Clinical Policy Title: Intensity modulated radiation therapy (IMRT)

Clinical Policy Number: 05.02.03

Effective Date: March 1, 2015
Initial Review Date: October 15, 2014
Most Recent Review Date: October 19, 2016
Next Review Date: October 2017

RELATED POLICIES:
CP 05.02.01 Proton beam therapy

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Coverage Policy

AmeriHealth Caritas District of Columbia considers the use of intensity modulated radiation therapy (IMRT) in instances where sparing the surrounding normal tissue is of added benefit to be clinically proven and, therefore, medically necessary when the following criteria are met:

- IMRT is being used for treatment of one of the conditions listed in Table #1.
- IMRT is required to reduce morbidity and avoid damage to critical structures adjacent to the cancer.
- An immediately adjacent target lesion has been irradiated and abutting portals must be established with high precision.
- Gross tumor volume (GTV) margins are concave or convex and in close proximity to critical structures which must be protected to avoid unacceptable morbidity and radiation exposure.
- When only IMRT techniques would decrease the probability of grade 2 or grade 3 radiation toxicity as compared to conventional radiation in greater than 15 percent of radiated similar cases.
## Table #1 — Indications for IMRT

IMRT is not a replacement therapy for conventional and 3-D conformal radiation therapy methods.

### Central nervous system primary metastatic or benign tumors of:
- Brain, brain stem, and spinal cord.
- Primary, metastatic tumors of the spine where the spinal cord tolerance may be exceeded with conventional treatment.

### Head and neck primary metastatic or benign tumors of:
- Orbits.
- Paranasal sinuses and nasal cavity.
- Hypopharynx, oropharynx, nasopharynx.
- Larynx (stage III – stage IV).
- Skull base.
- Aero-digestive tract.
- Salivary glands.
- Mucosal melanoma.
- Oral cavity and lips.

### Prostate carcinoma:
- Localized prostate cancer.
- Post-prostatectomy for dose escalation greater than or equal to 64 Gy, when PSA remains detectable at 6 months after surgery; or
  - PSA is detectable and increases on two or more lab determinations.
  - The individual has post-operative stage T3b to T4.
  - Postoperative pathology reveals positive surgical margins.

### Thoracic and abdominal malignancies when target volume is in proximity to critical structures:
- Non-small cell lung cancer in limited situations only, in which the tumor is fixed to the vertebral body, located at the superior sulcus or involving bilateral mediastinum, to avoid over dose of radiation to normal tissues.
- Selected cases of thoracic and abdominal malignancies. (There is still scant peer-reviewed literature on these sites.)

### Gastrointestinal malignancies:
- Anus / anal cancers.

### Breast cancer:
- Selected cases (i.e., not routine) of breast cancers if the lesion is in close proximity to the heart or other cardiovascular structure. (ASTRO, 2007)

### Limitations:

All other uses of IMRT are not medically necessary, including:
- Intrafraction localization and tracking of target or patient motion during delivery of radiation therapy.
- Treating all diagnoses not listed above as proven, including:
  - Colon cancer.
- Gastric cancer.
- Gynecological cancer (except where noted above).
- Lung cancer.
- Lymphoma.
- Pelvic bone cancer.
- Primary or secondary liver cancer.
- Rectal cancer.
- Secondary bone and articular cartilage cancer.
- Soft tissue sarcoma and all other neoplasms not listed above as proven.

Because of limited studies, small sample sizes and weak study designs, there is insufficient data to conclude IMRT is safe or effective for treating the neoplasms listed above. There is also little evidence to indicate IMRT increases survival in patients with these neoplasms.

**Alternative Covered Services:**

Standard surgical therapies, radiation therapies, chemotherapies as appropriate for the clinical condition, and proton beam therapy.

**Background**

IMRT is the use of beams with non-uniform fluence to deliver radiation to a target organ. It typically involves the use of techniques where the target is specified, organs at risk for collateral radiation scatter are identified, and a computer calculates the most appropriate field and fluence arrangement.

Currently, the most useful device for delivery of radiotherapy beams with dynamic modulation of energy fluence is the multileaf collimator (MLC). This is computer-controlled, and may be aimed at stationary targets (multisegmented static fields) or targets in motion (dynamic delivery). The latter technique requires rapidly moving MLC leaves (over 2 cm per second) and requires additional resources to measure the position of leaves and ensure accuracy. The former technique is easier to implement, as it requires fewer resources, but faces issues with beam “on” and “off” cycling and takes longer to deliver.

A third technique is intensity modulated arc therapy (IMAT). In this technique, the gantry rotates around the patient with the beam on, and the MLC leaves shift dynamically during treatment. This has the benefit of rapid treatment delivery but increases the volume of tissue being exposed to radiation.

Historically, the maximum radiation dose that could be given to a tumor site has been restricted by the tolerance and sensitivity of the surrounding nearby healthy tissues. When a tumor or condition is not eligible for treatment with normal stereotactic radiosurgery, conformal radiation may be used in one or more sessions. Three-dimensional conformal radiation therapy is less than 10 years old. It is only available with linear accelerator-based technology.

The Calypso® 4D Localization System is regulated by the FDA as a component of a medical linear
accelerator. This device received FDA 510(k) approval on July 28, 2006, as an adjunct to radiation therapy in patients who have undergone permanent implantation of at least two Beacon transponders. Intra-fraction localization and tracking systems, such as the Calypso 4D Localization System, are unproven for use in guiding radiotherapy. Results of available studies suggest the Calypso System can provide continuous information to guide prostate radiotherapy. However, although this technology has the potential to reduce complications of radiotherapy and improve local tumor control, none of the available studies reported clinical information related to the safety or efficacy of radiation therapy guided by the Calypso System.

Examples of approved devices and systems are the NOMOS Slit Collimator (BEAK™) (NOMOS Corp.); the Peacock™ System (NOMOS Corp.); the Varian Multileaf Collimator with dynamic arc therapy feature (Varian Oncology Systems); the Saturne Multileaf Collimator (GE Medical Systems); the Mitsubishi 120 Leaf Multileaf Collimator (Mitsubishi Electronics America Inc.); the Stryker Leibinger Motorized Micro Multileaf Collimator (Stryker Leibinger); the Mini Multileaf Collimator, model KMI (MRC Systems GMBH); and the Preference® IMRT Treatment Planning Module (Northwest Medical Physics Equipment Inc.). The RayPilot® system (Micropos Medical, Sweden) is not FDA approved for marketing in the U.S.

More precise techniques using one-session Gamma Knife® machines and other one-session linac technology are best utilized within the brain. Several manufacturers currently offer beneficial treatments with high-level linac technology that can perform both one-session radiosurgery and radiotherapy. The most well-recognized brand names at this time are the Novalis Tx® (Varian Medical Systems Inc. and BrainLab Inc.); Synergy S® (Elekta Inc.); and CyberKnife® (Accuray Inc.). All of these machines are robotic and image-guided, and can perform IMRT.

Searches

AmeriHealth Caritas District of Columbia searched PubMed and the databases of:

- UK National Health Services Center for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on October 3, 2016. Searched terms were: "intensity modulated radiation therapy (MeSH)" , "IMRT (MeSH)" , and "cancer."

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines** based on systematic reviews.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies.
which also rank near the top of evidence hierarchies.

Findings

There is a great deal of contemporary interest regarding IMRT for cancer of the prostate, spine, lung, breast, kidney, pancreas, liver, larynx, tongue, and sinus. As with conventional radiation therapy, treatment with IMRT involves a radiation oncologist and physicist. Should the treatment site be within the brain, a neurosurgeon is recommended to be a part of the team as well.

A new study (Patel 2014) of proton beam therapy in the treatment of a variety of advanced head and neck cancers compared to IMRT has found proton beam therapy significantly improved disease-free survival and tumor control when compared to IMRT. Researchers found disease-free survival to be significantly higher at five years for patients receiving proton therapy than for patients receiving IMRT (72 percent versus 50 percent). Tumor control did not differ between treatment groups at five years; however, tumor control was higher for patients receiving proton therapy than for IMRT at the longest follow-up (81 percent versus 64 percent).

Men with localized prostate cancer treated with IMRT have more than one quarter (26 percent) fewer late bowel and rectal side effects and a statistically improved lower dose of radiation to the bladder and rectum, compared to those who undergo 3D-CRT (Mychalski 2013). The authors also found there is a significant increase (15 percent) in rectal side effects associated with Caucasian men, compared to other races, regardless of the radiation treatment.

IMRT treatment for localized prostate cancer is better than conventional conformal radiation therapy (CRT) for reducing certain side effects (i.e., gastrointestinal and rectal toxicity) and preventing cancer recurrence (Sheets 2012).

There is no evidence from randomized controlled trials (RCTs) comparing IMRT with 3D-CRT for treatment of anal cancer. However, non-randomized studies of IMRT consistently demonstrate reduced toxicity and comparable tumor control for malignancies of the anal canal.

As for other abdominal (e.g., gastric, pancreatic, hepatobiliary) and pelvic (e.g., rectal, gynecologic) cancers, there is currently no evidence from randomized controlled trials comparing IMRT with other radiation modalities for the treatment of abdominal and pelvic cancers.

There is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management of IMRT for the treatment of colon cancer.

Policy updates:

Ricco (2016) retrospectively reviewed 270 consecutive men treated with either stereotactic body radiation therapy (SBRT, n = 150) or IMRT (n = 120) at a community hospital with organ confined prostate cancer from 2007–2012. There was no significant difference in freedom from biochemical failure (FFBF) between
SBRT versus IMRT ($p = 0.46$) with six-year actuarial FFBF of 91.9% for SBRT and 88.9% for IMRT. Overall toxicity was low.

Chen (2016) retrospectively evaluated the distant metastatic outcomes in 91 of 530 nasopharyngeal carcinoma (NPC) patients treated with IMRT plus chemotherapy from June 2006 – December 2011. Patients were treated with one fraction of IMRT daily for five days a week for 69.96–74.09 Gy, while 473 (89.2 percent) of patients also received chemotherapy. Patients were followed for a median follow-up duration of 49 months (range from five to 98 months). Chemotherapy failed to reduce cancer distant metastasis in early stage patients, the distant metastasis rate was 17.5 percent in stage III and 24.2 percent in stage IVA–IVB diseases, after IMRT and chemotherapy. The multivariate analysis showed that cancer remission duration, treatment modality, and metastatic site ($p < 0.001$, $p = 0.027$ and $p = 0.022$, respectively) were all independent predictors for overall survival of NPC patients after IMRT and chemotherapy.

Hayes (2016) reviewed 13 peer-reviewed studies, including six studies on IMRT for anal cancer and seven studies on IMRT for rectal cancer and determined that clinical outcomes following IMRT are similar to those seen with standard conformal radiotherapy for treating anal cancer and locally advanced rectal cancer, suggesting that IMRT may have similar efficacy. However, the use of IMRT to treat anal or rectal cancer did not consistently result in any additional benefit relative to traditional radiotherapy. IMRT may have a better toxicity profile since it resulted in fewer high-grade toxicities. Furthermore, evidence of low quality suggests that IMRT may have a better safety profile than standard radiotherapy, and that it may be as effective as standard radiotherapy for some patients with anal cancer. Evidence of very low quality suggests that IMRT may have a better safety profile than standard radiotherapy for rectal cancer, and that it may be as effective for local control; however, there is a lack of comparative data on long-term outcomes.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ricco (2016)</td>
<td>Key points:</td>
</tr>
<tr>
<td>The comparison of stereotactic body radiation therapy and IMRT for prostate cancer by NCCN risk groups</td>
<td>Retrospective review of 270 consecutive men treated with either SBRT ($n = 150$) or IMRT ($n = 120$) at a community hospital with organ confined prostate cancer between 2007 through 2012.</td>
</tr>
<tr>
<td>Chen (2016)</td>
<td>Key points:</td>
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<tr>
<td>Intensity-modulated radiotherapy controls nasopharyngeal carcinoma distant metastasis and improves</td>
<td>Retrospective review of distant metastatic outcomes in 91 of 530 nasopharyngeal carcinoma (NPC) patients treated with IMRT plus chemotherapy between June 2006 and December 2011.</td>
</tr>
<tr>
<td></td>
<td>Patients were treated with one fraction of IMRT daily for 5 days a week for 69.96–74.09 Gy, while 473 (89.2 %) of patients also received chemotherapy.</td>
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| survival of patients. | • Patients were followed for a median follow-up duration of 49 months (range from five to 98 months).  
• Chemotherapy failed to reduce cancer distant metastasis in early stage patients, the distant metastasis rate was 17.5% in stage III and 24.2% in stage IVA–B diseases, after IMRT and chemotherapy.  
• The multivariate analysis showed that cancer remission duration, treatment modality, and metastatic site (p < 0.001, p = 0.027 and p = 0.022, respectively) were all independent predictors for overall survival of NPC patients after IMRT and chemotherapy. |
| Hayes (2016)      | **Key points:**  
• Systematic review of 13 peer-reviewed studies, including six studies on IMRT for anal cancer and seven studies on IMRT for rectal cancer.  
• Determined that clinical outcomes following IMRT are similar to those seen with standard conformal radiotherapy for treating anal cancer and locally advanced rectal cancer, suggesting that IMRT may have similar efficacy.  
• IMRT may have a better toxicity profile since it resulted in fewer high-grade toxicities.  
• Evidence of low quality suggests that IMRT may have a better safety profile than standard radiotherapy, and that it may be as effective as standard radiotherapy for some patients with anal cancer.  
• Evidence of very low quality suggests that IMRT may have a better safety profile than standard radiotherapy for rectal cancer, and that it may be as effective for local control; however, there is a lack of comparative data on long-term outcomes. |
| Patel (2014)      | **Key points:**  
• Systematic review of 41 observational studies of treatment for malignant tumors arising within the nasal cavity and paranasal sinuses.  
• Overall survival and disease-free survival was significantly higher at five years for charged particle therapy than for photon therapy.  
• Analysis comparing proton beam therapy with intensity-modulated radiation therapy showed significantly higher disease-free survival at five years. |
| Hong (2014)       | **Key points:**  
• Study of technique for administering IMRT to head and neck cancers.  
• Authors demonstrated that smaller leafs within the MLC delivered an irradiation beam that can provide better dosimetric outcomes in IMRT.  
• Set a baseline for minimum requirements of treatment when assigning or introducing equipment for the treatment of head and neck cancers. |
<table>
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<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tr>
<td>Chang (2014)</td>
<td><strong>Key points:</strong></td>
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<tr>
<td></td>
<td>• Comparison of IMRT versus 3D conformal radiotherapy for administering treatment to non-small cell lung cancer.</td>
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<td></td>
<td>• Authors demonstrated an increasing tendency to use IMRT versus 3D in the treatment of non-small cell lung cancer, with a market penetration rate of 26.8% in 2009.</td>
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<tr>
<td></td>
<td>• However, among patients receiving potentially curative radiation there was no significant difference in overall survival or time spent hospitalized following treatment.</td>
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<td>Sheets (2012)</td>
<td><strong>Key points:</strong></td>
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<tr>
<td></td>
<td>• Study of IMRT, proton therapy, and conformal radiation therapy for primary prostate cancer from 2000 – 2009.</td>
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<tr>
<td></td>
<td>• Primary complications noted were gastrointestinal and urinary morbidity, erectile dysfunction, hip fractures, and additional cancer therapy.</td>
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<td></td>
<td>• IMRT patients were less likely to receive additional cancer therapy compared to conformal radiotherapy.</td>
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<tr>
<td>Michalski (2011)</td>
<td><strong>Key points:</strong></td>
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<tr>
<td></td>
<td>• Clinical trial inclusive of 763 patients of 3-dimensional conformal radiotherapy (3D-CRT) and IMRT.</td>
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<tr>
<td></td>
<td>• There was a statistically significant decrease in GI/GU toxicity for IMRT.</td>
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<td>Bauman (2010)</td>
<td><strong>Key points:</strong></td>
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<tr>
<td></td>
<td>• Systematic review of studies performed years 2000 – 2009 inclusive of ≥ 50 patients evaluating IMRT in treating prostate cancer.</td>
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<tr>
<td></td>
<td>• IMRT recommended over 3-D CRT for localized prostate cancer where dose escalation (&gt;70 Gy) is required.</td>
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<td></td>
<td>• Insufficient evidence for postoperative radical prostatectomy use was documented.</td>
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<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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</table>
| Ramaekers (2010) | Key points:  
- Systematic review of studies performed years 1990 – 2010 inclusive of ≥ 10 patients evaluating IMRT in treating head and neck cancer.  
- Found tumor control and survival similar for IMRT and proton beam therapy to be similar.  
- Proton beam therapy was associated with lower toxicity rates than IMRT. |

**Glossary**

**Anal canal cancer** — The superior border of the functional anal canal, separating it from the rectum, has been defined as the palpable upper border of the anal sphincter and puborectalis muscles of the anorectal ring. It is approximately 3 cm to 5 cm in length, and its inferior border starts at the anal verge, the lowermost edge of the sphincter muscles, corresponding to the introitus of the anal orifice (NCCN, 2012).

**3-dimensional conformal therapy (3-DCRT)** — Computed tomography-based techniques to deliver radiation more accurately and with higher doses. These techniques include the use of conformal particle beams, intensity-modulated photon (X-ray) beams, and proton beams. Conformal photon-beam therapy has become the standard external radiation therapy, although the more technically challenging intensity-modulated radiation is becoming more widely used.

**External beam therapy (EBT)** — A method for delivering a beam of high-energy X-rays to the location of the tumor. The beam is generated outside the patient (usually by a linear accelerator) and is targeted at the tumor site. These X-rays can destroy the cancer cells and careful treatment planning allows the surrounding normal tissues to be spared. No radioactive sources are placed inside the patient's body.

**Fluence** — Particle density or energy density, used to describe the output of a radiation field or of a laser beam.

**Gray (Gy)** — The international system unit of absorbed radiation dose.

**Head/neck cancers** — Cancers arising from the oral cavity and lips, larynx, hypopharynx, oropharynx, nasopharynx, paranasal sinuses and nasal cavity, salivary glands, mucosal melanoma and occult primaries in the head and neck cancers. Cancer of the cervical esophagus, trachea, lymphoma, and thyroid cancer are not head and neck cancers, even when they arise in that body area.

**Image guided radiation therapy (IGRT)** — This technique utilizes imaging technology to modify treatment delivery to account for changes in the position of the intended target. IGRT is used in conjunction with IMRT for tumors that are located near or within critical structures and/or tissue with inherent setup variation.
Intensity-modulated radiation therapy (IMRT) — Along with conformal therapy, radiation oncology techniques developed in the 1990s to capitalize on computers’ abilities to plan radiation delivery more precisely, thus maximizing exposure of tumors while avoiding surrounding tissues.

Linear accelerator (LINAC) — The device most commonly used for external beam radiation treatments for patients with cancer and to treat all parts/organs of the body.

Multileaf collimator (MLC) — A device made up of individual “leaves” of a high atomic-numbered material, usually tungsten, that can move independently in and out of the path of a particle beam in order to block it.

Non-small-cell lung cancer (NSCLC) — Referring to microscopic characteristics. Any type of lung cancer other than small cell, including squamous cell, large cell and adenocarcinoma. Lung cancer in never smokers is almost universally NSCLC, the majority adenocarcinoma, versus squamous cell or small cell, which are associated with tobacco use. NSCLCs are relatively insensitive to chemotherapy and are treated by surgery.

Sarcoma — A malignant tumor arising from tissues originating as embryonic mesenchyme or mesoderm: bone; cartilage; fat; muscle; vascular; or blood. They are named for the tissues they most closely resemble microscopically and behave with various levels of aggressiveness.

Stereotactic radiosurgery (SRS) — A form of radiation treatment that uses a 3-D external coordinate system to locate small lesions within the body for intervention. It requires a reliable and stable frame of reference, e.g., bone landmarks with a constant spatial relationship to soft tissues. Hence SRS applications have generally been restricted to the brain, although stereotactic breast biopsy is also performed. Ross (Cochrane 2010) classifies proton therapy among SRS procedures but found no completed RCTs for any brain AVM interventions meeting eligibility criteria for review.

Surveillance, epidemiology and end results (SEER) program — A collection of population-based cancer registries in the United States which collect and submit cancer incidence and follow-up data to the National Cancer Institute. The National Cancer Act of 1971 mandated the collection, analysis, and dissemination of data useful in the prevention, diagnosis and treatment of cancer leading to the establishment of the SEER Program.

Tungsten — Also known as wolfram, is a chemical element with the chemical symbol W and atomic number 74.

References

Professional society guidelines/other:

Bauman G, Rumble RB, Chen J, Loblaw A, Warde P. IMRT indications expert panel. The role of IMRT in prostate cancer. Toronto (ON): Cancer Care Ontario (CCO); 2010 Oct 27.


Peer-reviewed references:


Clinical trials:

Searched clinicaltrials.gov on October 3, 2016 using terms “intensity modulated radiotherapy” | Open Studies. 138 studies found, 5 relevant.


CMS National Coverage Determination (NCDs):

No records returned for NCD for IMRT.

Local Coverage Determinations (LCDs):

Intensity Modulated Radiation Therapy (IMRT): LCD L340880. Available at: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34080&ver=17&CovSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=imrt&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAAACAAAAAAA%3d%3d&. Accessed September 28th, 2016.

Intensity Modulated Radiation Therapy (IMRT): LCD L34217. Available at: https://www.cms.gov/medicare-
Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
<tr>
<td>77301</td>
<td>Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications.</td>
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<tr>
<td>77338</td>
<td>Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan.</td>
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<tr>
<td>77385</td>
<td>Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple</td>
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<tr>
<td>77386</td>
<td>Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex</td>
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<tr>
<td>77387</td>
<td>Guidance for localization of target volume for delivery of radiation treatment delivery, includes intrafraction tracking, when performed</td>
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<tr>
<td>4165F</td>
<td>3-dimensional conformal radiotherapy (3D-CRT) or intensity modulated radiation therapy (IMRT) received (PRCA)</td>
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<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
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<tr>
<td></td>
<td>Code list is extensive. See policy.</td>
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<thead>
<tr>
<th>HCPCS Level II</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
<tr>
<td>G6002</td>
<td>Stereoscopic x-ray guidance for localization of target volume for the delivery of radiation therapy</td>
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<tr>
<td>G6015</td>
<td>Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session</td>
<td></td>
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<tr>
<td>G6016</td>
<td>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</td>
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