Policy Statement

Intensity-modulated radiotherapy (IMRT) may be considered **medically necessary** for the treatment of head and neck cancers.

Intensity-modulated radiotherapy (IMRT) may be considered **medically necessary** for the treatment of thyroid cancers in close proximity to organs at risk (esophagus, salivary glands, spinal cord) 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 (IMRT) is considered **not medically necessary** for the treatment of thyroid cancers for all indications not meeting the criteria above.

Policy Guidelines

For this policy, head and neck cancers are those arising from the
- Oral cavity and lip
- Larynx
- Hypopharynx
- Oropharynx
- Nasopharynx
- Paranasal sinuses and nasal cavity
- Salivary glands
- 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. Table PG1 outlines radiation doses that are generally considered tolerance thresholds for these normal structures in the area of the thyroid. Clinical documentation based on dosimetry plans may be used to demonstrate that radiation by 3-dimensional conformal radiotherapy without intensity-modulated 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, Gray</th>
<th>TD 50/5, Gray</th>
</tr>
</thead>
<tbody>
<tr>
<td>Portion of Organ Involved</td>
<td>1/3</td>
<td>2/3</td>
</tr>
<tr>
<td>Esophagus</td>
<td>60</td>
<td>58</td>
</tr>
<tr>
<td>Salivary glands</td>
<td>32</td>
<td>32</td>
</tr>
<tr>
<td>Spinal cord</td>
<td>50 (5-10 cm)</td>
<td>NP</td>
</tr>
</tbody>
</table>


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;45 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>
</tbody>
</table>
### Constraints

<table>
<thead>
<tr>
<th>Organ</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Larynx</td>
<td><strong>mean ≤44 Gy, V50 ≤27%, max 63-66 Gy</strong> (when risk of tumor involvement is limited)</td>
</tr>
<tr>
<td>• TMJ/mandible</td>
<td><strong>max 70 Gy</strong> (if not possible, then V75 &lt;1 cc)</td>
</tr>
<tr>
<td>• Oral cavity</td>
<td>Non-oral cavity cancer: <strong>mean &lt;30 Gy</strong>, avoid hot spots &gt;60 Gy Oral cavity cancer: <strong>mean &lt;50 Gy</strong>, V50 &lt;1 cc, max 65 Gy</td>
</tr>
<tr>
<td>• Esophagus (cervical)</td>
<td><strong>V45 &lt;33%</strong></td>
</tr>
<tr>
<td>• Pharyngeal constrictors</td>
<td><strong>mean &lt;50 Gy</strong></td>
</tr>
<tr>
<td>• Thyroid</td>
<td><strong>V26 &lt;20%</strong></td>
</tr>
</tbody>
</table>

Thoracic (1.8-2.0 Gy/fx)

- **Brachial plexus**
  - max 66 Gy, V60 <5%

- **Lung (combined lung for lung cancer treatment)**
  - **mean <20-23 Gy, V20 <30%-35%**

- **Lung (ipsilateral lung for breast cancer treatment)**
  - **V25 <10%**

- **Single lung (after pneumonectomy)**
  - **V5 <60%, V20 <4-10%, MLD <8 Gy**

- **Bronchial tree**
  - max 80 Gy

- **Heart (lung cancer treatment)**
  - Heart **V45 <67%; V60 <33%**

- **Heart (breast cancer treatment)**
  - **V25 <10%**

- **Esophagus**
  - **V50 <32%; V60 <33%**

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: 27.2 Gy (8.6 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
### Organ Constraints

<table>
<thead>
<tr>
<th>Organ</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small bowel</td>
<td>$V_{45} &lt; 195 \text{ cc}$</td>
</tr>
<tr>
<td>Liver (metastatic disease)</td>
<td>$\text{mean liver} &lt; 32 \text{ Gy}$ (liver = normal liver minus gross disease)</td>
</tr>
<tr>
<td>Liver (primary liver cancer)</td>
<td>$\text{mean liver} &lt; 28 \text{ Gy}$ (liver = normal liver minus gross disease)</td>
</tr>
<tr>
<td>Colon</td>
<td>$45 \text{ Gy}, \text{ max dose} 55 \text{ Gy}$</td>
</tr>
<tr>
<td>Kidney (bilateral)</td>
<td>$\text{mean} &lt; 18 \text{ Gy}, V_{28} &lt; 20%$, $V_{23} &lt; 30%$, $V_{20} &lt; 32%$, $V_{12} &lt; 55%$. If mean kidney dose to 1 kidney $&gt; 18 \text{ Gy}$, then constrain remaining kidney to $V_{6} &lt; 30%$.</td>
</tr>
</tbody>
</table>

#### Gastrointestinal (GI) (single fraction)

<table>
<thead>
<tr>
<th>GI (single fraction)</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duodenum</td>
<td>$V_{16} &lt; 0.035 \text{ cc}, V_{11.2} &lt; 5 \text{ cc}$</td>
</tr>
<tr>
<td>Kidney (Cortex)</td>
<td>$V_{8.4} &lt; 200 \text{ cc}$</td>
</tr>
<tr>
<td>Kidney (Hilum)</td>
<td>$V_{10.6} &lt; 66%$</td>
</tr>
<tr>
<td>Colon</td>
<td>$V_{14.3} &lt; 20 \text{ cc}, V_{18.4} &lt; 0.035 \text{ cc}$</td>
</tr>
<tr>
<td>Jejunum/Ileum</td>
<td>$V_{15.4} &lt; 0.035 \text{ cc}, V_{11.9} &lt; 5 \text{ cc}$</td>
</tr>
<tr>
<td>Stomach</td>
<td>$V_{16} &lt; 0.035 \text{ cc}, V_{11.2} &lt; 10 \text{ cc}$</td>
</tr>
<tr>
<td>Rectum</td>
<td>$V_{18.4} &lt; 0.035 \text{ cc}, V_{14.3} &lt; 20 \text{ cc}$</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>GU (1.8-2.0 Gy/fx)</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Femoral heads</td>
<td>$V_{50} &lt; 5%$</td>
</tr>
<tr>
<td>Rectum</td>
<td>$V_{75} &lt; 15%, V_{70} &lt; 20%, V_{65} &lt; 25%$, $V_{60} &lt; 35%, V_{50} &lt; 50%$</td>
</tr>
<tr>
<td>Bladder</td>
<td>$V_{80} &lt; 15%, V_{75} &lt; 25%, V_{70} &lt; 35%$, $V_{65} &lt; 50%$</td>
</tr>
<tr>
<td>Testis</td>
<td>$V_{3} &lt; 50%$</td>
</tr>
<tr>
<td>Penile bulb</td>
<td>Mean dose to 95% of the volume $&lt; 50 \text{ Gy}$. $D_{70} \leq 70 \text{ Gy}$, $D_{50} \leq 50 \text{ Gy}$</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>GU (LDR prostate brachytherapy)</th>
<th>Constraints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urethra</td>
<td>Volume of urethra receiving 150% of prescribed dose ($U_{150}$) $\leq 30%$</td>
</tr>
<tr>
<td>Rectum</td>
<td>Volume of rectum receiving 100% of prescribed dose ($R_{100}$) $&lt; 0.5 \text{ cc}$</td>
</tr>
</tbody>
</table>

#### Gynecological (GYN)

<table>
<thead>
<tr>
<th>GYN</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 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 (CMS) decided not to implement these CPT codes and instead created HCPCS G codes with the language of the previous CPT codes. The following codes may be used for IMRT:

- **G6015**: Intensity modulated treatment delivery, single or multiple fields/arc(s), 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
Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications

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

Radiotherapy is a component in the treatment of head and neck cancers. Intensity-modulated radiotherapy (IMRT) has been proposed as a method to allow adequate radiation to the tumor, minimizing the radiation dose to surrounding normal tissues and critical structures.

Related Policies

- Charged-Particle (Proton or Helium Ion) Radiotherapy for Neoplastic Conditions
- Stereotactic Radiosurgery and Stereotactic Body Radiotherapy

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

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

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

Radiotherapy treatment planning systems have also been cleared for marketing by the FDA through the 510(k) process. They include the Prowess Panther (Prowess) in 2003, TiGRT (LinaTech) in 2009, and the Ray Dose (RaySearch Laboratories). FDA product code: MUJ.

Fully integrated IMRT systems also are available. These devices are customizable and support all stages of IMRT delivery, including planning, treatment delivery, and health record management. One such device cleared for marketing by the FDA through the 510(k) process is the Varian IMRT system (Varian Medical Systems). FDA product code: IYE.
Rationale

Background
Head and Neck Cancers
This evidence review focuses on cancers affecting 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.

Radiotherapy Techniques
Conventional External-Beam Radiotherapy
Methods to plan and deliver radiotherapy (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, 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 were also 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
Intensity-modulated radiotherapy (IMRT), which uses computer software and CT and magnetic resonance imaging 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 continuously rotating 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 a single imaging scan, a static 3D-CT image. Current methods seek to reduce positional uncertainty on 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.

**Head and Neck Cancers**

**Clinical Context and Test Purpose**

The purpose of intensity-modulated radiotherapy (IMRT) in patients who have head and neck cancers 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 the use of IMRT improve the net health outcome in patients with head and neck cancers?

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

**Patients**

The relevant population of interest is individuals with head and neck cancers. Head and neck cancers account for 3% to 5% of cancer cases in the United States. The generally accepted definition of head and neck cancers includes those 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.
**Interventions**
The test being considered is IMRT. A proposed benefit of IMRT is to reduce toxicity to adjacent structures, allowing dose escalation to the target area and fewer breaks during treatment to reduce side effects.

**Comparators**
The following practices are currently being used to make decisions about the treatment of head and neck cancers: 3-dimensional conformal radiotherapy (3D-CRT) and 2-dimensional radiotherapy (2D-RT).

**Outcomes**
The general outcomes of interest are locoregional control, overall survival (OS), and treatment-related morbidity. Evaluation of patient-reported outcomes and quality of life measures are also of interest.

**Timing**
Locoregional control and OS should be assessed at 1 and 5 years.

**Setting**
IMRT is delivered in tertiary oncology care settings where complex imaging, radiation physics, and treatment planning resources are available.

**Systematic Reviews**
Ursino et al (2017) published a systematic review of 22 studies (total N=1311 patients) evaluating swallowing outcomes in patients treated with 3D-CRT or IMRT for head and neck cancer. The heterogeneity of the population limited analysis, but reviewers concluded that IMRT produced markedly better results than 3D-CRT in terms of swallowing impairments, aspiration, pharyngeal residue, and functional parameters, especially when swallowing-related organs at risk were specifically taken into account during IMRT treatment planning. The analysis was limited by a lack of standardized evaluation questionnaires, objective instrumental parameter scores, amount and consistency of bolus administration, and timing of evaluations.

Marta et al (2014) reported on a systematic review and meta-analysis of 5 prospective phase 3 randomized trials comparing IMRT with 2D-RT or 3D-CRT for head and neck cancer. A total of 871 patients were randomized to IMRT (n=434) or to 2D-RT or 3D-CRT (n=437). Xerostomia grades 2, 3, or 4 were found to be significantly lower in patients treated with IMRT than with 2D-RT and 3D-CRT for all studies (hazard ratio, 0.76; 95% confidence interval, 0.66 to 0.87; p<0.001). Locoregional control and OS were similar across all 3 technologies.

A comparative effectiveness review on radiotherapy for head and neck cancers was published by Samson et al (2010) for the Agency for Healthcare Research and Quality. This report noted that, based on moderate strength evidence, IMRT reduced late xerostomia and improved quality of life domains related to xerostomia compared with 3D-CRT. Reviewers also found that no conclusions on tumor control or survival could be drawn from the evidence. An update, published by Ratko et al (2014), was consistent with and strengthened the findings of the original review on late xerostomia.

**Randomized Controlled Trials**
Of the 5 phase 3 RCTs included in the Marta meta-analysis (2014) meta-analysis, only 1 trial (Gupta et al [2012]) compared IMRT with 3D-CRT. Long-term results from this trial were published by Ghosh-Laskar et al (2016). This trial included 60 patients with squamous cell carcinoma of the head and neck and was powered to detect a 35% difference in toxicity between treatments (85% vs 50%). The proportion of patients with salivary gland toxicity was lower in the IMRT group (59%) than in the 3D-CRT group (69% p=0.009). The percentage of patients with substantial weight loss was significantly lower in the IMRT group at 1 and 2 years. There were no significant differences between the 2 groups for acute dysphagia, mucositis, dermatitis, or requirements for
tube feeding. Xerostomia decreased over follow-up in both groups, but significant differences in late salivary toxicity persisted through 5 years. At 2 years posttreatment, grade 2 or worse xerostomia was 0% in the IMRT group compared with 28% following 3D-CRT (p=0.017). At 5 years, salivary toxicity was 0% in the IMRT group compared with 17% following 3D-CRT (p=0.041). Locoregional control and OS did not differ significantly between groups.

The other 4 RCTs reviewed by Marta et al (2014) compared IMRT with 2D-RT. An RCT by Pow et al (2006) on IMRT for nasopharyngeal carcinoma (NPC) included only 45 patients. Nutting et al (2011) reported on the PARSPORT randomized phase 3 trial, which also compared conventional RT with parotid-sparing IMRT in 94 patients with T1, T2, T3, or T4 tumor stage, and N0, N1, N2, or N3, and M0 nodal stage pharyngeal squamous cell carcinoma. 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 rates continued to be significantly lower 2 years posttreatment in the IMRT group (29% vs 83%, respectively). At 24 months, rates of locoregional control, nonxerostomia late toxicities, and OS did not differ significantly between treatment groups.

Peng et al (2012) compared IMRT with 2D-RT in 616 patients with NPC. At a median follow-up of 42 months (range, 1-83 months), patients in the IMRT group had significantly lower radiation-induced toxicities. The 5-year OS rate was 80% in the IMRT group and 67% in the 2D-CRT group.

Nonrandomized Comparative Studies

Several nonrandomized comparative studies have evaluated late toxicities and quality of life from IMRT, 2D-RT, and 3D-CRT.

Qiu et al (2017) published a retrospective, single-center study comparing 2D-CRT and IMRT as treatments for NPC in children and adolescents. All 176 patients (74 treated with 2D-CRT, 102 with IMRT) identified for the study were between 7 and 20 years old and treated at single institution. The OS rate at 5 years was significantly higher for IMRT than 2D-CRT (90.4% vs 76.1%, respectively; hazard ratio, 0.30; 95% confidence interval, 0.12 to 0.78; p=0.007), as well as the 5-year disease-free survival rate (85.7% vs 71.2%, respectively; hazard ratio, 0.47; 95% confidence interval, 0.23 to 0.94; p=0.029). Grade 2, 3, and 4 xerostomia (52.7% vs 34%, respectively; p=0.015) and hearing loss (40.5% vs 22.5%, respectively; p<0.01) were also significantly lower with IMRT than with 2D-CRT. The duration of follow-up for late-onset radiation-induced toxicity and small sample size are limitations of the report.

A cross-sectional study by Huang et al (2016) assessed patients who had survived more than 5 years after treatment for NPC. Of 585 NPC survivors, data were collected on 242 patients who met study selection criteria (no history of tumor relapse or second primary cancers, cancer-free survival >5 years, completion of the self-reported questionnaire). Treatments were given from 1997 to 2007, with the transition to the IMRT system in 2002. One hundred patients were treated with IMRT. Prior to use of IMRT, treatments included 2D-RT (n=39), 3D-CRT (n=24), and 2D-RT plus 3D-CRT boost (n=79). Patients had scheduled follow-ups at 3- to 4-month intervals until 5 years posttreatment; then, at 6-month intervals thereafter. Late toxicities (e.g., neuropathy, hearing loss, dysphagia, xerostomia, neck fibrosis) were routinely assessed at clinical visits. At the time of the study, the mean follow-up was 8.5 years after 2D-RT or 3D-CRT, and 6.4 years after IMRT. The IMRT group had statistically and clinically superior results for both clinician-assessed and patient-assessed (global quality of life, cognitive functioning, social functioning, fatigue, and 11 scales of a head and neck module) outcomes with moderate effect sizes after adjusting for covariates (Cohen d range, 0.47-0.53). Late toxicities were less severe in the IMRT group, with adjusted odds ratios of 3.2, 4.8, 3.8, 4.1, and 5.3 for neuropathy, hearing loss, dysphagia, xerostomia, and neck fibrosis, respectively. No significant differences in late toxicities were observed between the 2D-RT and the 3D-CRT groups.

Vergeer et al (2009) compared IMRT with 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.\textsuperscript{12} The study included 241 patients with head and neck squamous cell carcinoma (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 that October, 91 patients received IMRT. The use of IMRT significantly reduced the mean dose to the parotid glands (27 gray [Gy] vs 43 Gy; \( p < 0.001 \)). During radiation, grade 3 or higher xerostomia at 6 weeks was significantly less common with IMRT (20\%) than after 3D-CRT (45\%). At 6 months, the prevalence of grade 2 or higher xerostomia was significantly lower after IMRT (32\%) than with 3D-CRT (56\%). Treatment with IMRT also had a positive effect on several general and head and neck cancer-specific HRQOL measures.

Rusthoven et al (2008) assessed outcomes for IMRT and 3D-CRT in patients who had oropharyngeal cancer.\textsuperscript{13} In this study, which treated 32 patients with IMRT and 23 with 3D-CRT, late xerostomia occurred in 15\% of the IMRT patients and in 94\% of the 3D-CRT patients.

\textbf{Section Summary: Head and Neck Cancer}

The literature on IMRT for head and neck cancer includes 3 systematic reviews, including a meta-analysis of RCTs. Most RCTs have compared IMRT with 2D-RT, which has been replaced by 3D-CRT. The single RCT that compared IMRT with 3D-CRT found a significant benefit of IMRT for reduced xerostomia that persisted through 5 years. Oncologic outcomes did not differ significantly between treatments. Nonrandomized cohort studies have compared IMRT with 3D-CRT or with 2D-RT plus 3D-CRT boost. These studies have supported findings of the RCT that both short- and long-term xerostomia is reduced with IMRT. HRQOL was also improved with IMRT compared with 3D-CRT with 2D-RT plus 3D-CRT boost. Comparators in these nonrandomized studies were generally older technologies (e.g., 2D-RT) with older treatment protocols, both of which limit interpretation of the results. However, more recent evidence has also supported the conclusions of the comparative effectiveness review that treatment of head and neck cancers with IMRT reduces xerostomia compared with other external-beam radiotherapy techniques. The evidence permits no conclusions on tumor control or survival.

\textbf{Thyroid Cancer}

\textbf{Clinical Context and Test Purpose}

The purpose of IMRT in patients who have thyroid cancer 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 the use of IMRT improve the net health outcome in patients with thyroid cancer?

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

\textbf{Patients}

The relevant population of interest is patients with thyroid cancer in close proximity to organs at risk. Anaplastic thyroid cancer occurs in less than 5\% of thyroid cancers.

\textbf{Interventions}

The test being considered is IMRT. A proposed benefit of IMRT is to reduce toxicity to adjacent structures, allowing dose escalation to the target area and fewer breaks during treatment to reduce side effects.

\textbf{Comparators}

The following practices are currently being used to make decisions about the treatment of thyroid cancer: 3-D CRT and 2D-RT. Conventional external-beam radiotherapy 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. In particular, for patients with anaplastic thyroid cancer variants, which are uncommon but have often demonstrated local invasion at the time of diagnosis, RT is a critical part of locoregional therapy.

Outcomes
The general outcomes of interest are locoregional control, OS, and treatment-related morbidity. Evaluation of patient-reported outcomes and quality of life measures are also of interest.

Timing
Locoregional control and OS should be assessed at 1 and 5 years.

Setting
IMRT is delivered in tertiary oncology care settings where complex imaging, radiation physics, and treatment planning resources are available.

Case Series
The best available evidence for this indication consists of case series. For example, the largest series comparing IMRT with 3D-CRT was published by Bhatia et al (2010).14 This series reviewed institutional outcomes for anaplastic thyroid cancer treated with 3D-CRT or IMRT in 53 consecutive patients. Thirty-one (58%) patients were irradiated with curative intent. Median radiation dose was 55 Gy (range, 470 Gy). Thirteen (25%) patients received IMRT to a median of 60 Gy (range, 39.9-69.0 Gy). The Kaplan-Meier estimate of OS at 1 year for definitively irradiated patients was 29%. Patients without distant metastases receiving 50 Gy or more had superior survival outcomes; in this series, use of IMRT or 3D-CRT did not influence toxicity.

Schwartz et al (2009) retrospectively reviewed single-institution outcomes for patients treated for differentiated thyroid cancer with postoperative conformal external-beam radiotherapy.15 One hundred thirty-one consecutive patients with differentiated thyroid cancer who underwent RT between 1996 and 2005 were included. Histologic diagnoses included 104 papillary, 21 follicular, and 6 mixed papillary-follicular types. Thirty-four (26%) patients had high-risk histologic types, and 76 (58%) had recurrent disease. Extraglandular disease progression was seen in 126 (96%) patients, microscopically positive surgical margins were seen in 62 (47%) patients, and gross residual disease was seen in 15 (11%) patients. Median RT dose was 60 Gy (range, 38-72 Gy). Fifty-seven (44%) patients 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 survival and OS. IMRT did not impact survival outcomes but was associated with less frequent severe late morbidity (12% vs 2%, respectively), primarily esophageal stricture.

Section Summary: Thyroid Cancer
The evidence on IMRT in individuals who have thyroid cancer includes nonrandomized, retrospective studies. High-quality studies that differentiate the superiority of any type of external-beam radiotherapy technique to treat thyroid cancer are not available. Limitations of published evidence include patient heterogeneity, variability in treatment protocols, short follow-up periods, inconsistency in reporting important health outcomes (e.g., OS vs progression-free survival or tumor control rates), and inconsistency in reporting or collecting outcomes. However, the published evidence plus additional dosimetry considerations together suggest IMRT for thyroid tumors may be appropriate in some circumstances (e.g., anaplastic thyroid carcinoma) or for thyroid tumors located near critical structures (e.g., salivary glands, spinal cord), similar to the situation for head and neck cancers. Given the rarity of both anaplastic thyroid cancer and papillary thyroid cancers that are not treatable by other methods, high-quality trials are unlikely. Thus, when adverse events could result if nearby critical structures receive toxic radiation doses,
the ability to improve dosimetry with IMRT may be accepted as meaningful evidence for its benefit.

Summary of Evidence
For individuals who have head and neck cancer who receive IMRT, the evidence includes comparative studies, systematic reviews, RCTs, and nonrandomized studies. Relevant outcomes are overall survival, functional outcomes, quality of life, and treatment-related morbidity. The single RCT that compared IMRT with 3-dimensional conformal radiotherapy found a significant benefit of IMRT on xerostomia that persisted through 5 years. Oncologic outcomes did not differ significantly between treatments. Nonrandomized cohort studies have supported the findings that both short- and long-term xerostomia are reduced with IMRT. Overall, the evidence has shown that IMRT significantly and consistently reduces both early and late xerostomia and improves quality of life domains related to xerostomia compared with 3-dimensional conformal radiotherapy. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have thyroid cancer in close proximity to organs at risk who receive IMRT, the evidence includes nonrandomized, retrospective studies. Relevant outcomes include overall survival, functional outcomes, quality of life, and treatment-related morbidity. High-quality studies that differentiate the superiority of any type of external-beam radiotherapy to treat thyroid cancer are not available. However, the published evidence plus additional dosimetry considerations together suggest IMRT may be appropriate for thyroid tumors in some circumstances, such as for anaplastic thyroid carcinoma or thyroid tumors located near critical structures (e.g., salivary glands, spinal cord), similar to the situation for head and neck cancers. Thus, when adverse events could result if nearby critical structures receive toxic radiation doses, the ability to improve dosimetry with IMRT might be accepted as meaningful evidence for its benefit. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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 2 physician specialty societies (3 reviewers) and 4 academic medical centers in 2012. There was uniform consensus that intensity-modulated radiotherapy (IMRT) is appropriate for the treatment of head and neck cancers. There was near-uniform consensus that 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 (e.g., salivary glands), thus decreasing risks of adverse effects (e.g., xerostomia, esophageal stricture).

Practice Guidelines and Position Statements
National Comprehensive Cancer Network
National Comprehensive Cancer Network guidelines (v.2.2018) on head and neck cancer note that: “Advanced radiation therapy technologies such as IMRT [intensity-modulated radiotherapy], image-guided radiation therapy (IGRT), and PBT [proton beam therapy] may offer clinically relevant advantages in specific circumstances to spare important organs at risk (OARS).… The demonstration of significant dose-sparing of these OARS reflects best clinical practice.”

Network guidelines for thyroid cancer (v.1.2018) support the use of intensity-modulated radiotherapy if unresectable, gross residual disease or locoregional recurrence threatens vital structures in the neck.
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 trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<td>NCT01216800</td>
<td>A Multicenter Randomized Study of Cochlear Sparing Intensity-Modulated Radiotherapy Versus Conventional Radiotherapy in Patients With Parotid Tumors</td>
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<td>NCT01955239</td>
<td>Prevention of Radiation-induced Parotid Gland Dysfunction by Parotid gland Stem-cell Sparing Intensity-modulated Radiotherapy (SCS-IMRT)</td>
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<td>May 2017 (completed)</td>
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<td>NCT02048254</td>
<td>A Randomized Control Trial (RCT) of Using Iodine-125 Brachytherapy Versus Intensity-modulated Radiation Therapy (IMRT) to Treat Inoperable Salivary Gland Cancer</td>
<td>90</td>
<td>Jun 2018 (unknown)</td>
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</table>

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/NMN**

The following services may be considered medically necessary when policy criteria are met. Services may be considered not medically necessary when policy criteria are not met.

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<th>Type</th>
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<td>Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications</td>
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<td>Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan</td>
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<td></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></td>
<td>Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex</td>
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<tr>
<td><strong>HCPCS</strong></td>
<td>G6015</td>
<td>Intensity modulated treatment delivery, single or multiple fields/arc/s, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session</td>
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<td>G6016</td>
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<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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<td>Beam Radiation of Ear using Photons &lt;1 MeV</td>
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### 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 governmental 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.