

EFFECTIVE DATE: 08|01|2023

POLICY LAST UPDATED: 04|05|2023

OVERVIEW

Intensity-modulated radiotherapy (IMRT) has been proposed as a method of RT that allows adequate RT to the tumor while minimizing the radiation dose to surrounding normal tissues and critical structures.

MEDICAL CRITERIA

Medicare Advantage Plans and Commercial Products

Abdomen, Pelvis and Chest

Intensity-modulated radiotherapy may be considered medically necessary as an approach to delivering radiotherapy for individuals with cancer of the anus/anal canal.

Intensity-modulated radiotherapy may be considered medically necessary for bladder cancer when ALL of the following has been met:

- To treat primary, non-metastatic bladder carcinoma; AND
- Treatment intent is curative

Intensity-modulated radiotherapy may be considered medically necessary when dosimetric planning with standard 3-dimensional conformal radiotherapy (3D-CRT) predicts that the radiation dose to an adjacent organ would result in unacceptable normal tissue toxicity for the treatment of cancer of the abdomen and pelvis, including but not limited to:

- stomach (gastric)
- hepatobiliary tract
- pancreas
- esophagus
- rectal locations
- gynecologic tumors (including cervical, endometrial, and vulvar cancers)

Breast

Intensity-modulated radiotherapy of the breast may be considered medically necessary when ONE of the following have been met;

1. As a technique to deliver whole-breast irradiation in patients receiving treatment for left-sided breast cancer after breast conserving surgery AND:

- Significant cardiac radiation exposure cannot be avoided using alternative radiation techniques; AND
- Intensity-modulated radiotherapy dosimetry demonstrates significantly reduced cardiac target volume radiation exposure; AND
- The target volume coverage results in cardiac radiation exposure that is expected to be greater than or equal to 25 Gy to 10 cm³ or more of the heart ($V_{25} \geq 10 \text{ cm}^3$) with 3D-CRT, despite the use of a complex positioning device (such as Vac-Lok); AND
- There is a reduction in the absolute heart volume receiving 25 Gy or higher by at least 20% (e.g., volume predicted to receive 25 Gy by 3D RT is 20 cm³, and the volume predicted by intensity-modulated radiotherapy is $\leq 16 \text{ cm}^3$).

OR

2. In individuals with right-sided breast cancer AND:

- The right breast measures greater than 500 cm³; AND
- Treatment planning with 3-dimensional (3D) conformal results in hot spots (focal regions with dose variation greater than 10% of target); AND
- The hot spots are able to be avoided with intensity-modulated radiotherapy

Central Nervous System Tumors

Intensity-modulated radiotherapy (IMRT) may be considered medically necessary when the criteria below has been met:

- For individuals with malignant or benign brain tumors when the tumor is proximate to organs at risk (brain stem, spinal cord, cochlea and eye structures including optic nerve and chiasm, lens and retina) AND
- The use of 3-dimensional conformal radiotherapy planning is not able to meet dose-volume constraints for normal tissue tolerance

Hippocampal-avoiding intensity-modulated radiotherapy may be considered medically necessary when the criteria below has been met:

- For individuals with brain tumor metastases outside a 5-mm margin around either hippocampus AND
- Expected survival \geq 4 months.

Head, Neck or Thyroid

Intensity-modulated radiotherapy may be considered medically necessary for the treatment of the following head and neck cancers:

- oral cavity and lip
- larynx,
- hypopharynx
- oropharynx
- nasopharynx
- paranasal sinuses and nasal cavity
- salivary glands
- occult primaries in the head and neck region.

Intensity-modulated radiotherapy may be considered medically necessary for the treatment of thyroid cancers when the criteria below is met:

- Tumor is in close proximity to organs at risk (esophagus, salivary glands, and spinal cord), AND;
- When 3-dimensional conformal radiation therapy (3D-CRT) planning is not able to meet dose volume constraints for normal tissue tolerance.

Lung

Intensity-modulated radiotherapy of the lung may be considered medically necessary when ALL of the following criteria have been met:

- Radiotherapy is being given with curative intent; AND
- 3D conformal wall expose $>$ 35% of normal lung tissue to more than 20 Gy dose-volume (V20); AND
- Intensity-modulated radiotherapy dosimetry demonstrates reduction in the V20 to at least 10% below the V20 that is achieved with the 3D plan (e.g., from 40% down to 30% or lower).

Prostate

Intensity-modulated radiotherapy of the prostate may be considered medically necessary when one of the following criteria is met:

- For the treatment of localized prostate cancer at radiation doses of 75.6 to 79.2 GY:
 - o Localized prostate cancer is confined to the prostate, or;
 - o Locally advanced cancer that is confined to adjacent structures, and/or local lymph nodes
- For treatment after radical prostatectomy as:
 - o Adjuvant therapy when there are adverse pathologic findings at prostatectomy or with a persistently detectable prostate-specific antigen (PSA) level post-prostatectomy
 - o Salvage therapy when there is evidence of biochemical or local recurrence when there is no evidence of distant metastatic disease

Sarcomas

Intensity-modulated radiotherapy (IMRT) may be considered medically necessary for sarcomas when ANY of the following conditions are met:

- for initial treatment of a primary pelvic soft tissue sarcoma
- for initial treatment of a primary retroperitoneal sarcoma
- for treatment of an extremity sarcoma
- to treat a previously irradiated field

PRIOR AUTHORIZATION

Prior authorization is required for Medicare Advantage Plans and recommended for Commercial Products via the online tool for participating providers.

POLICY STATEMENT

Medicare Advantage Plans and Commercial Products

Intensity-modulated radiotherapy may be considered medically necessary when the criteria above has been met.

Intensity-modulated radiotherapy is considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products as the evidence is insufficient to determine the effects of the technology on health outcomes for the following:

- as a technique of partial-breast irradiation after breast-conserving surgery
- as a technique of postmastectomy irradiation
- to deliver radiotherapy in individuals receiving palliative treatment for lung cancer
- for the treatment of all other indications not listed in the above medical criteria section

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable radiology benefits/coverage.

BACKGROUND

Conventional External-Beam Radiotherapy

Methods to plan and deliver radiotherapy 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 Radiation

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 (IMRT)

IMRT uses computer software and CT and magnetic resonance images, to offer 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 development has produced advanced techniques that may further improve RT treatment by improving dose distribution. These techniques are considered variations of IMRT. Volumetric modulated arc therapy delivers radiation from a continuous rotation of the radiation source. The principal advantage of volumetric modulated arc therapy is greater efficiency in treatment delivery time, reducing radiation exposure and improving target radiation delivery due to less patient motion. Image-guided RT involves the incorporation of imaging before and/or during treatment to more precisely deliver RT to the target volume.

For individuals who have gastrointestinal (GI) tract cancers who receive IMRT, the evidence includes nonrandomized comparative studies, retrospective series, and a systematic review. Relevant outcomes are overall survival (OS), disease-specific survival, recurrence, quality of life, and treatment-related morbidity. IMRT has been compared with 3-dimensional conformal radiotherapy (3D-CRT) for the treatment of stomach, hepatobiliary, and pancreatic cancers. Evidence has been inconsistent with the outcome of survival, with some studies reporting increased survival among patients receiving IMRT compared with patients receiving 3D-CRT, and other studies reporting no difference between groups. However, most studies found that patients receiving IMRT experienced significantly less GI toxicity compared with patients receiving 3D-CRT. The available comparative evidence, together with dosimetry studies of organs at risk, would suggest that IMRT decreases toxicity compared with 3D-CRT in patients who had GI cancers. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have gynecologic cancers who receive IMRT, the evidence includes a systematic review, 5 RCTs, and nonrandomized comparative studies. Relevant outcomes are OS, disease-specific survival, recurrence, quality of life, and treatment-related morbidity. There is limited comparative evidence on survival outcomes following IMRT or 3D-CRT. However, results are generally consistent that IMRT reduces GI and genitourinary toxicity. Based on evidence with other cancers of the pelvis and abdomen that are proximate to organs at risk, it is expected that OS with IMRT would be at least as good as 3D-CRT, with a decrease in toxicity. A reduction in GI toxicity is likely to improve the quality of life in patients with gynecologic cancer. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have anorectal cancer who receive IMRT, the evidence includes a small RCT (N=20), nonrandomized comparative studies, and case series. Relevant outcomes are OS, disease-specific survival, recurrence, quality of life, and treatment-related morbidity. Survival outcomes have not differed significantly between patients receiving IMRT and 3D-CRT. However, studies have found that patients receiving IMRT plus chemotherapy for the treatment of anal cancer experience fewer acute and late adverse events than patients receiving 3D-CRT plus chemotherapy, primarily in GI toxicity. A reduction in GI toxicity is likely to

improve the quality of life in patients with anorectal cancer. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have esophageal cancer who receive IMRT, the evidence includes a systematic review and nonrandomized comparative studies. Relevant outcomes are OS, disease-specific survival, recurrence, quality of life, and treatment-related morbidity. Survival outcomes have been mixed with some studies concluding that IMRT is associated with a significant improvement in OS, progression-free survival, or distant-metastases-free survival versus 3D-CRT and others reporting no difference between the radiotherapy techniques. IMRT appears to be associated with a reduced dose for organs at risk and may result in less radiation-induced toxicity. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have breast cancer who receive IMRT, the evidence includes systematic reviews, randomized controlled trials (RCTs), and nonrandomized comparative studies. Relevant outcomes are overall survival (OS), disease-specific survival, locoregional control, quality of life, and treatment-related morbidity. There is modest evidence from RCTs for a decrease in acute skin toxicity with IMRT compared with 2-dimensional (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 3-dimensional (3D) conformal RT (3D-CRT), these comparative data are of limited value. Studies comparing IMRT with 3D-CRT include 1 RCT comparing IMRT with deep inspiration breath hold (DIBH) to 3D-CRT, 2 additional RCTs comparing IMRT to 3D-CRT in women who had undergone breast-conserving surgery (with 1 RCT evaluating simultaneous vs. sequential boost therapy), 2 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 upon, or provide similar improvement in, clinical outcomes. The available studies on chest wall IMRT for postmastectomy breast cancer patients have 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 an improvement in the net health outcome.

For individuals who have lung cancer who receive IMRT, the evidence includes 1 RCT that focused on esophageal adverse events and multiple nonrandomized, retrospective, comparative studies. Relevant outcomes are OS, disease-specific survival, locoregional control, quality of life, 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, while reducing toxicity. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

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

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

For individuals who have brain tumor metastases who receive IMRT to avoid hippocampal exposure, the evidence includes a randomized trial, nonrandomized studies, and case series. Relevant outcomes are OS, DSS, functional outcomes, and treatment-related morbidity. One randomized trial and one prospective nonrandomized comparison study using IMRT to avoid hippocampal exposure showed less cognitive decline with IMRT than with either conventional whole-brain radiotherapy or prespecified historical controls. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Clinical input was obtained in 2012 on the use of IMRT, including its use close to critical structures. There was a near-uniform consensus that use of IMRT in the central nervous system is at least as effective as 3-dimensional conformal radiotherapy and that, given the adverse events that could result if nearby critical structures receive toxic radiation doses, IMRT dosimetric improvements should be accepted as meaningful evidence for its benefit. Input, a strong chain of evidence, and the potential to reduce harms supported a decision that IMRT may be considered medically necessary for the treatment of tumors of the central nervous system that are proximate to organs at risk.

For individuals who have head and neck cancer who receive IMRT, the evidence includes systematic reviews, randomized controlled trials (RCTs), and nonrandomized comparative studies. Relevant outcomes are overall survival (OS), functional outcomes, quality of life, and treatment-related morbidity. Recently published systematic reviews compared IMRT to 2-dimensional radiotherapy (2D-RT) and conformal radiotherapy (CRT) in patients with nasopharyngeal carcinoma (NPC). Results revealed a significant improvement in clinical oncologic outcomes (eg, OS, progression-free survival, locoregional control/survival) and toxicities such as xerostomia with IMRT in this patient population. A 2014 systematic review concluded that IMRT, when compared with 2D-RT or 3D-CRT, had no significant impact on OS or locoregional control in previously untreated patients with non-metastatic head and neck cancers; however, IMRT was associated with a significant improvement in xerostomia. One RCT compared 2 fractionation schedules of IMRT for locally advanced head and neck cancer and found a survival benefit in using simultaneous modulated accelerated radiotherapy boost over simultaneous integrated boost-IMRT. Nonrandomized cohort studies have supported the findings that both short- and long-term xerostomia are reduced with IMRT. Overall, 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 2D-RT or 3D-CRT. The evidence is sufficient to determine that the technology results in an 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 case series data. Relevant outcomes include OS, functional outcomes, quality of life, and treatment-related morbidity. High-quality studies that differentiate the superiority of any type of external beam RT 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 (eg, 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 an improvement in the net health outcome.

Clinical input obtained in 2012 provided a uniform consensus that IMRT is appropriate for the treatment of head and neck cancers. There was a near-uniform consensus that IMRT is appropriate in select patients with thyroid cancer. Respondents noted that IMRT for the head, neck, and thyroid tumors may reduce the risk of exposure to radiation in critical nearby structures (eg, spinal cord, salivary glands), thus decreasing the risks of adverse events (eg, xerostomia, esophageal stricture).

For individuals who have localized prostate cancer and are undergoing definitive RT who received IMRT, the evidence includes several prospective comparative studies, retrospective studies, and systematic reviews. Relevant outcomes are overall survival (OS), disease-free survival (DFS), disease specific survival, quality of life, and treatment-related morbidity. Although there are few prospective comparative trials, the evidence has generally shown that IMRT provides survival outcomes similar to 3-dimensional conformal radiotherapy (3D-

CRT) while reducing gastrointestinal (GI) and genitourinary (GU) toxicity. These findings are supported by treatment planning studies, which have predicted that IMRT improves target volume coverage and sparing of adjacent organs compared with 3D-CRT. A reduction in clinically significant complications of RT is likely to improve the quality of life for treated patients. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have prostate cancer and are undergoing RT after prostatectomy who receive IMRT, the evidence includes retrospective comparative studies, single-arm phase 2 trials, and systematic reviews. Relevant outcomes are OS, DFS, disease specific survival, quality of life, and treatment-related morbidity. Although the comparative studies are primarily retrospective, the evidence has generally shown that IMRT compared favorably to 3D-CRT with regard to GI and GU toxicity. Notably, a retrospective comparative study found a significant reduction in acute upper GI toxicity with IMRT compared with 3D-CRT, mainly due to better bowel sparing with IMRT. Another retrospective comparative study found a reduction in GU toxicity. A reduction in clinically significant complications of RT is likely to improve the quality of life for treated patients. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

CODING

Medicare Advantage Plans and Commercial Products

A4648 Tissue marker, implantable, any type, each (Note: This code is not separately reimbursed for institutional providers.)

Note: To ensure correct pricing of HCPC code **A4648** for the Calypso 4D localization system, the procedure/clinical notes and the invoice must be submitted.

The following codes are covered for Medicare Advantage Plans and Commercial Products when the criteria above is met:

- 77301** Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications
- 77338** Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan
- 77385** Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple (Institutional providers)
- 77386** Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex (Institutional providers)
- G6015** Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session: (Professional providers)
- 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: (Professional providers)

RELATED POLICIES

Non-Reimbursable Health Service Codes

Preauthorization via Web-Based Tool for Procedures

PUBLISHED

Provider Update, June 2023

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