Policy Statement

Intensity-modulated radiotherapy may be considered medically necessary for the treatment of tumors of the central nervous system when the tumor is proximate to organs at risk (brain stem, spinal cord, cochlea and eye structures including optic nerve and chiasm, lens and retina) and 3-dimensional conformal radiotherapy planning is not able to meet dose-volume constraints for normal tissue tolerance (see Policy Guidelines section).

Intensity-modulated radiotherapy is considered investigational for the treatment of tumors of the central nervous system for all indications not meeting the criteria above.

Policy Guidelines

Organs at risk are defined as normal tissues whose radiation sensitivity may significantly influence treatment planning and/or prescribed radiation dose. Organs at risk may be particularly vulnerable to clinically important complications from radiation toxicity. Table PG1 outlines radiation doses generally considered tolerance thresholds for these normal structures in the central nervous system. Dosimetry plans may be reviewed to demonstrate that radiation by 3-dimensional conformal radiotherapy would exceed tolerance doses to structures at risk.

Table PG1. Radiation Tolerance Doses for Normal Tissues

<table>
<thead>
<tr>
<th>Site</th>
<th>TD 5/5, Graya</th>
<th>TD 50/5, Grayb</th>
<th>Complication End Point</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1/3</td>
<td>2/3</td>
<td>3/3</td>
</tr>
<tr>
<td>Brain stem</td>
<td>60</td>
<td>53</td>
<td>50</td>
</tr>
<tr>
<td>Spinal cord, cm</td>
<td>50 (5-10)</td>
<td>NP</td>
<td>47 (20)</td>
</tr>
<tr>
<td>Optic nerve and chiasm</td>
<td>50</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>Retina</td>
<td>45</td>
<td>45</td>
<td>45</td>
</tr>
<tr>
<td>Eye lens</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
</tbody>
</table>


Radiation tolerance doses for the cochlea have been reported to be 50 gray. NP: not provided; TD: tolerance dose.

a TD 5/5 is the average dose that results in a 5% complication risk within 5 years.
b TD 50/5 is the average dose that results in a 50% complication risk within 5 years.

Intensity modulated radiation therapy may be covered for a diagnosis that is listed as investigational, not medically necessary, or not identified, for unusual cases when at least one of the following conditions are present:

- The target volume is in close proximity to critical structures that must be protected and both of the following: *(see Source below)*
  - Planned 3D-CRT exposure to critical adjacent structures is above normal tissue constraints
  - Planned IMRT exposure to these critical adjacent structures does not exceed normal tissue constraints
- An immediately adjacent area has been previously irradiated and abutting portals must be established with high precision
Requests for the above exceptions and all other indications not discussed in this policy will be reviewed on a case-by-case basis.

*The following Normal Tissue Constraint Guidelines are derived from the textbook: Radiation Oncology: A Question-Based Review published by Lippincott Williams & Wilkins, 2010 [author: Hristov et al., 2010]). According to the author, most dosages were derived from randomized studies or consensus guidelines however; pediatric dose constraints will vary greatly from protocol to protocol. Sources used in the development of the guidelines included the American Brachytherapy Society (ABS); Clinical practice guidelines from Johns Hopkins Hospital (JHH); the International Journal of Radiation Oncology *Biology* Physics (IJROBP); the National Comprehensive Cancer Network (NCCN), Quantitative Analyses of Normal Tissue Effects in the Clinic (QUANTEC); and the Radiation Therapy Oncology Group (RTOG) protocols at the time of publication.

The following guidelines are only intended to serve as a guide and may not be applicable to all clinical scenarios.

<table>
<thead>
<tr>
<th>Organ</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Central Nervous System (1.8-2.0 Gray/fraction [Gy/fx])</strong></td>
<td></td>
</tr>
<tr>
<td>• Spinal Cord</td>
<td>max 50 Gy (full cord cross-section); tolerance increases by 25% 6 mos after 1st course (for re-irradiation)</td>
</tr>
<tr>
<td>• Brain</td>
<td>max 72 Gy (partial brain); avoid &gt;2 Gy/fx or hyperfractionation</td>
</tr>
<tr>
<td>• Chiasm/Optic Nerves</td>
<td>max 55 Gy</td>
</tr>
<tr>
<td>• Brainstem</td>
<td>Entire brainstem &lt;54 Gy, V59 Gy &lt;1-10 cc</td>
</tr>
<tr>
<td>• Eyes (globe)</td>
<td>mean &lt;35 Gy, max 54 Gy</td>
</tr>
<tr>
<td>• Lens</td>
<td>max 7 Gy</td>
</tr>
<tr>
<td>• Retina</td>
<td>max 50 Gy</td>
</tr>
<tr>
<td>• Lacrimal Gland</td>
<td>max 40 Gy</td>
</tr>
<tr>
<td>• Inner ear/cochlea</td>
<td>mean &lt;45 Gy (consider constraining to &lt;35 Gy with concurrent cisplatin)</td>
</tr>
<tr>
<td>• Pituitary gland</td>
<td>max 45 Gy (for panhypopituitarism, lower for GH deficiency)</td>
</tr>
<tr>
<td>• Cauda equina</td>
<td>max 60 Gy</td>
</tr>
<tr>
<td><strong>Central Nervous System (single fraction)</strong></td>
<td></td>
</tr>
<tr>
<td>• Spinal Cord</td>
<td>max 13 Gy (if 3 fxs, max 20 Gy)</td>
</tr>
<tr>
<td>• Brain</td>
<td>V12 Gy &lt;5-10 cc</td>
</tr>
<tr>
<td>• Chiasm/Optic Nerves</td>
<td>max 10 Gy</td>
</tr>
<tr>
<td>• Brainstem</td>
<td>max 12.5 Gy</td>
</tr>
<tr>
<td>• Sacral plexus</td>
<td>V18 &lt;0.035 cc, V14.4 &lt;5 cc</td>
</tr>
<tr>
<td>• Cauda equina</td>
<td>V16 &lt;0.035 cc, V14 &lt;5 cc</td>
</tr>
<tr>
<td><strong>Head and Neck (1.8-2.0 Gy/fx)</strong></td>
<td></td>
</tr>
<tr>
<td>• Parotid gland(s)</td>
<td>mean &lt;25 Gy (both glands) or mean &lt;20 Gy (1 gland)</td>
</tr>
<tr>
<td>• Submandibular gland(s)</td>
<td>mean &lt;35 Gy</td>
</tr>
<tr>
<td>• Larynx</td>
<td>mean &lt;44 Gy, V50 &lt;27%, max 63-66 Gy (when risk of tumor involvement is limited)</td>
</tr>
<tr>
<td>• TMJ/mandible</td>
<td>max 70 Gy (if not possible, then V75 &lt;1 cc)</td>
</tr>
<tr>
<td>• Oral cavity</td>
<td>Non-oral cavity cancer: mean &lt;30 Gy, avoid hot spots &gt;60 Gy Oral cavity cancer: mean &lt;50 Gy, V55 &lt;1 cc, max 65 Gy</td>
</tr>
<tr>
<td>• Esophagus (cervical)</td>
<td>V45 &lt;33%</td>
</tr>
<tr>
<td>• Pharyngeal constrictors</td>
<td>mean &lt;50 Gy</td>
</tr>
<tr>
<td>• Thyroid</td>
<td>V26 &lt;20%</td>
</tr>
<tr>
<td><strong>Thoracic (1.8-2.0 Gy/fx)</strong></td>
<td></td>
</tr>
<tr>
<td>• Brachial plexus</td>
<td>max 66 Gy, V60 &lt;5%</td>
</tr>
<tr>
<td>• Lung (combined lung for lung cancer treatment)</td>
<td>mean &lt;20-23 Gy, V20 &lt;30%-35%</td>
</tr>
</tbody>
</table>
### Organ Constraints

<table>
<thead>
<tr>
<th>Organ</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung (ipsilateral lung for breast cancer treatment)</td>
<td>V25 &lt;10%</td>
</tr>
<tr>
<td>Single lung (after pneumonectomy)</td>
<td>V5 &lt;60%, V20 &lt;4-10%, MLD &lt;8 Gy</td>
</tr>
<tr>
<td>Bronchial tree</td>
<td>max 80 Gy</td>
</tr>
<tr>
<td>Heart (lung cancer treatment)</td>
<td>Heart V45 &lt;67%, V60 &lt;33%</td>
</tr>
<tr>
<td>Heart (breast cancer treatment)</td>
<td>V25 &lt;10%</td>
</tr>
<tr>
<td>Esophagus</td>
<td>V50 &lt;32%, V60 &lt;33%</td>
</tr>
</tbody>
</table>

### Thoracic (hypofractionation)

Note: the max dose limits refer to volumes >0.035 cc (~3 mm³).

#### Spinal cord
- 1 fraction: 14 Gy
- 3 fractions: 18 Gy (6 Gy/fx)
- 4 fractions: 26 Gy (6.5 Gy/fx)
- 5 fractions: 30 Gy (6 Gy/fx)

#### Esophagus
- 1 fraction: 15.4 Gy
- 3 fractions: 30 Gy (10 Gy/fx)
- 4 fractions: 30 Gy (7.5 Gy/fx)
- 5 fractions: 32.5 Gy (6.5 Gy/fx)

#### Brachial plexus
- 1 fraction: 17.5 Gy
- 3 fractions: 21 Gy (7 Gy/fx)
- 4 fractions: 27.5 Gy (6.8 Gy/fx)
- 5 fractions: 30 Gy (6 Gy/fx)

#### Heart/Pericardium
- 1 fraction: 22 Gy
- 3 fractions: 30 Gy (10 Gy/fx)
- 4 fractions: 34 Gy (8.5 Gy/fx)
- 5 fractions: 35 Gy (7 Gy/fx)

#### Great vessels
- 1 fraction: 37 Gy
- 3 fractions: 39 Gy (13 Gy/fx)
- 4 fractions: 49 Gy (12.25 Gy/fx)
- 5 fractions: 55 Gy (11 Gy/fx)

#### Trachea/Large Bronchus
- 1 fraction: 20.2 Gy
- 3 fractions: 30 Gy (10 Gy/fx)
- 4 fractions: 34.8 Gy (8.7 Gy/fx)
- 5 fractions: 40 Gy (8 Gy/fx)

#### Rib
- 1 fraction: 30 Gy
- 3 fractions: 30 Gy (10 Gy/fx)
- 4 fractions: 32 Gy (7.8 Gy/fx)
- 5 fractions: 32.5 Gy (6.5 Gy/fx)

#### Skin
- 1 fraction: 26 Gy
- 3 fractions: 30 Gy (10 Gy/fx)
- 4 fractions: 36 Gy (9 Gy/fx)
- 5 fractions: 40 Gy (8 Gy/fx)

#### Stomach
- 1 fraction: 12.4 Gy
- 3 fractions: 27 Gy (9 Gy/fx)
- 4 fractions: 30 Gy (7.5 Gy/fx)
- 5 fractions: 35 Gy (7 Gy/fx)

### Gastrointestinal (GI) (1.8–2.0 Gy/fx)

#### Stomach
- TD 5/5 whole stomach: 45 Gy

#### Small bowel
- V45 <195 cc

#### Liver (metastatic disease)
- mean liver <32 Gy (liver = normal liver minus gross disease)

#### Liver (primary liver cancer)
- mean liver <28 Gy (liver = normal liver minus gross disease)

#### Colon
- 45 Gy, max dose 55 Gy

#### Kidney (bilateral)
- mean <18 Gy, V28 <20%, V23 Gy <30%, V20 <32%, V12 <55%. If mean kidney dose to 1 kidney >18 Gy, then constrain remaining kidney to V6 <30%

### Gastrointestinal (GI) (single fraction)
8.01.59  Intensity-Modulated Radiotherapy: Central Nervous System Tumors

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<table>
<thead>
<tr>
<th>Organ</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Duodenum</td>
<td>V16 &lt;0.035 cc, V11.2 &lt;5 cc</td>
</tr>
<tr>
<td>• Kidney (Cortex)</td>
<td>V8.4 &lt;200 cc</td>
</tr>
<tr>
<td>• Kidney (Hilum)</td>
<td>V10.6 &lt;66%</td>
</tr>
<tr>
<td>• Colon</td>
<td>V14.3 &lt;20 cc, V18.4 &lt;0.035 cc</td>
</tr>
<tr>
<td>• Jejunum/Ileum</td>
<td>V15.4 &lt;0.035 cc, V11.9 &lt;5 cc</td>
</tr>
<tr>
<td>• Stomach</td>
<td>V16 &lt;0.035 cc, V11.2 &lt;10 cc</td>
</tr>
<tr>
<td>• Rectum</td>
<td>V18.4 &lt;0.035 cc, V14.3 &lt;20 cc</td>
</tr>
</tbody>
</table>

### Genitourinary (GU) (1.8-2.0 Gy/fx)

<table>
<thead>
<tr>
<th>Organ</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Femoral heads</td>
<td>V50 &lt;5%</td>
</tr>
<tr>
<td>• Rectum</td>
<td>V75 &lt;15%, V70 &lt;20%, V65 &lt;25%</td>
</tr>
<tr>
<td></td>
<td>V60 &lt;35%, V50 &lt;50%</td>
</tr>
<tr>
<td>• Bladder</td>
<td>V80 &lt;15%, V75 &lt;25%, V70 &lt;35%</td>
</tr>
<tr>
<td></td>
<td>V65 &lt;50%</td>
</tr>
<tr>
<td>• Testis</td>
<td>V3 &lt;50%</td>
</tr>
<tr>
<td>• Penile bulb</td>
<td>Mean dose to 95% of the volume &lt;50 Gy, D70 ≤70 Gy, D50 ≤50 Gy</td>
</tr>
</tbody>
</table>

### Genitourinary (GU) (LDR prostate brachytherapy)

<table>
<thead>
<tr>
<th>Organ</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Urethra</td>
<td>Volume of urethra receiving 150% of prescribed dose (Ur150) &lt;30%</td>
</tr>
<tr>
<td>• Rectum</td>
<td>Volume of rectum receiving 100% of prescribed dose (RV100) &lt;0.5 cc</td>
</tr>
</tbody>
</table>

### Gynecological (GYN)

<table>
<thead>
<tr>
<th>Organ</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Bladder point (cervical brachytherapy)</td>
<td>Max 80 Gy (LDR equivalent dose)</td>
</tr>
<tr>
<td>• Rectal point (cervical brachytherapy)</td>
<td>Max 75 Gy (LDR equivalent dose)</td>
</tr>
<tr>
<td>• Proximal vagina (mucosa) (cervical brachytherapy)</td>
<td>Max 120 Gy (LDR equivalent dose)</td>
</tr>
<tr>
<td>• Distal vagina (mucosa) (cervical brachytherapy)</td>
<td>Max 98 Gy (LDR equivalent dose)</td>
</tr>
</tbody>
</table>

### Coding

The following CPT codes are used for simple and complex intensity-modulated radiotherapy (IMRT) delivery:

- **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

The Centers for Medicare & Medicaid Services did not implement these CPT codes and instead created HCPCS G codes with the language of the previous CPT codes. Therefore, the following codes may be used for IMRT:

- **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

Code 77301 remains valid:

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

The following CPT code may also be used:

- **77338**: Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan

Code 77338 is to be reported only once per IMRT plan.
Description

Radiotherapy is an integral component of treating many brain tumors, both benign and malignant. Intensity-modulated radiotherapy (IMRT) is a method that allows adequate radiation to the tumor while minimizing the dose to surrounding normal tissues and critical structures. IMRT also allows additional radiation to penetrate specific anatomic areas simultaneously, delivering radiation at a larger target volume.

Related Policies

- Charged-Particle (Proton or Helium Ion) Radiotherapy for Neoplastic Conditions
- Hematopoietic Cell Transplantation for Central Nervous System Embryonal Tumors and Ependymoma
- Intensity-Modulated Radiotherapy: Cancer of the Head and Neck or Thyroid
- Intracavitary Balloon Catheter Brain Brachytherapy for Malignant Gliomas or Metastasis to the Brain
- Intraoperative Radiotherapy
- Stereotactic Radiosurgery and Stereotactic Body Radiotherapy
- Tumor Treatment Fields Therapy for Glioblastoma

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. 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.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

A number of devices for use in IMRT, including several linear accelerators and MLCs, have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process. Examples of approved devices and systems are the NOMOS Slit Collimator (BEAK™; NOMOS), the Peacock™ System (NOMOS), the Varian Multileaf Collimator with dynamic arc therapy feature (Varian Oncology Systems), the Satume Multileaf Collimator (GE Medical Systems), the Mitsubishi 120 Leaf Multileaf Collimator (Mitsubishi Electronics America), 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).

Rationale

Background

Radiotherapy And Brain Tumors

The standard approach to treat brain tumors depends on the type and location of the tumor. For glioblastoma multiforme, a high-grade malignant tumor, treatment is multimodal, with surgical resection followed by adjuvant radiotherapy (RT) and chemotherapy.¹
For benign and low-grade brain tumors, gross total resection remains the primary goal. However, RT may be used in select cases. Some examples are: when total resection is not possible, when a more conservative surgical approach may be necessary to achieve long-term treatment goals, and when atypical tumors may need RT even after gross total resection to reduce the risk of local recurrence. Therefore, RT, either definitive or in the postoperative adjuvant setting, remains an integral component in the management of residual, recurrent, and/or progressive benign and low-grade brain tumors for maximizing local control.2

Brain metastases occur in up to 40% of adults with cancer and can shorten survival and detract from the quality of life. Many patients who develop brain metastases will die of progressive intracranial disease. Among patients with good performance status, controlled extracranial disease, favorable prognostic features, and a solitary brain metastasis, randomized studies have shown that surgical excision followed by whole-brain radiotherapy (WBRT) prolongs survival.3 Stereotactic radiosurgery can replace surgery in certain circumstances, delivering obliteratively high single doses to discrete metastases.3 For bulky cerebral metastases, level 1 evidence has also shown that delivering a higher radiation dose with an SRS boost is beneficial in addition to standard WBRT. The use of a concomitant boost with intensity-modulated radiotherapy (IMRT) during WBRT has been attempted to improve overall local tumor control without the use of stereotactic radiosurgery to avoid additional planned radiation after WBRT (“phase 2” or SRS) and its additional labor and expense.3 Another indication for the use of IMRT in WBRT is to avoid radiation exposure to the hippocampus. It is thought that avoiding the hippocampus may minimize cognitive decline associated with WBRT.

Radiotherapy Techniques
Conventional External-Beam Radiotherapy
Methods to plan and deliver RT 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 radiotherapy.

Three-Dimensional Conformal Radiotherapy
Treatment planning evolved by using 3-dimensional images, typically 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 radiotherapy (3D-CRT).

Intensity-Modulated Radiotherapy
IMRT, which uses computer software and CT and magnetic resonance images, offers better conformality than 3D-CRT because it modulates the intensity of the overlapping radiation beams projected on the target and uses 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 beam 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 developments have produced advanced techniques that may further improve RT treatment by improving dose distribution. These techniques are considered variations of IMRT. Volumetric modulated arc therapy delivers radiation from a continuous rotation of the radiation source. The principal advantage of volumetric modulated arc therapy 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 deliver RT to the target volume more precisely.

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.

Literature Review
Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Multiple dose-planning studies generate 3-dimensional conformal radiotherapy (3D-CRT) and intensity-modulated radiotherapy (IMRT) treatment plans from the same scans and then compare predicted dose distributions within the target area and adjacent organs. Results of such planning studies have shown that IMRT is better than 3D-CRT with respect to conformity to, and dose homogeneity within, the target. Results have also demonstrated that IMRT spreads less radiation to nontarget areas. Dosimetry studies using stationary targets generally confirm these predictions. However, because patients move during treatment, dosimetry with stationary...
targets only approximate actual radiation doses received. Based on these dosimetry studies, radiation oncologists expect IMRT to improve treatment outcomes compared with those of 3D-CRT.

Comparative studies of radiation-induced adverse events from IMRT vs alternative radiation delivery would constitute definitive evidence of establishing the benefit of IMRT. Single-arm series of IMRT can give some insights into the potential for benefit, particularly if an adverse event 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, absent such comparative trials, it is likely that benefit from IMRT is at least as good as with other types of delivery.

In general, when the indication for IMRT is to avoid radiation to sensitive areas, dosimetry studies have been considered sufficient evidence to demonstrate that harm would be avoided by using IMRT. For other IMRT indications, such as using IMRT to provide better tumor control, comparative studies of health outcomes are needed to demonstrate such a benefit.

**Malignant Brain Tumors**

**Clinical Context and Therapy Purpose**

The purpose of IMRT in patients who have malignant brain tumors is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does treatment with IMRT improve health outcomes in individuals with malignant brain tumors?

The following PICOTS were used to select literature to inform this review.

**Patients**

The relevant population of interest is individuals with malignant brain tumors.

**Interventions**

The therapy being considered is IMRT.

**Comparators**

The following therapy is currently being used: 3D-CRT.

**Outcomes**

The general outcomes of interest are overall survival (OS), recurrence-free survival (locoregional control), reductions in symptoms, and treatment-related adverse events. A proposed benefit of IMRT is to reduce toxicity to adjacent structures, allowing dose escalation to the target area and fewer breaks in treatment courses due to a reduction in side effects. However, this may come with a loss of locoregional control and OS due to factors discussed above.

**Timing**

The time frame for outcome measures varies from short-term management of toxicity and symptoms to long-term procedure-related complications, cancer progression or recurrence, and OS.

**Setting**

IMRT is usually administered in an outpatient oncology setting.

**Systematic Reviews**

Amelio et al (2010) conducted a systematic review of the clinical and technical issues of using IMRT in newly diagnosed glioblastoma multiforme. Articles were selected through December 2009 and included 17 studies (9 on dosimetric data and technical considerations, 7 on clinical results, 1 on both dosimetric and clinical results) for a total of 204 treated patients and 148
patient datasets used in planning studies. No RCTs were identified, and a meta-analysis was not performed.

For the 6 articles related to planning studies that compared 3D-CRT with IMRT, the report by Fuller et al (2007) showed a noticeable difference between 3D-CRT and IMRT for the planning target volume (PTV; 13% benefit in V95 [volume that received 95% of the prescribed dose] from IMRT, $p < 0.001$); the remaining studies suggested that IMRT and 3D-CRT provided similar PTV coverage, with differences between 0% and 1%. Target dose conformity was improved with IMRT. The organs at risk in the studies typically were the brainstem, optic chiasm, optic nerves, lens, and retina. In general, IMRT provided better sparing of the organs at risk than 3D-CRT but with considerable variation from study to study.

Of the 8 studies that included clinical results, 3 were retrospective; one was a prospective phase 1 study, and 4 were prospective phase 2 single-institution studies. Of these, 2 used conventional total dose and dose per fraction, 2 used a hypofractionated regimen, and the others used a hypofractionated scheme with a simultaneous integrated boost. The median follow-up ranged from 8.8 to 24 months. Almost all patients (96%) completed treatment without interruption or discontinuation due to toxicity. Acute toxicity was reported as negligible, with grade 3 adverse events observed in only 2 studies at rates of 7% and 12%. Grade 4 toxicity was recorded in only 1 series, with an absolute rate of 3%. Data for late toxicities were available in 6 of 8 studies, with one recording grade 4 adverse events with an incidence of 20%. One- and 2-year OS rates varied between 30% and 81.9% and between 0% and 55.6%, respectively. When OS was reported as a median time and ranged from 7 to 24 months. Progression-free survival rates ranged from 0% to 71.4% at 1 year from 0% to 53.6% at 2 years. The median progression-free survival ranged from 2.5 to 12 months.

Reviewers also conducted a comprehensive qualitative comparison using data reported in the literature on similar non-IMRT clinical studies, offering the following conclusions. The planning comparisons revealed that 3D-CRT and IMRT provided similar results in terms of target coverage. IMRT was somewhat better than 3D-CRT in reducing the maximum dose delivered to the organs at risk—although the extent varied by case. IMRT was better than 3D-CRT when it came to dose conformity and sparing of the healthy brain tissue at medium to low doses; there were no aspects where IMRT performed worse than 3D-CRT.

This evidence was limited by a number of factors: there was an absence of comparative studies with clinical outcomes; all studies were small in size, from a single institution; most patients (53%) were retrospectively analyzed; and chemotherapy administration varied across studies.

**Dose-Planning Studies**

A representative sample of dose-planning, case series, and comparative studies are discussed next. For example, MacDonald et al (2007) compared the dosimetry of IMRT with 3D-CRT in 20 patients treated for high-grade glioma. Prescription dose and normal tissue constraints were identical for the 3D-CRT and IMRT treatment plans. The IMRT plan yielded superior target coverage compared with the 3D-CRT plan. The IMRT plan reduced the percent volume of brainstem receiving a dose greater than 45 gray (Gy) by 31% ($p = 0.004$) and the percent volume of brain receiving a dose greater than 18 Gy, 24 Gy, and 45 Gy by 10% ($p = 0.059$), 14% ($p = 0.015$), and 40% ($p < 0.001$), respectively. With IMRT, the percent volume of optic chiasm receiving more than 45 Gy was reduced by 30.4% ($p = 0.047$). Compared with 3D-CRT, IMRT significantly increased the tumor control probability ($p < 0.001$) and lowered the normal tissue complication probability for brain and brainstem ($p < 0.033$).

Narayana et al (2006) compared IMRT treatment plans with 3D plans performed in 20 patients of a case series of 58 patients. Regardless of tumor location, IMRT did not improve PTV compared with 3D planning. However, IMRT decreased the maximum dose to the spinal cord, optic nerves, and eye by 16%, 7%, and 15% respectively.
Nonrandomized Comparison Studies
Paulsson et al (2014) compared treatment failure rates in glioblastoma patients with differing target margins (the size of the region between tumor and edge of the PTV). In 161 patients, treatment margins were not associated with treatment failure. There was no difference in treatment failure rates between IMRT and 3D-CRT.

Section Summary: Malignant Brain Tumors
Dosimetry studies have demonstrated lower radiation exposure to organs at risk with IMRT treatment plans than with 3D-CRT treatment plans. Limited comparative evidence has shown lower rates of hearing loss with IMRT than with conventional RT. The evidence appears to be consistent in supporting lower neurotoxicity associated with IMRT. No conclusions can be made about the efficacy of IMRT compared with conventional RT.

Benign Brain Tumors
Clinical Context and Therapy Purpose
The purpose of IMRT in patients who have benign brain tumors is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does treatment with IMRT improve health outcomes in individuals with benign brain tumors?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest is individuals with benign brain tumors.

Interventions
The therapy being considered is IMRT.

Comparators
The following therapy is currently being used: 3D-CRT.

Outcomes
The general outcomes of interest are OS, recurrence-free survival (locoregional control), reductions in symptoms, and treatment-related adverse events. A proposed benefit of IMRT is to reduce toxicity to adjacent structures, allowing dose escalation to the target area and fewer breaks in treatment courses due to a reduction in side effects. However, this may come with a loss of locoregional control and OS due to factors discussed above.

Timing
The time frame for outcome measures varies from short-term management of toxicity and symptoms to long-term procedure-related complications, cancer progression or recurrence, and OS.

Setting
IMRT is usually administered in an outpatient oncology setting.

Case Series
The evidence for use of IMRT in patients with benign brain tumors consists mostly of case series. Previously discussed dosimetry studies, which evaluated patients with malignant brain tumors, should be generalizable to patients with benign tumors.

Milker-Zabel et al (2007) reported on results of treatment of complex-shaped meningiomas at the skull base with IMRT. Ninety-four patients received RT as primary treatment (n=26), for residual disease after surgery (n=14), or after local recurrence (n=54). Tumor histology, classified using World Health Organization, was grade 1 in 54.3%, grade 2 in 9.6%, and grade 3 in 4.2%.
Median follow-up was 4.4 years. The overall local tumor control rate was 93.6%. After IMRT, 69 patients had stable disease (by computed tomography [CT] or magnetic resonance imaging [MRI]), and 19 had a tumor volume reduction. Six patients had local tumor progression on MRI at a median of 22.3 months after IMRT. In 39.8% of patients, preexisting neurologic deficits improved. Treatment-induced loss of vision was seen in 1 of 53 re-irradiated patients with a grade 3 meningioma 9 months after retreatment with IMRT.

Mackley et al (2007) reported on outcomes of treating pituitary adenomas with IMRT.9 A retrospective chart review was conducted on 34 patients treated between 1998 and 2003. Median follow-up was 42.5 months. Radiographic local control was 89% and, among patients with secretory tumors, 100% had a biochemical response. One patient required salvage surgery for disease progression, resulting in a clinical progression-free survival of 97%. One patient who received more than 46 Gy experienced optic neuropathy 8 months after radiation.

Sajja et al (2005) reported on outcomes for 35 patients with 37 meningiomas treated with IMRT.10 Tumor histology was benign in 35 tumors and atypical in 2 tumors. The median CT with MRI follow-up was 19.1 months (range, 6.4-62.4 months). Fifty-four percent of the meningiomas had received surgery or radiosurgery before IMRT, and 46% were treated with IMRT, primarily after a diagnosis was established by CT or MRI. Three patients had local failure after treatment. No long-term complications from IMRT were documented among the 35 patients.

Section Summary: Benign Brain Tumors
The evidence on IMRT for treating benign brain tumors includes case series. Case series results have consistently shown with low radiation toxicity but have not demonstrated better tumor control or improved survival with IMRT vs other RT techniques. The dose-planning studies evaluating IMRT in patients with malignant tumors should generalize to patients with benign brain tumors because the benefit of minimizing radiation toxicity to sensitive brain areas is identical.

Brain Metastases
IMRT can deliver additional radiation boosts to specific metastases concurrent with whole-brain radiotherapy (WBRT). Clinicians have treated patients using this RT technique rather than treating them separately with WBRT and stereotactic radiosurgery, the latter having been shown to be more effective than WBRT alone in an RCT.

Clinical Context and Therapy Purpose
The purpose of IMRT to avoid hippocampal exposure in patients who have brain metastases is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does treatment with IMRT improve health outcomes in individuals with brain metastases when it is necessary to avoid hippocampal exposure?

The following PICOTS were used to select literature to inform this review.

**Patients**
The relevant population of interest is individuals with brain metastases.

**Interventions**
The therapy being considered is IMRT to avoid hippocampal exposure.

**Comparators**
The following therapy is currently being used: WBRT.

**Outcomes**
The general outcomes of interest are OS, recurrence-free survival, reductions in symptoms, and (locoregional control), reductions in symptoms, and treatment-related adverse events.
proposed benefit of IMRT is to reduce toxicity to adjacent structures, allowing dose escalation to the target area and fewer breaks in treatment courses due to a reduction in side effects. However, this may come with a loss of locoregional control and OS due to factors discussed above.

**Timing**
The time frame for outcome measures varies from short-term management of toxicity and symptoms to long-term procedure-related complications, cancer progression or recurrence, and OS.

**Setting**
IMRT is usually administered in an outpatient oncology setting.

**Nonrandomized Comparative Studies**
Gondi et al (2014) evaluated IMRT as a method to avoid radiation exposure to the hippocampus and prevent adverse cognitive events in patients receiving WBRT. Dosimetry studies had previously established techniques that avoided radiation exposure to this region but still provided coverage and conformality to the remaining brain. Dosimetry studies alone have not been sufficient to establish IMRT as a standard treatment because the toxic effects of radiation to the hippocampus are less well established. The Gondi study was a prospective trial with a prespecified comparison to a historical control group derived from a previously conducted clinical trial. The outcomes were standardized cognitive assessments, and health-related quality of life evaluated at baseline and 2-month intervals (out to 6 months).

Of 100 eligible patients, 42 patients were evaluable at 4 months; 17 patients were alive but did not have cognitive testing, and 41 had died. The mean decline in the primary cognitive end point was 7.0%, which was significantly less than the 30% decline in the historical control group (p<0.001). Median survival in the experimental group was 6.8 months and 4.9 months in the historical control group. Although the trial results suggested that hippocampal-sparing WBRT using IMRT is associated with less cognitive decline, the historical control design adds uncertainty to the conclusion. Because the experimental group had survived longer, even though the radiation dose was intended to be equivalent to the historical control, possible unmeasured patient factors associated with better survival may have also caused less cognitive decline. The trial did not provide conclusive evidence that hippocampal-sparing IMRT causes less cognitive decline.

**Case Series**
A retrospective study by Zhou et al (2014) evaluated the feasibility of WBRT plus simultaneous integrated boost with IMRT for inoperable brain metastases of non-small-cell lung cancer. Twenty-nine non-small-cell lung cancer patients with 87 inoperable brain metastases were included. All patients received WBRT at a dose of 40 Gy and simultaneous integrated boost with IMRT at a dose of 20 Gy concurrent with WBRT in week 4. Prior to each fraction of image-guided IMRT boost, online positioning verification and correction were used to ensure that the set-up errors were within 2 mm by cone beam CT in all patients. The 1-year intracranial control rate, local brain failure rate (BFR), and distant BFR were 63%, 14%, and 19%, respectively. The 2-year intracranial control rate, local BFR, and distant BFR were 42%, 31%, and 36%, respectively. Both the median intracranial progression-free survival and the median OS were 10 months; 6-month, 1-year, and 2-year OS rates were 66%, 41%, and 14%, respectively. Patients had better survival rates when their Score Index for Radiosurgery in Brain Metastases was greater than 5, when they had fewer than 3 intracranial lesions, and when they had a history of epidermal growth factor receptor tyrosine kinase inhibitor treatment. Radiation necrosis was observed in 3 (3.5%) lesions after RT. Grades 2 and 3 cognitive impairment with grade 2 radiation leukoencephalopathy were observed in 4 (14%) patients. No dosimetric parameters were found to be associated with these late toxicities. Patients who received epidermal growth factor receptor tyrosine kinase inhibitor treatment had higher incidences of grades 2 and 3 cognitive impairment with grade 2 leukoencephalopathy. This evidence would suggest WBRT plus simultaneous integrated boost
with IMRT is a tolerable treatment for non-small-cell lung cancer patients with inoperable brain metastases. However, the evidence does not permit conclusions about efficacy.

Section Summary: Brain Metastases
For treatment of brain metastases, IMRT has been investigated as a technique to avoid hippocampal radiation exposure when delivering WBRT and to deliver additional radiation to specific areas of the brain as a substitute for stereotactic radiosurgery. For both indications, studies are not definitive regarding improvements in health outcomes.

Summary of Evidence
For individuals who have malignant brain tumors who receive IMRT, the evidence includes dose-planning studies, nonrandomized comparison studies, and case series. Relevant outcomes are overall survival, disease-specific survival, morbid events, functional outcomes, and treatment-related morbidity. Case series results have consistently shown with low radiation toxicity but have not demonstrated better tumor control or improved survival with IMRT. Dose-planning studies have shown that IMRT delivers adequate radiation doses to tumors while simultaneously reducing radiation exposure to sensitive brain areas. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have benign brain tumors who receive IMRT, the evidence includes case series. Relevant outcomes are overall survival, disease-specific survival, functional outcomes, and treatment-related morbidity. Case series results have consistently shown low radiation toxicity but have not demonstrated better tumor control or improved survival with IMRT vs other radiotherapy techniques. It is expected that the dose-planning studies evaluating IMRT in patients with malignant tumors should generalize to patients with benign brain tumors because the benefit of minimizing radiation toxicity to sensitive brain areas is identical. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have brain tumor metastases who receive IMRT to avoid hippocampal exposure, the evidence includes nonrandomized comparison studies and case series. Relevant outcomes are overall survival, disease-specific survival, functional outcomes, and treatment-related morbidity. One prospective nonrandomized comparison study using IMRT to avoid hippocampal exposure showed a less cognitive decline with IMRT than with a prespecified historical control. Limitations of the historical control design and other aspects of the study make conclusions uncertain. The role of hippocampal radiation exposure as a cause of cognitive decline is less certain; thus, more definitive studies are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information
Clinical Input from 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 from Blue Cross Blue Shield Association, input was received from 3 specialty medical societies (8 reviewers) and 3 academic medical centers (3 reviewers) in 2012. There was near-uniform consensus that intensity-modulated radiotherapy (IMRT) to treat central nervous system tumors should be considered medically necessary, particularly for tumors in close proximity to critical structures. Reviewers considered the evidence sufficient that IMRT be regarded equally effective as 3-dimensional conformal radiotherapy; further, given the possible adverse events that could result if nearby critical structures receive toxic radiation doses (e.g., blindness), IMRT dosimetric improvements should be accepted as meaningful evidence for its benefit.
Practice Guidelines and Position Statements
The National Comprehensive Cancer Network guidelines on central nervous system cancers (v.1.2018) state that: “When RT [radiotherapy] is given to patients with low-grade gliomas, it is administered with restricted margins.... Every attempt should be made to decrease the RT dose outside the target volume. This can be achieved with 3-dimensional planning or intensity-modulated RT (IMRT).”

The guidelines did not address the use of intensity-modulated radiotherapy with high-grade tumors or metastases of the central nervous system.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently unpublished or uncompleted trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCTNo.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
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<tr>
<td>NCT03002532</td>
<td>Whole Brain Irradiation With Hippocampal Sparing for Brain Metastases From Breast Cancer: Neurocognitive Function and Prognosis Analysis</td>
<td>120</td>
<td>Aug 2017 (ongoing)</td>
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<td>NCT02393131</td>
<td>Neurocognitive Outcome of Conformal Whole Brain Radiotherapy With or Without Hippocampal Avoidance for Brain Metastases: A Phase II Single Blind Randomized Trial</td>
<td>60</td>
<td>Dec 2018</td>
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<tr>
<td>NCT02147028</td>
<td>Hippocampal Sparing Whole Brain Radiotherapy vs Conventional Whole Brain Radiotherapy in Patients With Brain Metastases (HIPPO)</td>
<td>84</td>
<td>Dec 2019</td>
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<td>NCT02360215</td>
<td>Memantine Hydrochloride and Whole-Brain Radiotherapy With or Without Hippocampal Avoidance in Reducing Neurocognitive Decline in Patients With Brain Metastases</td>
<td>510</td>
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<td>NCT02635009</td>
<td>Randomized Phase II/III Trial of Prophylactic Cranial Irradiation With or Without Hippocampal Avoidance for Small Cell Lung Cancer</td>
<td>304</td>
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<td><strong>Unpublished</strong></td>
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<td>NCT02832635</td>
<td>A Clinical Trial on Whole-brain Radiotherapy With Temozolomide Concurrent Chemotherapy or Avoidance of Hippocampus for Patients of Brain Metastases</td>
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<td>Dec 2017 (unknown)</td>
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NCT: national clinical trial.

References


**Documentation for Clinical Review**

**Please provide the following documentation (if/when requested):**

- History and physical and radiation oncology consultation report including:
  - Medical necessity for performing IMRT rather than conventional or 3D treatment planning
  - Past history of radiation (site) (if applicable)
  - Past surgical procedures (pertaining to request)
  - Primary cancer type and location
- Goals/requirements of the IMRT treatment plan and proposed IMRT treatment dose (dose volume histogram [DVH] - in color preferred; organs at risk)
- Comparison 3D-CRT dose volume histogram (DVH) (in color preferred; organs at risk) (as applicable)
- Radiology report(s) for the past 2 months

**Post Service**
Procedure report(s)
Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

MN/IE
The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

<table>
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<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
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<tr>
<td>CPT®</td>
<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></td>
<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></td>
<td>77385</td>
<td>Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple</td>
</tr>
<tr>
<td></td>
<td>77386</td>
<td>Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex</td>
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<tr>
<td>HCPCS</td>
<td>G6015</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>
</tr>
<tr>
<td></td>
<td>G6016</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>
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<td>Beam Radiation of Brain using Photons &lt;1 MeV</td>
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Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
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<tr>
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<td>Policy title change from Intensity Modulated Radiation Therapy (IMRT)</td>
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<td>BCBSA Medical Policy adoption</td>
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<td></td>
<td>Policy revision without position change</td>
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<td>10/01/2016</td>
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<tr>
<td>09/01/2018</td>
<td>Policy revision without position change</td>
<td>Medical Policy Committee</td>
</tr>
</tbody>
</table>
Definitions of Decision Determinations

Medically Necessary: A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state government is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.