Intensity-Modulated Radiation Therapy (IMRT): Head, Neck, Thyroid and Brain Cancers

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Next Review: 11/2014

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for intensity-modulated radiation therapy (IMRT) for head, neck and brain cancers when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered
Intensity-modulated radiation therapy may be considered medically necessary for the treatment of head and neck cancers.

Intensity-modulated radiation therapy may be considered medically necessary for the treatment of primary and metastatic brain cancers.

Intensity-modulated radiation therapy may be considered medically necessary for the treatment of thyroid cancers in close proximity to organs at risk (esophagus, salivary glands, and spinal cord) and 3-D CRT planning is not able to meet dose volume constraints for normal tissue tolerance. (see Considerations)

Considerations
For this policy, head and neck cancers are cancers arising from the oral cavity and lip, larynx, hypopharynx, oropharynx, nasopharynx, paranasal sinuses and nasal cavity, salivary glands, and occult primaries in the head and neck region.

Organs at risk are defined as normal tissues whose radiation sensitivity may significantly influence treatment planning and/or prescribed radiation dose. These organs at risk may be particularly vulnerable to clinically important complications from radiation toxicity. The following table outlines radiation doses that are generally considered tolerance thresholds for these normal structures in the area of the thyroid.

Radiation tolerance doses for normal tissues

<table>
<thead>
<tr>
<th>Site</th>
<th>TD 5/5 (Gy)a</th>
<th>TD 50/5 (Gy)b</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Portion of organ involved</td>
<td>Portion of organ involved</td>
</tr>
<tr>
<td>Esophagus</td>
<td>60 58 55</td>
<td>72 70 68</td>
</tr>
<tr>
<td>Salivary glands</td>
<td>32 32 32</td>
<td>46 46 46</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Site</th>
<th>Portion of organ involved</th>
<th>Complication End Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>Esophagus</td>
<td>1/3 2/3 3/3</td>
<td>Stricture, perforation</td>
</tr>
<tr>
<td>Salivary glands</td>
<td>1/3 2/3 3/3</td>
<td>Xerostomia</td>
</tr>
</tbody>
</table>
Spinal cord  |  50 (5-10 cm) | NP | 47 (20 cm) | 70 (5-10 cm) | NP | NP | Myelitis, necrosis

aTD 5/5, the average dose that results in a 5% complication risk within 5 years

bTD 50/5, the average dose that results in a 50% complication risk within 5 years

NP: not provided

cm=centimeters

The tolerance doses in the table are a compilation from the following two sources:


Kehwar TS, Sharma SC. Use of normal tissue tolerance doses into linear quadratic equation to estimate normal tissue complication probability. http://www.rooj.com/Radiation%20Tissue%20Tolerance.htm

**Description of Procedure or Service**

Radiation therapy is an integral component in the treatment of head and neck cancers. Intensity-modulated radiation therapy (IMRT) has been proposed as a method of radiation therapy that allows adequate radiation therapy to the tumor while minimizing the radiation dose to surrounding normal tissues and critical structures.

**Radiation techniques**

Conventional external beam radiation therapy. Over the past several decades, 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”.

3-dimensional conformal radiation (3D-CRT). 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 radiation therapy (IMRT). IMRT, which uses computer software and CT images, offers better conformity than 3D-CRT as it is able to modulate the intensity of the overlapping radiation beams projected on the target and to use multiply-shaped treatment fields. It uses a device (a multileaf collimator, MLC) which, coupled to 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 and 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.

Since most tumors move as patients breathe, dosimetry with stationary targets may not accurately reflect doses delivered within target volumes and adjacent tissues in patients. Furthermore, treatment planning and delivery are more complex, time-consuming, and labor-intensive for IMRT than for 3D-CRT. Thus, clinical studies must test whether IMRT improves tumor control or reduces acute and late toxicities when compared with 3D-CRT.

Multiple-dose planning studies have generated 3D-CRT and IMRT treatment plans from the same scans, then compared predicted dose distributions within the target and in adjacent organs at risk. Results of such planning studies show that IMRT improves on 3D-CRT with respect to conformality to, and dose homogeneity within, the target. Dosimetry using stationary targets generally confirms these predictions. Thus, radiation oncologists hypothesized that IMRT may improve treatment outcomes compared with those of 3D-CRT. However, these types of studies offer indirect evidence on treatment benefit from IMRT, and it is difficult to relate results of dosing studies to actual effects on health outcomes.

Comparative studies of radiation-induced side effects from IMRT versus alternative radiation delivery are probably the most important type of evidence in establishing the benefit of IMRT. Such studies would answer the question of whether the theoretical benefit of IMRT in sparing normal tissue translates into real health outcomes. Single-arm series of IMRT can give some insights into the potential for benefit, particularly if an adverse effect that is expected to occur at high rates is shown to decrease by a large amount. Studies of treatment benefit are also important to establish that IMRT is at least as good as other types of delivery, but in the absence of such comparative trials, it is likely that benefit from IMRT is at least as good as with other types of delivery.

Head and Neck Tumors
Head and neck cancers account for approximately 3% to 5% of cancer cases in the United States. The generally accepted definition of head and neck cancers includes cancers arising from the oral cavity and lip, larynx, hypopharynx, oropharynx, nasopharynx, paranasal sinuses and nasal cavity, salivary glands, and occult primaries in the head and neck region. Cancers generally not considered as head and neck cancers include uveal and choroidal melanoma, cutaneous tumors of the head and neck, esophageal cancer, and tracheal cancer. Thyroid cancers are also addressed in this policy. External beam radiation therapy is uncommonly used in the treatment of thyroid cancers but may be considered in patients with anaplastic thyroid cancer and for locoregional control in patients with incompletely resected high-risk or recurrent differentiated (papillary, follicular, or mixed papillary-follicular) thyroid cancer.

Rationale
This policy was originally created in 2009 and was regularly updated with searches of the MEDLINE database. The most recent literature search was performed for the period of July 2010 through April 2013. The following is a summary of the key findings to date.

Introduction
Intensity-modulated radiotherapy (IMRT) methods to plan and deliver radiation therapy (RT) are not uniform. IMRT may use beams that remain on as multi-leaf collimators (MLCs) that 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 of these methods 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 one imaging scan, a static 3-dimensional (3D) computed tomography (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.

**Head and Neck Cancers**

**Systematic Reviews.**

A systematic review published in 2008 summarized evidence on the use of IMRT for a number of cancers, including head and neck, prostate, gynecologic, breast, lung, and gastrointestinal tract. (1) This review mentions that the ability of IMRT to generate concave dose distributions and tight dose gradients around targets may be especially suitable to avoid organs at risk, such as the spinal cord or optic structures in head and neck cancer.

This review identified 20 studies (1 randomized controlled trial [RCT] and 19 case series) for IMRT in treatment of head and neck cancers. However, the RCT was for 2-dimensional (2D) RT compared to IMRT. (2) Four studies (including the RCT) were for treatment of nasopharyngeal carcinoma, 3 for sinonasal cancer, and 13 were for cancer involving the oropharynx, hypopharynx, larynx, and oral cavity. The majority of the studies reviewed showed a decrease in xerostomia with use of IMRT. However, there was variability in measurement, e.g., flow rate versus symptoms. The case series of sinonasal cancers showed less ocular toxicity (e.g., blindness) after use of IMRT. The authors of this review recognize the limitations and biases of the studies used in their analysis. With this limitation, they support the finding of decreased xerostomia (as well as improved salivary gland function) with use of IMRT in head and neck cancers involving the oral cavity, larynx, oropharynx, and hypopharyngeal area.

A comparative effectiveness review was published in 2010 on radiotherapy treatment for head and neck cancers by Samson and colleagues from BCBSA’s Technology Evaluation Center under contract with the Agency for Healthcare Research and Quality (AHRQ). (3) This report noted that based on moderate evidence, IMRT reduces late xerostomia and improves quality-of-life domains related to xerostomia compared with 3-dimensional conformal radiation (3D-CRT). The report also noted that no conclusions on tumor control or survival could be drawn from the evidence comparing IMRT to 3D-CRT.

In 2011, Tribius and Bergelt reviewed 14 studies that compared the quality-of-life outcomes of head and neck cancer treatment with IMRT versus 2D-RT or 3D-CRT. (4) The most commonly used quality-of-life questionnaire was the European Organization for Research and Treatment Quality-of-Life Questionnaire (EORTC QLQ-C30), which was sometimes paired with the head and neck cancer module H&N35. Statistically significant improvements were observed with IMRT over 2D-RT and 3-dimensional conformal radiation (3D-CRT) in xerostomia, dry mouth, sticky saliva, and eating-related functions. However, the authors noted the study populations were heterogeneous and quality-of-life assessment tools varied. Therefore, further prospective randomized studies were recommended. Other evidence reviews, in 2010, came to similar conclusions in that treatment with IMRT resulted in reductions in acute and/or late xerostomia than other radiotherapies for head and neck cancer. (5, 6)

**Randomized controlled trials.**

An RCT by Pow and colleagues on IMRT for nasopharyngeal carcinoma was published in 2006. (2) However, as noted above, this RCT compared IMRT to conventional, 2-dimensional (2D) RT. In 2011, Nutting and colleagues reported on the PARSPORT randomized Phase III trial, which also compared conventional RT to parotid-sparing IMRT in 94 patients with T1-4, N0-3, M0 pharyngeal squamous-cell carcinoma. (7) One year after treatment, grade 2 or worse xerostomia was reported in 38% of patients in the IMRT group, which was significantly lower than the reported 74% in the conventional RT group. Xerostomia continued to be significantly less prevalent 2 years after treatment in the IMRT group (29%
vs. 83%, respectively). At 24 months, rates of locoregional control, non-xerostomia late toxicities, and overall survival were not significantly different.

Non-randomized comparative studies.
In 2009, Vergeer et al. published a report that compared IMRT and 3D-CRT for patient-rated acute and late xerostomia, and health-related quality of life (HRQoL) among patients with head and neck squamous cell carcinoma (HNSCC). (8) The study included 241 patients with HNSCC (cancers arising from the oral cavity, oropharynx, hypopharynx, nasopharynx, or larynx and those with neck node metastases from squamous cell cancer of unknown primary) treated with bilateral irradiation with or without chemotherapy. All patients were included in a program that prospectively assessed acute and late morbidity and HRQoL at regular intervals. Before October 2004, all patients were treated with 3D-CRT (n=150); starting in October 2004, 91 patients received IMRT. The use of IMRT resulted in a significant reduction of the mean dose to the parotid glands (27 Gy vs. 43 Gy; p<0.001). During radiation, grade 3 or higher xerostomia at 6 weeks was significantly less with IMRT (approximately 20%) than with 3D-CRT (approximately 45%). At 6 months, the prevalence of grade 2 or higher xerostomia was significantly lower after IMRT (32%) versus 3D-CRT (56%). Treatment with IMRT also had a positive effect on several general and head and neck cancer-specific HRQoL dimensions. The authors concluded that IMRT results in a significant reduction of xerostomia, as well as other head and neck symptoms, compared with standard 3D-CRT in patients with HNSCC.

de Arruda and colleagues reported on their experience treating 50 patients with oropharyngeal cancer (78% stage IV) with IMRT between 1998 and 2004. (9) Eighty-six percent also received chemotherapy. This study found 2-year progression-free survival of 98% and regional progression-free survival of 88%, results similar to the 85% to 90% rates for locoregional control reported in other published studies. The rate for grade 2 xerostomia was 60% for acute and 33% for chronic (after 9 months or more of follow-up); these rates are lower than the 60% to 75% generally reported with RT.

Hoppe et al. reported on experience treating 37 patients with cancer of the paranasal sinuses, nasal cavity, and lacrimal glands with postoperative IMRT between 2000 and 2007. (10) In this report with 28-month median follow-up, there was no early or late grade 3 or 4 radiation–induced opthalmologic toxicity. Two-year local progression-free survival was 75%, and overall survival (OS) was 80%.

Braam et al. reported on a Phase II study that compared IMRT to conventional RT in oropharyngeal cancer. (11) This study appeared to use 2D RT. The mean dose to the parotid glands was 48 Gy for RT and 34 Gy for IMRT. Both stimulated parotid flow rate, and parotid complications (more than 25% decrease in flow rate) were greater in the RT group. At 6 months after treatment, 56% of IMRT patients and 81% of RT patients were found to have parotid complications.

Rusthoven and colleagues compared outcomes with use of IMRT and 3D-CRT in patients with oropharyngeal cancer. (12) In this study, in which 32 patients were treated with IMRT and 23 with 3D-CRT, late xerostomia occurred in 15% of the IMRT patients and 94% of the 3D-CRT patients. There was also a trend toward improved locoregional control of the tumor with IMRT.

Hodge and colleagues compared outcomes for patients with oropharyngeal cancer in the pre-IMRT era to those obtained in the IMRT era. (13) In this study of 52 patients treated by IMRT, the late xerostomia rate was 56% in the IMRT patients, compared to 63% in those who did not receive IMRT. The authors noted that outcomes in these patients improved at their institution since the introduction of IMRT but that multiple factors may have contributed to this change. They also noted that even in the IMRT-era, the parotid-sparing benefit of IMRT cannot always be used, for example, in patients with bulky primary tumors and/or bilateral upper cervical disease.

Rades et al. reported on 148 patients with oropharyngeal cancer treated with RT. (14) In this study, late xerostomia was noted in 17% of those treated with IMRT compared with 73% of those who received 3D-CRT and 63% of those who received standard radiation therapy.
Thyroid Cancer
Studies on use of IMRT for thyroid cancers are few. In thyroid cancer, radiation therapy is generally used for 2 indications. The first indication is treatment of anaplastic thyroid cancer, and the second indication is potential use for locoregional control in patients with incompletely resected high-risk or recurrent differentiated (papillary, follicular, or mixed papillary-follicular) thyroid cancer. Anaplastic thyroid cancer occurs in a minority (less than 5%) of thyroid cancer. The largest series comparing IMRT to 3D-CRT was published by Bhatia and colleagues. (15) This study reviewed institutional outcomes for anaplastic thyroid cancer treated with 3D-CRT or IMRT for 53 consecutive patients. Thirty-one (58%) patients were irradiated with curative intent. Median radiation dose was 55 gray (Gy; range, 4-70 Gy). Thirteen (25%) patients received IMRT to a median 60 Gy (range, 39.9-69.0 Gy). The Kaplan-Meier estimate of overall survival (OS) at 1 year for definitively irradiated patients was 29%. Patients without distant metastases receiving 50 Gy or higher had superior survival outcomes; in this series, use of IMRT versus 3D-CRT did not influence toxicity. The authors concluded that outcomes for anaplastic thyroid cancer treated with 3D-CRT or IMRT remain equivalent to historic results and that healthy patients with localized disease who tolerate full-dose irradiation can potentially enjoy prolonged survival. Schwartz and colleagues reviewed institutional outcomes for patients treated for differentiated thyroid cancer with postoperative conformal external-beam radiotherapy. (16) This was a single-institution retrospective review of 131 consecutive patients with differentiated thyroid cancer who underwent RT between January 1996 and December 2005. Histologic diagnoses included 104 papillary, 21 follicular, and 6 mixed papillary-follicular types. Thirty-four patients (26%) had high-risk histologic types and 76 (58%) had recurrent disease. Extraglandular disease spread was seen in 126 patients (96%), microscopically positive surgical margins were seen in 62 patients (47%), and gross residual disease was seen in 15 patients (11%). Median RT dose was 60 Gy (range, 38-72 Gy). Fifty-seven patients (44%) were treated with IMRT to a median dose of 60 Gy (range, 56-66 Gy). Median follow-up was 38 months (range, 0-134 months). Kaplan-Meier estimates of locoregional relapse-free survival, disease-specific survival, and OS at 4 years were 79%, 76%, and 73%, respectively. On multivariate analysis, high-risk histologic features, M1 (metastatic) disease, and gross residual disease were predictors for inferior disease-specific and OS. IMRT did not impact survival outcomes but was associated with less frequent severe late morbidity (12% vs. 2%, respectively), primarily esophageal stricture. The authors concluded that conformal external-beam radiotherapy provides durable locoregional disease control for patients with high-risk differentiated thyroid cancer if disease is reduced to microscopic burden and that IMRT may reduce chronic radiation morbidity, but additional study is required.

Ongoing Clinical Trials
A search of online site Clinicaltrials.gov identified many studies on IMRT for head and neck cancers. In a randomized Phase III trial, IMRT is being compared to conventional radiation therapy for patients with oropharyngeal or hypopharyngeal cancer who are at risk of developing xerostomia (NCT00081029). IMRT is being compared with 3D-CRT in another randomized Phase III trial to determine hearing loss outcomes in patients who have undergone parotid tumor surgery (NCT01216800). Several other studies will evaluate IMRT with and without chemotherapy or monoclonal antibodies for head and neck tumors. No clinical trials on IMRT for thyroid cancer were identified.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 2 physician specialty societies (3 reviewers) and 4 academic medical centers while this policy was under review in 2012. There was uniform consensus in responses that suggested IMRT is appropriate for the treatment of head and neck cancers. There was near-uniform consensus in responses that suggested IMRT is appropriate in select patients with thyroid cancer. Respondents noted IMRT for head, neck, and thyroid tumors may reduce the risk of exposure to radiation in critical nearby structures such as the spinal cord and salivary glands, thus decreasing
risks of adverse effects such as xerostomia and esophageal stricture. Given the possible adverse events that could result if nearby critical structures receive toxic radiation doses, IMRT dosimetric improvements should be accepted as meaningful evidence for its benefit.

Summary
Radiation therapy is an integral component in the treatment of head and neck cancers. Intensity-modulated radiation therapy (IMRT) has been proposed as a method of radiation therapy that allows adequate radiation therapy to the tumor while minimizing the radiation dose to surrounding normal tissues and critical structures.

In general, the evidence to assess the role of IMRT in the treatment of cancers of the head and neck suggests that IMRT provides tumor control rates comparable to existing radiotherapy techniques. In addition, while results are not uniform across all studies, the majority of the studies show a marked improvement in the rate of late xerostomia, a clinically significant complication of radiation therapy that leads to decreased quality of life for patients. Thus, based on the published literature that provides data on outcomes of treatment, IMRT is a radiation therapy technique that can be used in the treatment of head and neck cancers. Clinical input also provided uniform consensus that IMRT is appropriate for the treatment of head and neck cancers. Therefore, its use in this clinical application may be considered medically necessary.

There are limited data on use of IMRT for thyroid cancer. The published literature consists of small case series with limited comparison among techniques for delivering radiation therapy. Due to the limitations in this evidence, clinical input was obtained. There was near-uniform consensus that the use of IMRT for thyroid tumors may be appropriate in some circumstances such as for anaplastic thyroid carcinoma or for thyroid tumors that are located near critical structures such as the salivary glands or spinal cord. When possible adverse events could result if nearby critical structures receive toxic radiation doses, the ability to improve dosimetry with IMRT should be accepted as meaningful evidence for its benefit. The results of the vetting, together with a strong indirect chain of evidence and the potential to reduce harms, led to the decision that IMRT may be considered medically necessary for the treatment of thyroid cancers in close proximity to organs at risk (esophagus, salivary glands, and spinal cord) and 3-dimensional conformal radiation (3-D CRT_ planning is not able to meet dose volume constraints for normal tissue tolerance.

Practice Guidelines and Position Statements
The National Comprehensive Cancer Network (NCCN) guidelines on head and neck cancers comment that, in order to minimize dose to critical structures, either IMRT or 3D-CRT is recommended for cancers of the oropharynx and nasopharynx, and maxillary sinus or paranasal/ethmoid sinus tumors. The guidelines also indicate: “[t]he application of IMRT to other sites (e.g., oral cavity, larynx, hypopharynx, salivary glands) is evolving and may be used at the discretion of the treating physicians.” (17) NCCN guidelines for thyroid cancer state that when considering external-beam radiation therapy for the treatment of anaplastic thyroid cancer, IMRT may be useful to reduce toxicity. (18)

The American College of Radiology and the American Society for Therapeutic Radiation and Oncology note IMRT is a widely used treatment option for many indications including head and neck tumors. (19)

The National Cancer Institute (NCI) indicates IMRT may be appropriate for head and neck cancers in several instances. For radiation of cervical lymph nodes (for primary cancer of unknown origin) and untreated primary occult metastatic squamous neck cancer, IMRT may have less short- and long-term toxicity than conventional radiation therapy in terms of xerostomia, acute dysphagia, and skin fibrosis. (20, 21) For nasopharyngeal cancer, the NCI indicates IMRT results in a lower incidence of xerostomia and may provide a better quality of life than conventional 3-D or 2-D radiation therapy. (22) IMRT may also be appropriate in select cases of recurrent nasopharyngeal cancer per the NCI. (22) Finally, to prevent or reduce the extent of salivary gland hypofunction and xerostomia, the NCI indicates parotid-sparing IMRT is recommended as a standard approach in head and neck cancers, if oncologically feasible. (23)
Medicare National Coverage
There is no national coverage determination.

References
Rationale for Brain Cancers
The published evidence is limited mainly to feasibility studies of IMRT for malignant glioma including 1 open, nonrandomized comparison of 25 patients who received IMRT and 60 patients who received EBI, and 8 case series (n=10 to 58). The results of the comparative study showed a benefit of IMRT compared with conventional EBI (progression-free survival at 2 years, 53.6% versus 17.6%; and overall survival at 2 years, 56% versus 19%). IMRT was associated with a higher failure rate due to CSF dissemination although the difference from the EBI group was not statistically significant. However, in the uncontrolled case series, the survival times (median 7 to 14.4 months) were similar to those achieved historically with conventional EBI (median 8 to 14 months). In most of the case series studies, the majority of patients had local tumor recurrence by the end of the study. IMRT did not improve time to disease progression compared with conventional EBI. In both the case series and the comparative study, IMRT was generally well tolerated with few major adverse effects reported. No late toxicity was reported; however, such effects can be missed when survival times are relatively short.

Based on an analysis of the limited available evidence, it is difficult to determine whether IMRT improves survival compared with EBI despite the fact that the comparative study showed a positive effect since in all of the case series, IMRT displayed similar efficacy as EBI. No definitive conclusions can be drawn about the efficacy and safety of the IMRT for malignant gliomas in the absence of data from well-designed randomized controlled trials. However, the shorter treatment duration for hypofractionated regimens (2 or 4 weeks versus 6 weeks or longer) and the possible reduction in toxicity of IMRT compared with EBI may provide some palliative benefits for these patients who have a limited life expectancy. There are no published standards regarding its use (optimal technique, fraction size, dose, duration, etc.), which are also needed for a rigorous assessment of the value of IMRT for malignant glioma.

Reference:

Billing Coding/Physician Documentation Information
0073T 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
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
Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session

Stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy

**Additional Policy Key Words**

N/A

**Policy Implementation/Update Information**

11/1/09 New policy; may be considered medically necessary.
1/1/10 Coding updated.
11/1/10 Policy statement revised to include primary and malignant brain cancers as medically necessary.
1/1/11 Policy statement revised to include IMRT for thyroid cancer as investigational.
11/1/11 Policy statement on brain cancer corrected from “malignant” to “metastatic.”
11/1/12 Policy statement on thyroid tumors changed - may be medically necessary for the treatment of thyroid cancers in close proximity to organs at risk (esophagus, salivary glands and spinal cord) and 3-D CRT planning is not able to meet dose volume constraints for normal tissue tolerance.
11/1/13 No policy statement changes.

State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.