



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.

Policy

This Policy applies to the following Fallon Health products:

- Medicare Advantage (Fallon Medicare Plus, Fallon Medicare Plus Central)
- MassHealth ACO
- NaviCare HMO SNP
- NaviCare SCO
- PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
- Community Care

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

Medicare Advantage (Fallon Medicare Plus, Fallon Medicare Plus Central)

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Medicare statutes and regulations do not have coverage criteria for intensity modulated radiation therapy (IMRT). Medicare does not have an NCD for IMRT. National Government Services, Inc., the Part A/B Medicare Administrative Contractor with jurisdiction in the Plan's service area does not have an LCD for IMRT. National Government Services, Inc. has an LCD for Prostate Rectal Spacers (L37485) (Medicare Coverage Database search 04/22/2024).

MassHealth ACO

Fallon Health follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity

Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

MassHealth does not have Medical Necessity Guidelines for IMRT, therefore the Plan's coverage criteria are applicable.

NaviCare HMO SNP, NaviCare SCO

For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Fallon Health Clinical Coverage Criteria

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	>= 50% of heart would receive >= 20Gy
Lung	>= 30% of combined lung volume would receive >= 20Gy or mean lung dose >= 20Gy
Spinal Cord	Any portion would receive a dose above 45Gy
Liver	>= 60% of liver volume would receive >= 30Gy or Mean liver dose >= 32Gy
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.
5. 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:

1. For members with primary lung cancer where concurrent chemotherapy and radiation is to be used.
2. 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)
3. 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)
4. 3D results in mean heart dose \geq 20Gy
5. 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 breath hold to minimize the risk of inadequate coverage.

Prostate

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

For requests for polyethylene glycol (PEG) hydrogel rectal spacers (CPT 55874) for Medicare Advantage, NaviCare and PACE plan members undergoing IMRT for clinically localized prostate cancer, refer to the National Government Services, Inc. LCD for Prostate Rectal Spacers (L37485) for coverage criteria.

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.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Code	Description
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
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

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Policy history

Origination date:	01/01/2015
Review/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), 06/25/2021 (Added clarifying language related to Medicare Advantage, MassHealth ACO, NaviCare and PACE under Policy section), 04/23/2024 (annual review, updated Medicare and MassHealth regulatory language under Policy section).

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.