



Intensity Modulated Radiation Therapy (IMRT)

Clinical Coverage Criteria

Overview

Intensity Modulated Radiation Therapy (IMRT) is a technology in radiation oncology that delivers radiation more precisely to the tumor while relatively sparing the surrounding normal tissues. It is an advanced form of three-dimensional conformal radiation therapy (3D CRT) that allows for varying intensities of radiation to produce dose distributions that are more conformal than those possible with standard 3D CRT.

IMRT is a computer-based method of planning for, and delivery of, narrow, patient specific, spatially and temporally modulated beams of radiation to solid tumors within a patient. IMRT planning and delivery uses an approach for obtaining the highly conformal dose distributions needed to irradiate complex targets positioned near, or invaginated by, sensitive normal tissues, thus improving the therapeutic ratios.

Definitions

Clinical Target Volume (CTV): The physician draws a margin around the Gross Target Volume (GTV) to generate a (CTV) which encompasses the volume of tissue at risk for microscopic disease (not visible on imaging studies).

Conformal therapy: The use of careful planning and delivery techniques designed to focus external radiation on a tumor and surrounding tissue which need treatment and protect areas which do not need treatment; three-dimensional conformal radiation therapy (3D CRT) and intensity modulated radiation therapy (IMRT) are examples of conformal therapy.

Gross Tumor Volume (GTV): The Radiation Oncologist reviews the three-dimensional images and outlines the target treatment of the image set. The summation of these contours defines the (GTV).

Intensity Modulated Radiation Therapy (IMRT): An approach to three-dimensional planning and treatment that optimizes the delivery of radiation to irregularly shaped volumes through a process called inverse planning and delivery of radiation that results in modulated fluence (intensity) of photon beams. By varying the fluence across multiple treatment fields, the radiation dose can be modulated to conform to irregular shapes and to design a heterogeneous dose distribution.

Planned Target Volume (PTV): To account for potential set-up variation or organ/patient motion. A final margin is added as such.

Three-dimensional conformal radiation therapy (3D CRT): An external radiation treatment approach that focuses on directing the radiation energy to the tumor target while sparing the surrounding normal tissues.

Policy

Intensity Modulated Radiation Therapy (IMRT) requires prior authorization. These requests must be supported by the treating provider(s) medical records.

Documentation that supports all of the following must be submitted to Fallon Health for review:

1. A prescription that clearly defines the goals and requirements of the treatment plan, including the specific dose constraints for the target(s) and nearby critical structures.
2. A statement by the treating physician documenting the special need for performing IMRT on the patient in question, rather than performing conventional or 3-dimensional treatment planning and delivery.
3. Approved IMRT inverse plan that meets prescribed dose constraints for the planning target volume and surrounding normal tissue using either dynamic multi-leaf collimator or segmented multi-leaf collimator) (typical number of steps (segments) per gantry angle required to meet IMRT delivery is 5), or inverse planned IMRT solid compensator to achieve intensity modulated radiation delivery.
4. The target verification methodology must include the following:
 - Documentation of the clinical treatment volume (CTV) and the planning target volume (PTV).
 - Documentation of immobilization and patient positioning.
 - Evidence that monitor units obtained from the IMRT treatment plan were checked by an independent method before the patient's first treatment, and that agreement met documented department standards.
 - Documentation that fluence distributions were re-computed in a phantom and that this distribution was shown to be in good agreement with an independent dosimetric measurement.

Coverage and Criteria are dependent on the disease location. Fallon Health will cover IMRT for the following disease sites. Coverage may be restricted by plan type.

Abdomen and Pelvic:

IMRT may be medically necessary when the tumor is in close proximity to at risk organs and 3D-CRT planning is not able to meet the dose volume constraints for normal tissue tolerances as noted in the below table:

For tumors of esophagus, stomach, pancreas, hepatobiliary tract, rectum, colon, and small bowel:

Tissue	Dose/Volume Threshold
Heart	$\geq 50\%$ of heart would receive $\geq 20\text{Gy}$
Lung	$\geq 30\%$ of combined lung volume would receive $\geq 20\text{Gy}$ or Mean lung dose $\geq 20\text{Gy}$
Spinal Cord	Any portion would receive a dose above 45Gy
Liver	$\geq 60\%$ of liver volume would receive $\geq 30\text{Gy}$ or Mean liver dose $\geq 32\text{Gy}$

Kidney	>=33% of combined kidney volume would receive >=20Gy (two functional kidneys are present) or For one functioning kidney or kidney transplant, IMRT provides a lower dose than achievable with 3D
Small Intestine	>=195cc would receive >=45Gy
Stomach	>10% would receive >=45Gy or >=5% would receive >=50Gy
Femoral Head	Would receive >=45Gy

For Tumors of the cervix or endometrium:

Tissue	Dose/Volume Threshold
Rectosigmoid	>=60% of rectosigmoid area would receive >=30Gy
Bladder	>=35% would receive >=45Gy
Femoral Head	Would receive >=45Gy
Small Intestine	Would receive >=45Gy

IMRT may be medically necessary for vulvar malignancies. Any other uses of IMRT (E.g. Uterine Cancer) are considered Investigational and not covered.

Breast:

IMRT to treat the breast is generally considered Investigational. Fallon Health Medical Director's will review the request on a case by case basis when there is clear indication of a risk to the heart/lungs.

Tissue	Dose/Volume Threshold
Heart	>=25% of heart >=5 Gy
Lung	>=30% of ipsilateral lung >=20 Gy Or >=20% of combined lung volume >=20 Gy

Central Nervous System:

IMRT may be medically necessary when the tumor is in close proximity to at risk organs (brain stem, spinal cord, cochlea and eye structures including optic nerve and chiasm, lens and retina) and 3-D CRT planning is not able to meet dose volume constraints for normal tissue tolerance.

Head, Neck, Thyroid:

1. It is essential the surrounding tissue be spared.
2. IMRT is the only treatment that would decrease the probability of grade 2 or 3 radiation toxicity when compared with conventional radiation in greater than 15% of similar cases.
3. Important dose limiting structures adjacent to, but outside the Planned Target Volume (PTV) are sufficiently close and require IMRT to assure for safety and morbidity reduction.
4. An immediate adjacent volume has been irradiated and abutting portals must be established with high precision.

- Gross Tumor Value (GTV) margins are close in proximity to critical structures and must be protected to avoid unacceptable morbidity.

Lung:

IMRT may be medically necessary when the tumor is in close proximity to at risk organs and 3D-CRT planning is not able to meet the dose volume constraints for normal tissue tolerance. All the below must be met:

- For members with primary lung cancer where concurrent chemotherapy and radiation is to be used.
- The percent of normal lung receiving more than 20 Gy (V20) accounts for more than 35% of the normal lung, defined as the total lung volume minus the planning target volume (PTV)
- An IMRT plan will reduce the V20 to at least 10% below the V20 that is achieved with the 3D-CRT plan (for example, from 40% down to 30% or lower)
- 3D results in mean heart dose ≥ 20 Gy
- There is documentation that the treatment plan addresses tumor motion that is both accounted for and managed such that:
 - A 4D planning CT scan was performed and the primary tumor and included lymph nodes were observed to move less than 1 cm and this degree of motion was included in the planning tumor volume; or
 - A 4D planning CT scan was performed and respiratory gating will be employed to minimize the risk of inadequate coverage; or
 - A 3D planning CT scan was performed with free-breathing, end-inspiration and end-expiration breathhold to minimize the risk of inadequate coverage.

Prostate:

- In the treatment of localized prostate cancer with an intact prostate receiving a radiation dose of ≥ 75 Gy, or
- In the treatment of prostate cancer post-prostatectomy when the prostatic bed will receive a radiation dose of ≥ 65 Gy.

Any other use of IMRT is considered Investigational and not covered.

Additionally Fallon Health will review IMRT for Anal Cancer; however IMRT to treat Colon Cancer is considered Investigational.

Exclusions

- Any use of IMRT other than outlined in this policy.

Codes

Code type	Code	Description
CPT	77301	Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specification
	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

HCPCS	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

References

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Policy History

Origination date:	01/01/2015
Approval(s):	Technology Assessment Committee: 12/03/2014 (adopted as new policy, consolidated IMRT for Breast Cancer Policy into this policy, 2015 CPT codes updated) 10/28/2015 (updated references, clarified exception language for IMRT of the Breast) 01/27/2016 (head, neck, thyroid now covered for all plan types, modified lung criteria for Commercial and MassHealth) 03/22/2017 (coverage is now the same for all plan types and Medicare retired their local coverage determination, lowered 3D volume threshold when critical organ in heart, updated references), 03/28/2018 (updated references), 03/27/2019 (updated references)

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy

between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans. For Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this policy.