiation oncologist including the 3-D dose volume..."
- In Item J, changed "histograms" to "histogram"
- In Item J, removed "as opposed to conventional radiation therapy" from the end of paragraph.

In the Documentation section:
- Revised the following language:
  "As recommended by ASTRO, documentation in the patient’s medical records must support:
  1. The reasonable and necessary requirements as outlined in the Policy section.
  2. The prescription must define the dose to the target and the dose constraints to the nearby critical structures.
  3. A note of medical necessity for IMRT, by the treating physician.
  4. Signed IMRT inverse plan that meets prescribed dose constraints for the planning target volume (PTV) and surrounding normal tissue.
  5. The target verification methodology must include the following:
     a. Documentation of the clinical treatment volume (CTV) and the planning target volume (PTV).
     b. Documentation of immobilization and patient positioning.
  6. Independent basic dose calculations of monitor units have been performed for each beam before the patient's first treatment.
  7. Documentation of fluence distributions (re-computed and measured in a phantom or dosimetry measuring device) is required.
  8. Identification of structures that transverse high-and low-dose regions created by respiration is indicated. Voluntary breath-holding alone is not a satisfactory solution for accounting for organ motion."

In the Coding section:
- Added the following Diagnosis codes: 180.0-180.9, 182.0-182.8, V10.40, V10.41

Updated Reference section.

10-15-2012
In the Policy section:
- Added statement, "IMRT is considered medically necessary for the following indications:" to the beginning of the policy section.
- In Item A, removed "IMRT of the prostate is considered medically necessary in patients with non-metastatic..." and added "of the prostate" to read "Prostate cancer for dose escalation >75Gy of the prostate and for...
- In Item B, removed, "IMRT is considered medically necessary in the treatment of patients with" to read "head and neck cancer, with the exception..."
- In item C, removed "IMRT is considered medically necessary in patients with CNS lesions" and added "Cancer involving the CNS"
In Item D, removed IMRT is considered medically necessary for patients of squamous cell and added "or vulva" to read "Carcinoma of the anus and vulva."

In Item E, removed "IMRT is considered medically necessary in the treatment of individuals with" to read "Anaplastic thyroid cancer."

In Item H, removed "IMRT is considered medically necessary in individuals with" to read "Pediatric tumors (e.g., Ewing Sarcoma, Wilms' Tumor)."

Added Item I, "Breast cancer when at least one of the following is met:
1. Heart—3D results in ≥ 25% of heart receiving ≥ 30Gy; OR
2. Lung—3D results in ≥ 30% of ipsilateral lung receiving ≥20 Gy, OR
3. Skin / Soft Tissue—3D results in ≥ 5% of intended breast receiving ≥7% of prescribed dose OR

Medial lesion where 3D results in ≥ 10% of contralateral breast receiving ≥ 10Gy."

Added Item J, "Esophagus, Stomach, Pancreas, Hepatobiliary Tract, Rectum, Colon, Small Bowel, when at least one of the following is met:
1. Heart—3D result in ≥50% of heart receiving ≥30 Gy, OR
2. Lung—3D results in ≥30% of combined lung volume receiving ≥ 20% Gy, OR
3. Spinal Cord—3D result in any portion of the spinal cord receiving a dose above 45 Gy; OR
4. Liver—3D results in ≥60% of liver volume receiving ≥ 30 Gy, OR
5. Kidney—3D results in ≥33% of combined kidney volume receiving ≥ 20 Gy (two functional kidneys are present); OR
   For one functioning kidney or kidney transplant, IMRT provides a lower dose than achievable with 3D; OR
6. Small Intestine—3D results in ≥ 195cc of small intestine receiving ≥ 45 Gy; OR
7. Stomach—3D results in ≥ 10% of stomach receiving ≥45 Gy OR
8. Femoral head—3D results in a femoral head receiving ≥ 45 Gy."

Added Item K, "Lung, when at least one of the following is met:
1. Heart—3D results in ≥ 50% of heart receiving ≥30 Gy; OR
2. Lung—3D results in ≥ 30% of combined lung volume receiving ≥ 20Gy OR
   Mean lung dose of ≥ 20 Gy; OR
3. Spinal cord—3D results in any portion of the spinal cord receiving a dose above 45 Gy, OR
4. Liver—3D results in 60% of liver volume receiving ≥ 30 Gy OR
   Mean liver dose ≥32 Gy; OR
5. Femoral head—3D results in a femoral head receiving ≥ 45 Gy OR
6. Small intestine—3D results in ≥ 195cc of small intestine receiving ≥ 45 Gy; OR
7. Stomach—3D results in ≥ 10% of stomach receiving ≥ 45 Gy OR
   5% receiving ≥ 50 Gy; OR
8. Rectosigmoid—3D results in ≥ 60% of rectosigmoid area receiving ≥ 30 Gy; OR
9. Bladder—3D results in ≥ 35% of bladder receiving ≥ 45 Gy; OR
10. Kidney—3D results in 33% of combined kidney volume receiving ≥ 20 Gy (two functional kidneys are present) OR
   For one functioning kidney or kidney transplant IMRT provides a lower dose than achievable with 3D."
- Added Item M, "Sarcomas of the Extremities, when at least one of the following is met:
  1. Head / Neck—IMRT covered if head and neck structures would receive any radiation via 3D; OR
  2. Femur—3D results in ≥ 50% of contiguous femur cortex receiving ≥ 50 Gy"
- In Item N, removed "IMRT is considered medically necessary in" to read "Individuals who require repeat irradiation..."
- In Item O, removed "IMRT may also be medically necessary for" to read "Other radiosensitive tumors where critical structures..."

In the Coding section:
- Added Diagnosis codes: 174.0-174.9

<table>
<thead>
<tr>
<th>Date</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-11-2013</td>
<td>Policy reviewed.</td>
</tr>
<tr>
<td></td>
<td>In Coding section:</td>
</tr>
<tr>
<td></td>
<td>• Added ICD-10 Diagnosis codes. <em>(Effective October 1, 2014)</em></td>
</tr>
<tr>
<td>01-01-2015</td>
<td>Updated Reference section.</td>
</tr>
<tr>
<td></td>
<td>In Coding section:</td>
</tr>
<tr>
<td></td>
<td>• Added CPT/HCPCS Codes:  77385, 77386, G6015, G6016 <em>(Effective January 1, 2015)</em></td>
</tr>
<tr>
<td></td>
<td>• Deleted CPT Codes:  77418, 0073T <em>(Effective January 1, 2015)</em></td>
</tr>
<tr>
<td>10-13-2015</td>
<td>Updated Description section.</td>
</tr>
</tbody>
</table>

In Policy section:
- In Item O, updated ASTRO medical policy indications, removed "IMRT is not a replacement therapy for conventional or three-dimensional conformal radiation therapy methods," "clinical," "and at least one of the following conditions is met," and added "to the patient. Examples of reasons why IMRT might be advantageous include the following," to read, "IMRT is considered reasonable and necessary in instances where sparing the surrounding normal tissue is of added clinical benefit to the patient. Examples of reasons why IMRT might be advantageous include the following:"
- In Item O 1, removed "that must be protected" and added "one or more" and "and a steep dose gradient outside the target must be achieved and avoid exceeding the tolerance dose to the critical structure(s)" to read, "The target volume is in close proximity to one or more critical structures and a steep dose gradient outside the target must be achieved and avoid exceeding the tolerance dose to the critical structure(s)."
- In Item O 2, removed previous language and added "A decrease in the amount of dose inhomogeneity in a large treatment volume is required to avoid an excessive dose "hotspot" within the treated volume to avoid excessive early or late normal tissue toxicity."
- Added new Item O 3.
- In Item O 4 (previous Item O 3), removed, "and abutting portals must be established with high precision" and added "The same or" and "and the dose distribution within the patient must be sculpted to avoid exceeding the cumulative tolerance dose of nearby normal tissue" to read, "The same or an immediately adjacent area has been previously irradiated, and the dose distribution within the patient must be sculpted to avoid exceeding the cumulative tolerance dose of nearby normal tissue."
- Removed previous Items O 4 and 5.

Under "Documentation":
- In Item 2, removed "defining the dose to the target and" and added "which defines the goals and requirements of the treatment plan," and "specific" to read, "The prescription which defines the goals and requirements of the treatment plan, including the specific dose constraints to the target and nearby critical structures."
- In Item 5, removed "including" and added" must include" to read, "The target verification methodology must include the following:"
- In Item 7, added "is required" to read, "Documentation of fluence distributions (re-computed and measured in a phantom or dosimetry measuring device) is required."

**In Coding section:**
- In first bullet, removed "that specifically described IMRT:" and "(Intensity modulated treatment delivery, single or multiple fields/archs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session)" and "(compensator-based beam modulated treatment delivery of inverse planned treatment using three or more high resolution (milled or cast) compensator convergent beam modulated fields, per treatment session), were," and added "was" to read, "Effective in 2015, code 77418 and 0073T were deleted and new codes for simple and complex IMRT delivery were created: 77385, 77386."

**Updated References section.**

<table>
<thead>
<tr>
<th>10-26-2016</th>
<th>Updated Description section.</th>
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</thead>
<tbody>
<tr>
<td><strong>In Policy section:</strong></td>
<td></td>
</tr>
<tr>
<td>- Under Documentation, removed &quot;include&quot; and added &quot;support&quot; to read, &quot;As recommended by ASTRO, the IMRT treatment record must support:&quot;.</td>
<td></td>
</tr>
<tr>
<td>- Under Documentation Item 6, added &quot;have been&quot; to read, &quot;Independent basic dose calculations of monitor units have been performed for each beam before the patient's first treatment.&quot;</td>
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<td>- Updated coding bullets.</td>
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<tr>
<td><strong>Updated References section.</strong></td>
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<table>
<thead>
<tr>
<th>03-15-2017</th>
<th>In Coding section:</th>
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<tbody>
<tr>
<td>- Added ICD-10 codes: C51.0, C51.1, C51.2, C51.8, C51.9, C52, C53.0, C53.1, C53.8, C53.9, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C56.1, C56.2, C57.01, C57.02, C57.11, C57.12, C57.21, C57.22, C57.3, C57.4, C57.7, C57.8, C58, C79.61, C79.62, C79.82, C79.89, D39.11, D39.12, D39.8.</td>
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</table>

| 08-15-2017 | Title changed from "Intensity Modulated Radiation Therapy (IMRT)."

**Updated Description section.** |
<table>
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<tr>
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<tr>
<td><strong>In Coding section:</strong></td>
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</tr>
</thead>
<tbody>
<tr>
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<td></td>
</tr>
<tr>
<td>- Removed ICD-9 codes.</td>
<td></td>
</tr>
<tr>
<td>- Added ICD-10 codes: C43.111, C43.112, C43.121, C43.122, C44.1021, C44.1022, C44.1091, C44.1092, C44.1121, C44.1122, C44.1191, C44.1192, C44.1221, C44.1222, C44.1291, C44.1292, C44.1321, C44.1322, C44.1391, C44.1392, C44.1921, C44.1922, C44.1991, C44.1992, D03.111, D03.112, D03.121, D03.122.</td>
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<tr>
<td>- Removed ICD-10 codes: C43.11, C43.12, C44.102, C44.109, C44.112, C44.119, C44.122, C44.129, C44.191, C44.192, C44.199, D03.11, D03.12.</td>
<td></td>
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<tr>
<td><strong>Updated References section.</strong></td>
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</thead>
<tbody>
<tr>
<td><strong>In Policy section:</strong></td>
<td></td>
</tr>
</tbody>
</table>
| - In Item I A 1, removed "for dose escalation >75 Gy of the prostate and for postoperative radiation of the prostate to a dose of at least 6300 cGy" and replaced with "1. As a definitive treatment for non-metastatic and appropriate oligometastatic cases of prostate cancer using standard fractionation or equivalent hypofractionated schedules (eg, 7920 cGy in 44 fractions, 7800 cGy in 39 fractions, 7000 cGy in 28 fractions, 6000 cGy in 20 fractions). 2. As adjuvant or salvage radiation therapy with curative intent for individuals who are post-prostatectomy, with biochemical failure, and without distant metastasis when >64 Gy in standard fractionation or equivalent hypofractionation will be given."

**Updated References.** |
Updated References section.

In Policy Documentation section:
- Added "NOTE: Comparison 3D-CRT dose volume histogram (DVH) in color"

REFERENCES


Other References
1. Blue Cross and Blue Shield of Kansas Radiology Liaison Committee, February 2008; February 2009; February 2010; February 2011; May 2019.
3. Blue Cross and Blue Shield of Kansas Medical Consultant, Practicing Board-Certified Radiation Oncologist (548), September 2011.
4. Blue Cross and Blue Shield of Kansas Medical Consultant, Practicing Board Certified Radiation Oncologist (548), March 2012.
5. Blue Cross and Blue Shield of Kansas Medical Consultant, Practicing Board Certified Radiation Oncologist (548), April 2012.