Intensity-modulated radiotherapy (IMRT) may be considered medically necessary as a technique to deliver whole-breast irradiation in patients receiving treatment for left-sided breast cancer after breast-conserving surgery when all the following conditions have been met:

- Significant cardiac radiation exposure cannot be avoided using alternative radiotherapy, and
- IMRT dosimetry demonstrates significantly reduced cardiac target volume radiation exposure (see Policy Guidelines section).

IMRT may be considered investigational as a technique of partial-breast irradiation after breast-conserving surgery.

IMRT of the chest wall is considered investigational as a technique of postmastectomy irradiation.

IMRT may be considered medically necessary as a technique to deliver radiotherapy in patients with lung cancer when all of the following conditions are met:

- Significant cardiac radiation exposure cannot be avoided using alternative radiotherapy, and
- IMRT dosimetry demonstrates significantly reduced cardiac target volume radiation exposure (see Policy Guidelines section).

IMRT is considered investigational as a technique of postmastectomy irradiation.

IMRT of the chest wall is considered investigational as a technique of postmastectomy irradiation.
Radiotherapy is being given with curative intent,

Three-dimensional conformal radiotherapy will expose >35% of normal lung tissue to more than a 20-Gy dose-volume (V20), and

IMRT dosimetry demonstrates a reduction in the V20 to at least 10% below the V20 that is achieved with the 3-dimensional plan (eg, from 40% down to 30% or lower).

IMRT is considered not medically necessary as a technique to deliver radiotherapy in patients receiving palliative treatment for lung cancer.

IMRT is not medically necessary for the treatment of breast or lung cancer for all indications not meeting the criteria above.

POLICY GUIDELINES

Table PG1 outlines radiation doses generally considered tolerance thresholds for these normal structures for the chest and abdomen. Dosimetry plans may be used to demonstrate that radiation by 3-dimensional conformal radiotherapy (3D-CRT) would exceed tolerance doses to structures at risk.

Table PG1. Radiation Tolerance Doses for Normal Tissues of the Chest and Abdomen

<table>
<thead>
<tr>
<th>Site</th>
<th>TD 5/5, Gray¹</th>
<th>TD 50/5, Gray²</th>
<th>Complication End Point</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Portion of Organ Involved</td>
<td>Portion of Organ Involved</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1/3</td>
<td>2/3</td>
<td>3/3</td>
</tr>
<tr>
<td>Heart</td>
<td>60</td>
<td>45</td>
<td>40</td>
</tr>
<tr>
<td>Lung</td>
<td>45</td>
<td>30</td>
<td>17.5</td>
</tr>
<tr>
<td>Spinal cord</td>
<td>50</td>
<td>50</td>
<td>47</td>
</tr>
</tbody>
</table>


⁠NP: not provided; TD: tolerance dose.

¹TD 5/5 is the average dose that results in a 5% complication risk within 5 years.
²TD 50/5 is the average dose that results in a 50% complication risk within 5 years.

The following is an example of clinical guidelines that may be used with intensity-modulated radiotherapy (IMRT) in left-sided breast lesions:

- The target volume coverage results in cardiac radiation exposure that is expected to be greater than or equal to 25 gray (Gy) to 10 cm³ or more of the heart (V25 ≥10 cm³) with 3D-CRT, despite the use of a complex positioning device (eg, Vac-Lok), and

- With the use of IMRT, there is a reduction in the absolute heart volume receiving 25 Gy or more by at least 20% (eg, volume predicted to receive 25 Gy by 3D-CRT is 20 cm³, and the volume predicted by IMRT is ≤16 cm³).

The following are examples of criteria to define large breast size when using IMRT to avoid hot spots, as derived from randomized studies:

- Donovan et al (2007) enrolled patients with “higher than average risk of late radiotherapy-adverse effects,” which included patients having larger breasts. The authors stated that while breast size is not particularly good at identifying women with dose inhomogeneity falling outside current International Commission on Radiation Units and Measurements guidelines,
they excluded women with small breasts (≤500 cm³), who generally have fairly good dosimetry with standard 2-dimensional compensators.

- In the trial by Pignol et al (2008), which reported that the use of IMRT significantly reduced the proportion of patients experiencing moist desquamation, breast size was categorized as small, medium, or large by cup size. Multivariate analysis found that smaller breast size was significantly associated with a decreased risk of moist desquamation (p<0.001).

CODING
The following CPT codes are used for simple and complex IMRT delivery:

77385 Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple
77386 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 (Intensity-modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications) remains valid.

The following CPT code may also be used and is to be reported only once per IMRT plan:

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

BENEFIT APPLICATION

BLUECARD/NATIONAL ACCOUNT ISSUES
State or federal mandates (eg, Federal Employee Program) may dictate that certain U.S. Food and Drug Administration‒approved devices, drugs, or biologics may not be considered investigational, and thus these devices may be assessed only by their medical necessity.

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

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

**Intensity-Modulated Radiotherapy**

Intensity-modulated radiotherapy (IMRT), which uses computer software along with 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 therapy is its 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 for tumors and adjacent normal tissues by various techniques. Patient immobilization cradles and skin or bony markers are used to minimize day-to-day variability in patient positioning. In
addition, many tumors have irregular edges that preclude drawing tight margins on CT scan slices when radiation oncologists contour the tumor volume. It is unknown whether omitting some tumor cells or including some normal cells in the resulting target affects outcomes of IMRT.

Investigators are exploring an active breathing control device combined with moderately deep inspiration breath-holding techniques to improve conformality and dose distributions during IMRT for breast cancer.\(^1\) Techniques presently being studied with other tumors (eg, lung cancer)\(^2\) either gate beam delivery to the patient’s respiratory movement or continuously monitor tumor (by in-room imaging) or marker (internal or surface) positions to aim radiation more accurately at the target. The impact of these techniques on outcomes of 3D-CRT or IMRT for breast cancer is unknown. However, it appears likely that respiratory motion alters the dose distributions actually delivered while treating patients from those predicted by plans based on static CT scans or measured by dosimetry using stationary (nonbreathing) targets.

**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) cleared in 2006, and the decimal tissue compensator (Southeastern Radiation Products), cleared in 2004. FDA product code: IXI. Intensity modulators may be added to standard linear accelerators to deliver IMRT when used with proper treatment planning systems.

RT planning systems have also been cleared for marketing by FDA through the 510(k) process. They include the Prowess Panther (Prowess) in 2003, TiGRT (LinaTech) in 2009, and the Ray Dose (RaySearch Laboratories) in 2008. FDA product code: MUJ.

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

**RATIONALE**

This evidence review was created in December 2005 and has been regularly updated with searches of the MEDLINE database. The most recent literature update was performed through May 6, 2019.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and 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 technology, two domains are examined: the relevance, and 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 radiation (3D-CRT) and intensitymodulated 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 conformality to, and dose homogeneity within, the target. Results have also demonstrated that IMRT delivers 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 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 indications, such as using IMRT to provide better tumor control, comparative studies of health outcomes are needed to demonstrate such a benefit.

Breast Cancer

Clinical Context and Therapy Purpose

The purpose of the use of IMRT in patients who have breast 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 health outcomes in patients with breast cancer?

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

Patients

The relevant population of interest are women with breast cancer.

Interventions

The therapy being considered is IMRT. Radiotherapy (RT) is an integral component of the treatment of breast cancer. IMRT has been proposed as a method of RT that allows adequate radiation to the tumor while minimizing the radiation dose to surrounding normal tissues and critical structures. IMRT is performed by radiation oncologists in tertiary outpatient clinical settings.

Comparators

The following therapy is currently being used to make decisions about breast cancer: 2D and 3D-CRT. 3D-CRT is performed by radiation oncologists in tertiary outpatient clinical settings.
Outcomes

The general outcomes of interest are overall survival (OS), recurrence-free survival (locoregional control), and treatment-related adverse events (eg, radiation dermatitis).

The grading of acute radiation dermatitis is relevant to studies of IMRT for the treatment of breast cancer. Acute radiation dermatitis is graded on a scale of 0 (no change) to 5 (death). Grade 2 is moderate erythema and patchy moist desquamation, mostly in skin folds; grade 3 is moist desquamation in other locations and bleeding with minor trauma. Publications have also reported on the potential for IMRT to reduce radiation to the heart (left ventricle) in patients with left-sided breast cancer and unfavorable cardiac anatomy. This is a concern because of the potential development of late cardiac complications (eg, coronary artery disease) following FRT to the left breast.

In addition, IMRT may reduce toxicity to structures adjacent to tumors, 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. Thus, outcomes of interest are toxicity, QOL, locoregional recurrence, and OS.

Follow-up after IMRT varies by the staging of breast cancer and patient age at diagnosis. Five-year to ten-year follow-up to monitor for recurrence have been recommended.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.

b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

d. Studies with duplicative or overlapping populations were excluded.

Whole-Breast Irradiation With IMRT vs 2-Dimensional Radiotherapy

Systematic Reviews

Dayes et al (2012) conducted a systematic review of the evidence for IMRT for whole-breast irradiation in the treatment of breast cancer to quantify its potential benefits and to make recommendations for radiation treatment programs. Based on a review of 6 studies (total n=2012 patients) published through March 2009 (1 RCT, 3 retrospective cohort studies, 1 historically controlled trial, 1 prospective cohort), reviewers recommended IMRT over conventional RT after breast-conserving surgery to avoid acute adverse events associated with radiation. There were insufficient data to recommend IMRT over conventional RT based on oncologic outcomes or late toxicity. The RCT included in this review was the Canadian multicenter trial by Pignon et al (2008), reported next. In this RCT, IMRT was compared with 2D-RT. Computed tomography scans were used in treatment planning for both arms of the study. The types of conventional RT regimens used in the other studies were not reported.

Randomized Controlled Trials

The multicenter, double-blind RCT by Pignon et al (2008, 2016) evaluated whether breast IMRT would reduce the rate of acute skin reaction (moist desquamation), decrease pain, and improve QOL compared with 2D-RT using wedges. Patients were assessed each week up to six weeks after RT and then at eight to ten years. A total of 358 patients were randomized between 2003 and 2005 at 2 Canadian
centers, and 331 were analyzed. Of these, 241 patients were available for long-term follow-up. The trialists noted that breast IMRT significantly improved the dose distribution compared with 2D-RT. They also noted a lower proportion of patients with moist desquamation during or up to 6 weeks after RT (31% with IMRT vs 48% with standard treatment; p=0.002). A multivariate analysis found the use of breast IMRT and smaller breast size were significantly associated with a decreased risk of moist desquamation. The presence of moist desquamation significantly correlated with pain and a reduced QOL. At a median follow-up of 9.8 years, there was no significant difference in chronic pain between treatment arms. Young age (p=0.013) and pain during RT (p<0.001) were associated with chronic pain. Poorer self-assessed cosmetic outcome (p<0.001) and QOL (p<0.001) were also associated with pain during RT.

Donovan et al (2002) reported on an RCT comparing outcomes for 2D-RT using wedged, tangential beams with IMRT in 300 breast cancer patients. In a 2007 abstract, investigators reported interim cosmetic outcomes at 2 years postrandomization for 233 evaluable patients. Donovan et al (2007) reported subsequently on this trial. Enrolled patients had "higher than average risk of late radiotherapy-adverse effects," which included patients with larger breasts. Trialists stated that while breast size was not particularly good at identifying women with dose inhomogeneity falling outside current International Commission on Radiation Units and Measurements guidelines, their trial excluded women with small breasts (≤500 cm³), who generally have fairly good dosimetry with standard 2D compensators. All patients were treated with 6 or 10 megavolt photons to a dose of 50 gray (Gy) in 25 fractions in 5 weeks followed by an electron boost to the tumor bed of 11.1 Gy in 5 fractions. The primary endpoint (change in breast appearance) was scored from serial photographs taken before RT and at 1-, 2-, and 5-year follow-ups. Secondary endpoints included patient self-assessments of breast discomfort, breast hardness, QOL, and physician assessments of breast induration. Two hundred forty (79%) patients with 5-year photographs were available for analysis. Change in breast appearance was identified in 71 (58%) of 122 allocated standard 2D treatment compared with 47 (40%) of 118 patients allocated IMRT. Significantly fewer patients in the IMRT group developed palpable induration assessed clinically in the center of the breast, pectoral fold, inframammary fold, and at the boost site. No significant differences between treatment groups were found in patient-reported breast discomfort, breast hardness, or QOL. The authors concluded that minimization of unwanted radiation dose inhomogeneity in the breast reduced late adverse events. While the change in breast appearance differed statistically, a beneficial effect on QOL was not demonstrated.

Barnett et al (2009) published baseline characteristics and dosimetry results of a single-center RCT assessing IMRT for early breast cancer after breast-conserving surgery. Subsequently, Barnett et al (2012) reported on the 2-year interim results of their RCT. In this trial, 1145 patients with early breast cancer were evaluated for external-beam radiotherapy. Twenty-nine percent had adequate dosimetry with standard RT. The other 815 patients were randomized to IMRT or 2D-RT. Inhomogeneity occurred most often when the dose-volume was greater than 107% (V107) of the prescribed dose to a breast volume greater than 2 cm³ with conventional RT. When breast separation was 21 cm or more, 90% of patients had received greater than V107 of the prescribed dose to greater than 2 cm³ with standard radiation planning. The incidence of acute toxicity did not differ significantly between groups. Additionally, photographic assessment scores for breast shrinkage did not differ significantly between groups. The authors noted overall cosmesis after 2D-RT and IMRT was dependent on surgical cosmesis, suggesting breast shrinkage and induration were due to surgery rather than radiation, thereby masking the potential cosmetic benefits of IMRT.

**Whole-Breast Irradiation With IMRT vs 3D-CRT**
Randomized Controlled Trials

In their RCT, Jagsi et al (2018) assess whether IMRT with deep inspiration breath hold (DIBH) reduces cardiac or pulmonary toxicity of breast RT compared to 3D-CRT, the current standard RT. The study included 62 women with node-positive breast cancer in whom RT was indicated for treating the left breast or chest-wall and the internal mammary, infraclavicular and supraclavicular nodal regions. The primary outcome was the percentage decrease in heart perfusion at one year post-treatment compared to baseline, measured using attenuation corrected single-photon emission computed tomography. A secondary outcome was a change in left ventricular ejection fraction. The 3D-CRT group received ≥ 5 Gy to 15.8% of the left ventricle; the IMRT-DIBH group received 5.6% to the left ventricle (P < 0.001).

At one year, no differences in perfusion of the heart were detected; however, significant differences were found in left ventricular ejection fraction. In the 3D-CRT arm, six patients had > 5% changes in left ventricular ejection fraction, and the IMRT-DIBH arm had one patient with > 5% change. The authors contend that their study is important because it demonstrates that the IMRT-DIBH technique’s reduction in cardiac dose could be associated with better preservation of cardiac left ventricle function—a potentially clinically meaningful finding. One limitation of this study is its small size, and only one follow-up scan was conducted at one year due to resource constraints. A six-month scan might have shown greater differences between the two arms.

Nonrandomized Comparative Studies

Hardee et al (2012) compared the dosimetric and toxicity outcomes after treatment with IMRT or 3D-CRT for whole-breast irradiation in 97 consecutive patients with early-stage breast cancer, who were assigned to either approach after partial mastectomy based on insurance carrier approval for reimbursement for IMRT. IMRT significantly reduced the maximum radiation dose to the breast (Dmax median, 110% for 3D-CRT vs 107% for IMRT; p<0.001) and improved median dose homogeneity (median, 1.15 for 3D-CRT vs 1.05 for IMRT; p<0.001) compared with 3D-CRT. These dosimetric improvements were seen across all breast volume groups. Grade 2 dermatitis occurred in 13% of patients in the 3D-CRT group and in 2% in the IMRT group. IMRT moderately decreased rates of acute pruritus (p=0.03) and grade 2 and 3 subacute hyperpigmentation (p=0.01). With a minimum of six months of follow-up, the treatment was reported to be similarly well-tolerated by both groups, including among women with large breast volumes.

Guttmann et al (2018) published a single-center retrospective analysis of 413 women who received tangential whole-breast irradiation between 2011 and 2015 (see Table 1). Of the patients, 212 underwent IMRT and 201 received 3D-CRT. The main endpoint was a comparison of acute radiation dermatitis (grade 2+), and secondary endpoints were acute fatigue and breast pain. Grade 2+ radiation dermatitis was experienced by 59% of 3D-CRT patients and 62% of IMRT (p=0.09). There was also no significant difference between 3D-CRT and IMRT for breast pain (grade 2+, 18% vs 18%, respectively; p=0.33) or fatigue (grade 2+, 18% vs 25.5%, respectively; p=0.24) (see Table 2). A study limitation was that follow-up varied across patients because those treated with IMRT completed treatment one week sooner than those treated with 3D-CRT.

Table 1. Summary of Key Nonrandomized Trials Characteristics

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Type</th>
<th>Country</th>
<th>Dates</th>
<th>Participants</th>
<th>Treatment</th>
<th>Comparator</th>
<th>FU</th>
</tr>
</thead>
</table>

FU: follow-up; 3D-CRT: 3-dimensional conformal radiotherapy; IMRT: intensity-modulated radiotherapy.
### Intensity-Modulated Radiotherapy of the Breast and Lung

#### Acute Radiation Dermatitis

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#### Acute Fatigue

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#### Acute Breast Pain

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</table>

#### Chest Wall Irradiation

A few studies have examined the use of IMRT for chest wall irradiation in postmastectomy breast cancer patients. Available studies have focused on treatment planning and techniques to improve dose distributions to targeted tissues while reducing radiation to normal tissue and critical surrounding structures (e.g., heart, lung). An example is a study by Rudat et al (2011), in which treatment planning for chest wall irradiation with IMRT was compared with 3D-CRT in 20 postmastectomy patients. The authors reported IMRT significantly decreased heart and lung high-dose volume with a significantly improved conformity index compared with 3D-CRT. However, there were no significant differences in the homogeneity index. The authors noted longer-term prospective studies are needed to further assess cardiac toxicity and secondary lung cancer risk with multifield IMRT, which while reducing high-dose...
volume, increases mean heart and lung dose. As noted, health outcomes were not reported in this study.

Ho et al (2019) published the long-term pulmonary outcomes of a feasibility study of inverse-planned, multibeam intensity modulated radiation therapy in node-positive breast cancer patients receiving regional nodal irradiation. While the authors' primary endpoint was feasibility, they also observed the incidence of radiation pneumonitis grade 3 or greater and changes in pulmonary function. The later endpoints were measured with the Common Terminology Criteria for Adverse Events and pulmonary function tests and community-acquired pneumonia questions. Of 104 completed follow-up procedures, the overall rate of respiratory toxicity was 10.6%, with 1 grade 3 radiation pneumonitis event.

Rastogi et al (2018) published a retrospective study of 107 patients receiving RT postmastectomy to the left chest wall. Patients were treated with 3D-CRT (n=64) or IMRT (n=43). The planning target volume, homogeneity index, and conformity index for both groups were compared. IMRT had a significantly improved conformity index score (1.127) compared with 3D-CRT (1.254; p<0.001), while results for both planning target volume (IMRT, 611.7 vs 3D-CRT, 612.2; p=0.55) and homogeneity index (IMRT, 0.094 vs 3D-CRT, 0.096; p=0.83) were comparable. Furthermore, secondary analyses showed that IMRT differed had significantly lower mean- and high-dose volumes to the heart and ipsilateral lung (p<0.001 and p<0.001, respectively), while 3D-CRT had superior low-dose volume (p<0.001). The study was limited by its small population size and short follow-up.

**Section Summary: Breast Cancer**

There is modest evidence from RCTs that IMRT decreases acute skin toxicity more than 2D-RT for whole-breast irradiation. One RCT reported improvements in moist desquamation of skin but did not find differences in grade 3 or 4 skin toxicity, pain symptoms, or QOL. Another RCT found a change in breast appearance but not QOL. A third RCT reported no differences in cosmetic outcomes at two years for IMRT or 2D-RT. Dosimetry studies have demonstrated that IMRT reduces inhomogeneity of radiation dose, thus potentially providing a mechanism for reduced skin toxicity. However, because whole-breast RT is now delivered by 3D-CRT, these comparison data are of limited value. Studies comparing IMRT with 3D-CRT include one RCT comparing IMRT with DIBH to 3D-CRT, two nonrandomized comparative assessments of whole-breast IMRT, and studies on treatment planning for chest wall IMRT. These studies have suggested that IMRT might improve short-term clinical outcomes. No studies have reported on health outcomes after IMRT for chest wall irradiation in breast cancer patients postmastectomy. Available studies have only focused on treatment planning and techniques. The risk of secondary lung cancers needs further evaluation. Additionally, cardiac and pulmonary toxicity needs further evaluation. Despite this, strong evidence supports the use of IMRT for left-sided breast lesions in which alternative types of RT cannot avoid toxicity to the heart and lungs.

**Lung Cancer**

**Clinical Context and Therapy Purpose**

The purpose of IMRT in patients who have lung 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 health outcomes in patients with lung cancer?

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

**Patients**
The relevant population of interest are individuals with lung cancer.

Interventions

The therapy being considered is IMRT. RT is an integral component of the treatment of lung cancer. IMRT has been proposed as a method of RT that allows adequate radiation to the tumor while minimizing the radiation dose to surrounding normal tissues and critical structures. IMRT is performed by radiation oncologists in tertiary outpatient clinical settings.

Comparators

The following therapy is currently being used to make decisions about lung cancer: 3D-CRT. 3D-CRT is performed by radiation oncologists in tertiary outpatient clinical settings.

Outcomes

The general outcomes of interest are OS, recurrence-free survival, and treatment-related adverse events.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.

b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

d. Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

Bezjak et al (2012) conducted a systematic review that examined the evidence on the use of IMRT for the treatment of lung cancer to quantify its potential benefits and make recommendations for RT programs considering adopting this technique in Ontario, Canada. This review consisted of 2 retrospective cohort studies (through March 2010) reporting on cancer outcomes, which was considered insufficient evidence on which to make evidence-based recommendations. These 2 cohort studies reported on data from the same institution; the study by Liao et al (2010; reported below) indicated that patients assessed in their cohort (n=409) were previously reported in the cohort by Yom et al (2010), (n=290) but it is not clear exactly how many patients were added in the second report. However, due to the known dosimetric properties of IMRT and extrapolating from clinical outcomes from other disease sites, reviewers recommended that IMRT be considered for lung cancer patients when the tumor is proximate to an organ at risk, where the target volume includes a large volume of an organ at risk, or where dose escalation would be potentially beneficial while minimizing normal tissue toxicity.

Nonrandomized Comparative Studies

Chun et al (2017) reported on a secondary analysis of a trial that assessed the addition of cetuximab to a standard chemotherapy regimen and radiation dose escalation. Use of IMRT or 3D-CRT was a stratification factor in the 2×2 design. Of 482 patients in the trial, 53% were treated with 3D-CRT and 47% were treated with IMRT, though treatment allocation was not randomized. Compared with the 3D-CRT group, the IMRT group had larger planning treatment volumes (486 mL vs 427 mL, p=0.005), larger
planning treatment volume/volume of lung ratio (median, 0.15 vs 0.13; p=0.13), and more stage IIIB breast cancer patients (38.6% vs 30.3%, p=0.056). Even though there was an increase in treatment volume, IMRT was associated with less grade 3 or greater pneumonitis (3.5% vs 7.9%, p=0.039) and a reduced risk (odds ratio, 0.41; 95% confidence interval, 0.171 to 0.986; p=0.046), with no significant differences between the groups in 2-year OS, progression-free survival, local failure, or distant metastasis-free survival.

The nonrandomized comparative study by Liao et al (2010) compared patients who received RT, along with chemotherapy, for inoperable non-small-cell lung cancer (NSCLC) at a single institution. This study retrospectively compared 318 patients who received computed tomography plus 3D-CRT and chemotherapy from 1999 to 2004 (mean follow-up, 2.1 years) with 91 patients who received 4-dimensional computed tomography plus IMRT and chemotherapy from 2004 to 2006 (mean follow-up, 1.3 years). Both groups received a median dose of 63 Gy. Disease endpoints were a locoregional progression, distant metastasis, and OS. Disease covariates were gross tumor volume, nodal status, and histology. The toxicity endpoint was grade 3, 4, or 5 radiation pneumonitis; toxicity covariates were gross tumor volume, smoking status, and dosimetric factors. Using Cox proportional hazards models, the hazard ratios (HRs) for IMRT were less than one for all disease endpoints; the difference was significant only for OS. The median survival was 1.40 years for the IMRT group and 0.85 years for the 3D-CRT group. The toxicity rate was significantly lower in the IMRT group than in the 3D-CRT group. The volume of the lung receiving 20 Gy was higher in the 3D-CRT group and was a factor in determining toxicity. Freedom from distant metastasis was nearly identical in both groups. The authors concluded that treatment with 4-dimensional computed tomography plus IMRT was at least as good as that with 3D-CRT in terms of the rates of freedom from locoregional progression and metastasis. This retrospective study found significant reductions in toxicity and improvement in survival. The nonrandomized, retrospective aspects of this study from a single-center limit the ability to draw definitive treatment conclusions about IMRT.

Harris et al (2014) compared the effectiveness of IMRT, 3D-CRT, or 2D-RT in treating stage III NSCLC using a cohort of patients from the Surveillance, Epidemiology, and End Results-Medicare database treated between 2002 and 2009. OS was better with IMRT and 3D-CRT than with 2D-CRT. In univariate analysis, improvements in OS (HR=0.90, p=0.02) and cancer-specific survival (HR=0.89, p=0.02) were associated with IMRT. However, IMRT was similar to 3D-CRT after controlling for confounders in OS (HR=0.94, p=0.23) and cancer-specific survival (HR=0.94, p=0.28). On multivariate analysis, toxicity risks with IMRT and 3D-CRT were also similar. Likewise, results were similar for the propensity score-matched models and the adjusted models.

Shirvani et al (2013) reported on a U.S. cancer center study that assessed the use of definitive IMRT in limited-stagesmall-cell lung cancer treated with definitive RT. In this study of 223 patients treated from 2000 to 2009, 104 received IMRT and 119 received 3D-CRT. Median follow-up times were 22 months (range, 4-83 months) for IMRT and 27 months (range, 2-147 months) for 3D-CRT. In both multivariable and propensity score-matched analyses, OS and disease-free survival did not differ between IMRT and 3D-CRT. However, rates of esophagitis-related percutaneous feeding tube placements were lower with IMRT (5%) than with 3D-CRT (17%; p=0.005).

Ling et al (2016) compared IMRT with 3D-CRT in patients who had stage III NSCLC treated with definitive RT. In this study of 145 consecutive patients treated between 1994 and 2014, the choice of treatment was at the treating physician's discretion but all IMRT treatments were performed in the last 5 years. The authors found no significant differences between the groups for any measure of acute toxicity (grade ≥2 esophagitis, grade ≥2 pneumonitis, percutaneous endoscopic gastrostomy, narcotics,
hospitalization, or weight loss). There were no significant differences in oncologic and survival outcomes.

Koshy et al (2017) published a retrospective cohort analysis of patients with stage III NSCLC, comparing those treated with IMRT and with non-IMRT.22 Using the National Cancer Database, 7493 patients treated between 2004 and 2011 were assessed. Main outcomes were OS and the likelihood and effects of radiation treatment interruption, defined as a break in the treatment of four or more days. OS for non-IMRT and IMRT patients, respectively, were 18.2 months and 20 months (p<0.001) (see Table 4). Median survival with and without a radiation treatment interruption was 16.1 and 19.8 months, respectively (p<0.001), and IMRT significantly reduced the likelihood of a radiation treatment interruption (odds ratio, 0.84; p=0.04). The study was limited by unavailable information regarding radiation treatment planning and potential mechanisms affecting survival, and by a possible prescription, bias causing patients with better performance status to be given IMRT.

Table 3. Summary of Key Observational Comparative Study Characteristics

<table>
<thead>
<tr>
<th>Study</th>
<th>Study Type</th>
<th>Country</th>
<th>Dates</th>
<th>Participants</th>
<th>Treatment</th>
<th>Comparator</th>
<th>FU</th>
</tr>
</thead>
</table>

FU: follow-up; IMRT: intensity-modulated radiotherapy.

Table 4. Summary of Key Observational Comparative Study Results

<table>
<thead>
<tr>
<th>Study</th>
<th>Median Overall Survival, months</th>
</tr>
</thead>
<tbody>
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<td>Koshy et al (2017)22</td>
<td>20.0</td>
</tr>
<tr>
<td>Non-intensity-modulated radiotherapy</td>
<td>18.2</td>
</tr>
</tbody>
</table>

Section Summary: Lung Cancer

For the treatment of lung cancer, no RCTs were identified that compared IMRT with 3D-CRT. Dosimetry studies have reported that IMRT can reduce radiation exposure to critical surrounding structures, especially for large lung tumors. Based on nonrandomized comparative studies, IMRT appears to produce survival outcomes comparable with those of 3D-CRT, with a reduction in adverse events.

Summary of Evidence

For individuals who have breast cancer who receive IMRT, the evidence includes RCTs and nonrandomized comparative studies. The relevant outcomes are OS, disease-specific survival, QOL, and treatment-related morbidity. There is modest evidence from RCTs for a decrease in acute skin toxicity with IMRT compared with 2D-RT for whole-breast irradiation, and dosimetry studies have demonstrated that IMRT reduces inhomogeneity of radiation dose, thus potentially providing a mechanism for reduced skin toxicity. However, because whole-breast RT is now delivered by 3D-CRT, these comparative data are of limited value. Studies comparing IMRT with 3D-CRT include one RCT comparing IMRT with DIBH to 3D-CRT, two nonrandomized comparative studies on whole-breast IMRT, and a few studies on chest wall IMRT. These studies suggest that IMRT requires less radiation exposure to nontarget areas and may improve short-term clinical outcomes. The available studies on chest wall IMRT for postmastectomy breast cancer patients have only focused on treatment planning and techniques. However, when dose-planning studies have indicated that RT will lead to unacceptably high radiation doses, the studies...
suggest IMRT will lead to improved outcomes. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Strong evidence supports the use of IMRT for left-sided breast lesions in which alternative types of RT cannot avoid toxicity to the heart. Based on available evidence, input from clinical vetting, a strong chain of evidence, and the potential to reduce harms, IMRT may be considered medically necessary for whole-breast irradiation when (1) alternative forms of RT cannot avoid cardiac toxicity, and (2) IMRT dose-planning demonstrates a substantial reduction in cardiac toxicity. IMRT for the palliative treatment of lung cancer is considered not medically necessary because conventional radiation techniques are adequate for palliation.

For individuals who have lung cancer who receive IMRT, the evidence includes nonrandomized, retrospective, comparative studies. The relevant outcomes are OS, disease-specific survival, QOL, and treatment-related morbidity. Dosimetry studies have shown that IMRT can reduce radiation exposure to critical surrounding structures, especially in large lung tumors. Based on nonrandomized comparative studies, IMRT appears to produce survival outcomes comparable to those of 3D-CRT and reduce toxicity. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Clinical vetting also provided strong support for IMRT when alternative RT dosimetry exceeds a threshold of V20 to at least 35% of normal lung tissue. Based on available evidence, clinical vetting, a strong chain of evidence, and the potential to reduce harms, IMRT may be considered medically necessary for lung cancer when (1) RT is given with curative intent, (2) alternative RT dosimetry demonstrates radiation dose exceeding V20 for at least 35% of normal lung tissue, and (3) IMRT reduces the V20 of radiation to the lung at least 10% below the V20 of 3D-CRT (eg, 40% reduced to 30%).

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.

2012 Input

In response to requests, input was received from 2 physician specialty societies and 3 academic medical centers (3 reviewers) while this policy was under review in 2011. There was a near-uniform consensus in responses that whole-breast and lung intensity-modulated radiotherapy (IMRT) is appropriate in select patients with breast and lung cancer. Respondents noted IMRT might reduce the risk of cardiac, pulmonary, or spinal cord exposure to radiation in some cancers such as those involving the left breast or large cancers of the lung. Respondents also indicated whole-breast IMRT might reduce skin reactions and potentially improve cosmetic outcomes. Partial-breast IMRT was not supported by respondents, and the response was mixed on the value of chest wall IMRT postmastectomy.

2010 Input

In response to requests, input was received from 1 physician specialty society and 2 academic medical centers (3 reviewers) while this policy was under review in 2010. Input suggested that IMRT is used in select patients with breast cancer (eg, some cancers involving the left breast) and lung cancer (eg, some large cancers).
Practice Guidelines and Position Statements
National Comprehensive Cancer Network

Breast Cancer
Current NCCN guidelines (v.1.2019) for breast cancer indicate that for whole-breast irradiation, uniform dose distribution, and minimization of toxicity to normal tissue are treatment objectives and list various approaches to achieve this, including IMRT. The guidelines state that "Greater target dose homogeneity and sparing of normal tissues can be accomplished using compensators such as wedges, forward planning using segments, and intensity-modulated radiation therapy (IMRT)." The guidelines indicate chest wall and regional lymph node irradiation may be appropriate postmastectomy in select patients but IMRT is not mentioned as a technique for irradiation in these circumstances.

Lung Cancer
Current NCCN guidelines (v.4.2019) for non-small-cell lung cancer indicate that "More advanced technologies are appropriate when needed to deliver curative RT [radiotherapy] safely. These technologies include (but are not limited to) ... IMRT/VMAT [volumetric modulated arc therapy].... Nonrandomized comparisons of using advanced technologies versus older techniques demonstrate reduced toxicity and improved survival." IMRT is included in the technologies listed.

American Society for Radiation Oncology
Breast Cancer
The American Society for Radiation Oncology (2018) published evidence-based guidelines on whole-breast irradiation with or without low axilla inclusion. The guidance recommended a "preferred" radiation dosage of "4000 cGy [centigray] in 15 fractions or 4250 cGy in 16 fractions".

Lung Cancer
The American Society for Radiation Oncology (2018) has also published evidence-based guidelines on radiotherapy for lung cancer. The guidelines recommended "moderately hypofractionated palliative thoracic radiation therapy" with chemotherapy as palliative care for stage III and IV incurable non-small-cell lung cancer. In 2017, the Society updated its guidelines on stage I to IIIA resectable non-small-cell lung cancer. Adjuvant radiotherapy was not recommended.

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.

Some local Medicare Part B carriers have indicated that IMRT for the lung is considered medically necessary. These documents do not detail the rationale for this conclusion.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 5.
Table 5. 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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<tr>
<td><strong>Ongoing</strong></td>
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<tr>
<td>NCT02440191</td>
<td>Postoperative Radiotherapy With Intensity-modulated Radiation Therapy (IMRT) Using Simultaneous Integrated Boost Versus 3-Dimensional Conformal Radiotherapy (3D-CRT) in Early Breast Cancer: a Prospective Randomized Trial</td>
<td>690</td>
<td>Apr 2018 (ongoing)</td>
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<tr>
<td>NCT00520702</td>
<td>A Randomized Trial to Compare Time To Common Toxicity Criteria for Adverse Effect (CTC AEC) 3.0 Grade Treatment Related Pneumonitis (TRP) in Patients With Locally Advanced Non-Small Cell Carcinoma (NSCLC) Receiving Concurrent Chemoradiation Radiation Treated With 3-Dimensional Conformal Radiation Therapy (3D CRT, ARM 1) vs Intensity Modulated Radiation (IMRT, ARM 2) Using 4 Dimensional CT Planning and Image-Guided Adaptive Radiation Therapy (IGART)</td>
<td>168</td>
<td>Oct 2018 (ongoing)</td>
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<tr>
<td>NCT01185132</td>
<td>A Phase III Randomized Study Comparing Intensity Modulated Planning vs 3-dimensional Planning for Accelerated Partial Breast Radiotherapy</td>
<td>660</td>
<td>Jul 2028</td>
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<tr>
<td><strong>Unpublished</strong></td>
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</table>

NCT: national clinical trial.

ESSENTIAL HEALTH BENEFITS

The Affordable Care Act (ACA) requires fully insured non-grandfathered individual and small group benefit plans to provide coverage for ten categories of Essential Health Benefits (“EHBs”), whether the benefit plans are offered through an Exchange or not. States can define EHBs for their respective state.

States vary on how they define the term small group. In Idaho, a small group employer is defined as an employer with at least two but no more than fifty eligible employees on the first day of the plan or contract year, the majority of whom are employed in Idaho. Large group employers, whether they are self-funded or fully insured, are not required to offer EHBs, but may voluntary offer them.

The Affordable Care Act requires any benefit plan offering EHBs to remove all dollar limits for EHBs.

REFERENCES


### CODES

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<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>
</tr>
<tr>
<td></td>
<td>77385</td>
<td>Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple complex</td>
</tr>
<tr>
<td></td>
<td>77386</td>
<td></td>
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<tr>
<td>HCPCS</td>
<td>G6015</td>
<td>Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session</td>
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<tr>
<td></td>
<td>G6016</td>
<td>Compensator-based beam modulation treatment delivery of inverse planned treatment using 3 or more high resolution</td>
</tr>
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</table>
Intensity-Modulated Radiotherapy of the Breast and Lung

(milled or cast) compensator, convergent beam modulated fields, per treatment session

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<th>Place of Service</th>
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<td>Malignant neoplasm of bronchus and lung code range</td>
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<tr>
<td>ICD-10-PCS</td>
<td>C50.011-C50.929</td>
<td>Malignant neoplasm of breast code range</td>
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<td>DM000ZZ,</td>
<td>Radiation oncology, breast, beam radiation, codes by anatomical</td>
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<td>DM001ZZ,</td>
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<td></td>
<td>DM002ZZ,</td>
<td>photons 1-10 MeV and photons &gt; 10 MeV)</td>
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<td></td>
<td>DM010ZZ,</td>
<td>Radiation oncology, respiratory system, beam radiation lung,</td>
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<td>codes by modality (photons &lt; 1 MeV, photons 1-10 MeV and</td>
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**POLICY HISTORY**

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<td>Diagnosis coding in code table updated to align with the policy statements.</td>
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<td>New CPT and HCPCS codes added.</td>
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<tr>
<td>08/11/16</td>
<td>Replace policy</td>
<td>Policy updated with literature review through June 6, 2016; reference 20 added; references 22, 24, and 26 updated; some references removed; Rationale revised. Policy statements unchanged.</td>
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<tr>
<td>07/25/17</td>
<td>Replace policy</td>
<td>Policy updated with literature review through June 2, 2017; references 7 and 16 added; references 20-22 updated. Policy statements unchanged.</td>
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<td>07/25/18</td>
<td>Replace policy</td>
<td>Blue Cross of Idaho adopted changes as noted. Policy updated with literature review through May 10, 2018; references 1-2, 12, 14, 21, and 25-26 added. Policy statements unchanged.</td>
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<td>Blue Cross of Idaho adopted changes as noted, effective</td>
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07/22/2019. Policy updated with literature review through May 6, 2019; references added. Policy statements unchanged.