Intensity Modulated Radiation Therapy (IMRT) Clinical Coverage Criteria

Overview

Intensity Modulated Radiation Therapy (IMRT) is a technology in radiation oncology that delivers radiation that conforms closely to the targeted tumor while relatively sparing the surrounding normal tissues.

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.

Requests for IMRT must be supported by documentation the patient's medical records. The medical record documentation must support the medical necessity of the services as stated in this policy.

Medical record 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 specific dose objectives for the target and nearby critical structures.
2. A signed IMRT plan that corresponds to the approved prescription.
3. The medical record must include the following:
    - Documentation of the gross treatment volumes (GTVs), clinical target volumes (CTVs), internal target volumes (ITVs), and the planning target volume (PTV).
    - Documentation of dose volume histograms (DVH) for targets and organs at risk (OARs).
    - Documentation of immobilization and patient positioning.
4. Evidence that basic dose calculations of monitor units have been performed for each beam before the patient's first treatment.
5. Documentation that fluence distributions were re-computed in a phantom or dosimetry measuring device.
6. Documentation supporting identification of structures that transverse high and low-dose regions created by respiration is indicated when billing for respiratory motion management stimulation.

Fallon Health Clinical Coverage Criteria

Fallon Health Clinical Coverage Criteria for intensity-modulated radiation therapy (IMRT) apply to all products.

IMRT is considered reasonable and medically necessary in instances where sparing the surrounding normal tissue is of added clinical benefit to the patient. This may include instances in which clinically relevant tolerances of normal tissues are exceeded for a single plan or in the re-irradiation setting. Based on this principle, IMRT may be considered reasonable and medically

necessary for the definitive treatment (i.e. radiation treatments for cancer with a curative intent) of the cancers listed below as specified in the ASTRO Model Policy for IMRT. Requests will be evaluated based on applicable NCCN and ASTRO guidelines.

1. Primary malignant or benign bone tumors
2. Central nervous system tumors (primary, metastatic, or benign) including the brain, brainstem, spinal cord, and ocular tumors
3. Head and Neck Cancers including but not limited to cancers of the nasopharynx, nasal cavity, paranasal sinuses, oropharynx, oral cavity, hypopharynx, larynx , thyroid, or salivary glands
4. Breast cancer, including:
    a. Bilateral breast cancer requiring nodal treatment on at least one side
    b. Breast cancer patients being treated with definitive intent and member has unfavorable anatomy (e.g., pectus excavatum) that would deliver unacceptably high doses to organs-at-risk
    c. Early-stage breast cancer in which dose to the heart is unacceptably high with conventional photon or photon/electron using cardiac sparing techniques
    d. Accelerated partial breast irradiation (APBI), regardless of laterality;
    e. Patients in whom internal mammary lymph nodes are targeted
    f. Breast cancer patients who have limited ipsilateral arm range of motion and require treatment in the arms down position
    g. Post-mastectomy radiotherapy when member has had bilateral implant-based reconstruction
    h. Whole breast radiotherapy in members with bilateral augmentation implants;
5. Thoracic cancer, including:
    a. Primary or secondary tumors of the mediastinum, including thymic tumors, mediastinal tumors, mediastinal lymphomas and thoracic sarcomas
    b. Early-stage lung cancer for which SBRT is not feasible secondary to anatomic considerations
    c. Stage III non-small cell lung cancer
    d. Locally advanced lung cancer in which IMRT significantly reduces dose to normal tissues (ex: bilateral mediastinal disease, paraspinal tumors, N3 disease, reducing esophageal dose;
    e. Malignant pleural mesothelioma
6. Gastrointestinal cancer, including:
    a. Hepatocellular cancer, bile duct, gallbladder and cholangiocarcinoma
    b. Primary cancers of the esophagus and gastroesophageal junction
    c. Abdominal malignancies, including primary pancreatic, gastric and adrenal cancers
    d. Primary and secondary liver cancers
    e. Anal and colorectal cancers
7. Sarcomas including retroperitoneal sarcomas, desmoid tumors and extremity sarcomas
8. Gynecological malignancies including cervical, vulvar, vaginal and endometrial
9. Genitourinary cancers including prostate, renal, bladder, penile and ureteral

IMRT may be covered for a condition that is not listed above, including recurrences or metastases in selected cases. Requests for exceptions will be evaluated on a case-by-case basis when at least one of the following conditions is present:

- Use of clinically appropriate radiation dose and a non-IMRT technique would increase the probability of clinically meaningful normal tissue toxicity, [e.g., as specified by the Radiation Therapy Oncology Group (RTOG) or QUANTEC guidelines] and demonstrated on a comparison of treatment plans for the IMRT and non-IMRT technique (e.g., three-dimensional conformal treatment plan)
- The same or an immediately adjacent area has been previously irradiated, and the dose distribution within the individual must be sculpted to avoid exceeding the cumulative tolerance dose of nearby normal tissue

Hypofractionation

Dose distribution may be delivered in conventional doses or higher doses over a shorter period of time (hypofractionated).

Hypofractionation may be considered reasonable:

- In the treatment of early breast cancer receiving whole breast irradiation (WBI), with or without inclusion of the low axilla, the preferred dose-fractionation scheme is hypofractionated WBI to a dose of 4000 centigray (cGy) in 15 fractions or 4250 cGy in 16 fractions. Use of boost should be based on shared decision-making that considers patient, tumor, and treatment factors, and the task force delineates specific subgroups in which it recommends or suggests use or omission of boost, along with dose recommendations (ASTRO Evidence-Based Guideline: Radiation Therapy for the Whole Breast, Smith et al., 2018).
- In the treatment of localized prostate cancer, strong consensus was reached for offering moderate hypofractionation (240-340 cGy per fraction) across risk groups to patients choosing external beam radiation therapy. Regimens of 6000 cGy delivered in 20 fractions of 300 cGy and 7000 cGy delivered in 28 fractions of 250 cGy are recommended since they are supported by the largest evidentiary base (ASTRO, ASO and AUA Evidence-Based Guideline: Hypofractionated Radiation Therapy for Localized Prostate Cancer, Morgan et al., 2018).

To date, the comparative effectiveness and harms of hypofractionation versus conventional radiation for definitive therapy have not been studied for many cancer types; only breast and prostate cancers have been adequately studied in randomized controlled trials. Among other cancers, including pancreatic, melanoma, head and neck, rectal, bladder, and lung cancer, evidence for hypofractionation is currently limited.

Medicare

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 are does not have an LCD for IMRT. Coverage criteria for IMRT are not fully established by Medicare; therefore, the Plan's coverage criteria are applicable.

National Government Services, Inc. has an LCD for Prostate Rectal Spacers (L37485) (Medicare Coverage Database search 08/23/2025).

MassHealth

MassHealth does not have Guidelines for Medical Necessity Determination for IMRT; therefore, the Plan's coverage criteria are applicable (MassHealth website search 08/23/2025).

Exclusions

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

Evidence Summary

Organs at Risk

The safe use of radiation therapy requires compliance with dose/volume constraints for organs at risk. Organs at risk are the health tissues/organs near the clinical target volume that may be particularly vulnerable to clinically important complications from radiation toxicity. The heart, for example, in radiation therapy of the left breast cancer, is an organ at risk. Tolerance to ionizing radiation from organs at risk (dose constraints), is one of the main factors limiting the choice of radiation therapy dose.

The majority of the dose–volume-constraints published in the literature refer to conventional 2 Gray (Gy) per fraction deliveries.

Radiation is measured in Gray (Gy), where one Gray is equivalent to the absorption of one joule of radiation energy by one kilogram of matter.

One centigray is equivalent to one-hundredth of a gray (0.01 Gy). Centigray is useful in dose calculations, where precise dosages are crucial for effective treatment and minimizing harm to healthy tissue.

1 cGy = 0.01 Gy
1 Gy = 100 cGy

Dose Constraint References

Radiation Therapy Oncology Group (RTOG) Radiation Dose Constraints Available from: https://en.wikibooks.org/wiki/Radiation_Oncology/Toxicity/RTOG

Quantitative Analyses of Normal Tissue Effects in the Clinic (QUANTEC) Available from: https://en.wikibooks.org/wiki/Radiation_Oncology/Toxicity/QUANTEC

Dose–Volume Constraints for Organs at Risk in Radiotherapy (CORSAIR) Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9600677/

Fractionation

Fractionation refers to the process of dividing the total dose of radiation into smaller doses, called fractions, delivered over a specified period. This approach is used to maximize destruction of malignant cells while minimizing damage to healthy tissues. The importance of fractionation protocols cannot be overstated, as they impact not only the efficacy of treatment but also the patient's quality of life during and after therapy.

Conventional fractionation is the most common type of fractionation. Typically, conventional fractionation is:

- Doses ranging from 180cGy to 200cGy.
- Given once a day, 5 days a week.
- Given over 6 to 7 weeks.

Other types of fractionation include hypofractionation and hyperfractionation.

Hypofractionation

Hypofractionation is a treatment regimen in which the total dose of radiation is divided into larger doses per fraction, resulting in fewer fractions and shorter overall treatment durations compared to conventional fractionation (Landsteiner A et al., 2023). Hypofractionation is differentiated from ultrahypofractionation in the treatment of prostate cancer.

Breast Cancer

The standard treatment for early-stage breast cancer is breast conservation therapy, which consists of breast conserving surgery followed by adjuvant radiation therapy, with or without adjuvant systemic agents. Multiple large, randomized trials of invasive breast cancer over the past half-century have demonstrated that radiation therapy significantly reduces locoregional recurrence after breast conserving surgery, resulting in high rates of breast preservation and excellent survival (Gupta et al., 2018). Adjuvant radiation therapy for early-stage breast cancer is commonly delivered as 1.8-2.0 Gy per fraction for 25 to 28 fractions (total dose of 45-50 Gy) to the whole breast (with or without an additional tumor bed boost) and is known as conventionally fractionated whole breast irradiation (CF-WBI). CF-WBI begins approximately 1 month after surgery and lasts for 5–7 weeks. Three-dimensional conformal radiotherapy (3D-CRT) or intensity modulated radiotherapy (IMRT) techniques are used. In either case, techniques are used to ensure uniform dose coverage of the whole breast while minimizing the dose to the thoracic organs (the heart and lungs).

Four major randomized, prospective phase III clinical trials compared hypofractionated whole breast irradiation (HF-WBI) to CF-WBI for early breast cancer and assessed tumor control outcomes with long-term follow-up:

- Royal Marsden Hospital and Gloucestershire Oncology Centre (RMH/GOC) in the United Kingdom (Yarnold et al., 2005, Owen et al., 2006)
- Ontario Clinical Oncology Group (OCOG) in Canada (Whelan et al., 2002, Whelan et al., 2010)

- Standardization of Breast Radiotherapy (START) Trial A and B (Start Trialists Group, 2008, Haviland et al., 2013, Start Trialists Group, 2008b)

The START A trial included two 13-fraction regimens (39 and 41.6 Gy) and 5-year results for local tumor control and late toxicity were found to be noninferior to CF-WBI. The START-B trial compared 40 Gy in 15 fractions over 3 weeks (used in the UK and Canada for decades) to CF-WBI (Hopwood et al., 2010). Five-year results again suggested that hypofractionation is noninferior to conventional fractionation in terms of both IBTR and late toxicity.

- Large prospective, randomized phase III trials have demonstrated that hypofractionated treatment results in equivalent tumor controls, better or improved acute and late toxicity, and better or improved breast cosmesis compared to conventionally fractionated regimens for early-stage breast cancer.
- Hypofractionated whole breast irradiation has become the new standard of care for breast conservation therapy; preferred regimens are 40 Gy in 15 fractions or 42.5 Gy in 16 fractions with or without a tumor bed boost.
- Randomized trials are ongoing to assess efficacy and safety of hypofractionated treatment in locally advanced breast cancers that require regional nodal treatment; early data support its use however broad adoption awaits long-term results.

The OCOG and START trials are considered to be practice-changing in the field of breast radiation oncology. Whereas historically it was standard to deliver a course of whole breast radiotherapy over five to seven weeks, with long-term data from these trials it has become well-accepted that shorter hypofractionated courses of three to four weeks are equivalent in tumor control and may even improve toxicity and breast cosmesis. Long-term results demonstrate that there are very few disadvantages of HF-WBI, and as such, led ASTRO to revise its consensus guidelines in 2018 (Smith et al., 2018) to recommend HF-WBI as standard practice in most women with early-stage breast cancers (Gupta et al., 2018).

ASTRO Evidence-Based Guideline: Radiation Therapy for the Whole Breast (Smith et al., 2018)
This guideline discusses factors that might or should affect fractionation decisions.

> Overall Statement
> Statement KQ1A. For women with invasive breast cancer receiving whole breast irradiation with or without inclusion of the low axilla, the preferred dose-fractionation scheme is hypofractionated WBI to a dose of 4000 centigray (cGy) in 15 fractions or 4250 cGy in 16 fractions.
> - Recommendation strength: Strong
> - Quality of evidence: High
> - Consensus: 100%
>
> Use of boost should be based on shared decision-making that considers patient, tumor, and treatment factors, and the task force delineates specific subgroups in which it recommends or suggests use or omission of boost, along with dose recommendations. When planning, the volume of breast tissue receiving >105% of the prescription dose should be minimized and the tumor bed contoured with a goal of coverage with at least 95% of the prescription dose. Dose to the heart, contralateral breast, lung, and other normal tissues should be minimized.

Prostate Cancer

Clinically Localized Prostate Cancer: AUA/ASTRO Guideline. Part III: Principles of Radiation and Future Directions (Eastham et al., 2022)
Part III of the three-part series dedicated to Clinically Localized Prostate Cancer: AUA/ASTRO Guideline discusses principles of radiation and offers several future directions of further relevant study in patients diagnosed with clinically localized prostate cancer. Refer to Parts I and II for discussion of risk assessment, staging, and risk-based management (Part I), and principles of active surveillance and surgery and follow-up (Part II).

> 28. Clinicians should utilize dose escalation when EBRT is the primary treatment for patients with prostate cancer. (Strong Recommendation; Evidence Level: Grade A)

Since the 1990s, multiple phase III randomized prospective studies have compared dose-escalated EBRT (DE-EBRT) using both 3-D conformal radiation therapy (3DCRT) and IMRT with standard dose EBRT and have consistently demonstrated improved biochemical progression-free survival (PFS) with dose escalation. Multiple randomized trials have compared escalated versus conventional dose radiation therapy in patients with localized prostate cancer. The trials enrolled a mix of low-, intermediate-, and high-risk patients. The trials consistently demonstrated
that escalated dose radiation therapy was associated with decreased rates of biochemical failure or recurrence.

29. Clinicians may counsel patients with prostate cancer that proton therapy is a treatment option, but it has not been shown to be superior to other radiation modalities in terms of toxicity profile and cancer outcomes. (Conditional Recommendation; Evidence Level: Grade C)

To date, no prospective study has demonstrated improved disease control or side effects with proton beam radiation therapy (PBRT) compared to IMRT. Proponents of PBRT have offered that it has dosimetric advantages compared to IMRT. That is, while the target volume for both techniques includes the prostate and a margin of normal tissue (bladder and rectum) that is irradiated to the prescribed dose, proton beam delivers lower integral doses and mean doses to normal tissues than IMRT. However, this dosimetric difference has not been shown to result in fewer side effects or better patient reported QOL. Indeed, the existing peer-reviewed literature suggests that clinical outcomes (eg, complications, patient reported QOL) are similar. Randomized trials are ongoing comparing IMRT and PBRT using long-term side effects and QOL as the primary endpoints (eg, PARTIQoL, which has a primary endpoint of bowel function at 24 months).

30. Clinicians should offer moderate hypofractionated EBRT for patients with low- or intermediate-risk prostate cancer who elect EBRT. (Strong Recommendation; Evidence Level: Grade A).

Using fewer (but larger dose) radiation treatments (ie, hypofractionation) may be more convenient for patients with prostate cancer electing radiation therapy. A systematic review (Hickey et al., 2019) compared hypofractionated (>2 Gy per fraction, range 2.35 to 3.4 Gy) versus conventionally fractionated (1.8 to 2 Gy) EBRT in patients with localized prostate cancer. This review included 10 randomized trials (N=8,278). In pooled analyses, no differences were noted between hypofractionation versus conventional fractionation with regard to biochemical recurrence-free survival (HR 0.88, 95% CI 0.68 to 1.13, 5 trials), metastasis-free survival (HR 1.07, 95% CI 0.65 to 1.76, 5 trials), prostate cancer-specific survival (HR 1.00, 95% CI 0.72 to 1.39, 8 trials), or overall survival (HR 0.94, 95% CI 0.83 to 1.07, 10 trials). There were also no differences identified with regard to acute genitourinary radiation therapy toxicity (Relative Risk [RR] 1.03, 95% CI 0.95 to 1.11), late genitourinary radiation therapy toxicity (RR 1.05, 95% CI 0.93 to 1.18), or late gastrointestinal radiation therapy toxicity (RR 1.10, 95% CI 0.68 to 1.78).

38. In patients with high-risk prostate cancer electing radiation therapy, clinicians may offer radiation to the pelvic lymph nodes. (Conditional Recommendation; Evidence Level: Grade B)

39. When treating the pelvic lymph nodes with radiation, clinicians should utilize IMRT with doses between 45 Gy to 52 Gy. (Strong Recommendation; Evidence Level: Grade B)

ASTRO, ASO and AUA Evidence-Based Guideline: Hypofractionated Radiation Therapy for Localized Prostate Cancer (Morgan et al., 2018)
External beam radiation therapy (EBRT) is a standard definitive treatment for men with localized prostate cancer. In this guideline, hypofractionation is subdivided into moderate hypofractionation (fraction size 240-340 cGy) and ultrahypofractionation (fraction size ≥500 cGy). The fraction size gap created by these definitions (ie, >340 cGy but <500 cGy) represents a little-studied range that

is outside of the scope of this document. Conventional fractionation is defined as a fraction size of 180 to 200 cGy.

Based on high-quality evidence, strong consensus was reached for offering moderate hypofractionation across risk groups to patients choosing external beam radiation therapy.

Hypofractionated radiation therapy provides important potential advantages in cost and convenience for patients, and these recommendations are intended to provide guidance on moderate hypofractionation and ultrahypofractionation for localized prostate cancer. The limits in the current evidentiary base—especially for ultrahypofractionation—highlight the imperative to support large-scale randomized clinical trials and underscore the importance of shared decision making between clinicians and patients.

KQ 1: In patients with localized prostate cancer who are candidates for EBRT, how does moderately hypofractionated EBRT (240-340 cGy per fraction) compared to conventionally fractionated EBRT (180- 200 cGy per fraction) in terms of prostate cancer control, toxicity, and quality of life, based on

- Prostate cancer risk stratification group?
- Patient age, comorbidity, anatomy (eg, prostate gland volume), and baseline urinary function?

Prostate cancer control outcomes: Impact of risk stratification group

Statement KQ1A: In men with low-risk prostate cancer who decline active surveillance and receive EBRT to the prostate with or without radiation to the seminal vesicles, moderate hypofractionation should be offered.

- Recommendation strength: Strong
- Quality of evidence: High
- Consensus: 100%

Statement KQ1B: In men with intermediate-risk prostate cancer receiving EBRT to the prostate with or without radiation to the seminal vesicles, moderate hypofractionation should be offered.

- Recommendation strength: Strong
- Quality of evidence: High
- Consensus: 100%

Statement KQ1C: In men with high-risk prostate cancer receiving EBRT to the prostate, but not
including pelvic lymph nodes, moderate hypofractionation should be offered.

- Recommendation strength: Strong
- Quality of evidence: High
- Consensus: 94%

Statement KQ1D: In patients who are candidates for EBRT, moderate hypofractionation should be offered regardless of patient age, comorbidity, anatomy, or urinary function. However, physicians should discuss the limited follow-up beyond 5 years for most existing RCTs evaluating moderate hypofractionation.

- Recommendation strength: Strong
- Quality of evidence: High
- Consensus: 94%

Four large, prospective, RCTs with over 6000 patients, as well as additional single-institution randomized trials, demonstrate that EBRT to the prostate using moderate hypofractionation provides prostate cancer control similar to that of EBRT delivered using conventional fractionation.

Toxicity and Quality of Life

Statement KQ1E: Men should be counseled about the small increased risk of acute gastrointestinal (GI) toxicity with moderate hypofractionation. Moderately hypofractionated

EBRT has a similar risk of acute and late genitourinary and late GI toxicity compared with conventionally fractionated EBRT. However, physicians should discuss the limited follow-up beyond 5 years for most existing RCTs evaluating moderate hypofractionation.

- Recommendation strength: Strong
- Quality of evidence: High
- Consensus: 100%

KQ 2: In patients with localized prostate cancer who are candidates for EBRT, how do moderately hypofractionated EBRT regimens used in clinical trials compare in terms of prostate cancer control, toxicity, and quality of life, and can particular regimens be recommended based on prostate cancer risk stratification group, age, comorbidity, anatomy (eg, prostate gland volume), and baseline urinary function?

Statement KQ2A: Regimens of 6000 cGy delivered in 20 fractions of 300 cGy and 7000 cGy delivered in 28 fractions of 250 cGy are suggested since they are supported by the largest evidentiary base. One optimal regimen cannot be determined because most of the multiple fractionation schemes evaluated in clinical trials have not been compared head to head.

- Recommendation strength: Conditional
- Quality of evidence: Moderate
- Consensus: 100%

Statement KQ2B: One moderately hypofractionated regimen is not suggested over another for cancer control for specific risk groups, and the efficacy of moderately hypofractionated EBRT regimens does not appear to be affected by patient age, comorbidity, anatomy, or urinary function.

- Recommendation strength: Conditional
- Quality of evidence: Moderate
- Consensus: 100%

Multiple moderately hypofractionated regimens have been evaluated in RCTs, including 6000 cGy in 20 fractions of 300 cGy and 7000 cGy in 28 fractions of 250 cGy. Significant differences in the populations enrolled in the trials, endpoint definitions, and use of concomitant androgen deprivation therapy preclude across-trial comparisons of the efficacy of the various regimens.

KQ 8: In patients with localized prostate cancer who are receiving moderately hypofractionated or ultrahypofractionated EBRT, how does treatment using IMRT compare to treatment with 3-dimensional conformal radiation therapy (3-D CRT) in terms of prostate cancer control, toxicity, and quality of life?

Statement KQ8A: Nonmodulated 3-D CRT techniques are not recommended when delivering moderately fractionated or ultrahypofractionated prostate EBRT.

- Strength of recommendation: Strong
- Quality of evidence: Moderate
- Consensus: 100%

National Comprehensive Cancer Network (NCCN) Prostate Cancer Version 2.2026- September 15, 2025

NCCN guidelines state that highly conformal radiation therapy (CRT), such as IMRT, should be used to treat prostate cancer. Photon and proton beam radiation are both effective at achieving highly CRT with acceptable and similar biochemical control and long-term side effect profiles. The cost of proton therapy is almost double that of IMRT (MS-25).

The second-generation 3D technique, IMRT, has been used increasingly in practice. IMRT reduced the risk of gastrointestinal toxicities and rates of post-recurrence therapy compared to 3D-CRT in some but not all older studies, although treatment cost is increased (MS-26).

More recently, moderately hypofractionated image-guided IMRT regimens (2,4 to 4 Gy per fraction over 4-6 weeks) have been tested in randomized trials, and their efficacy has been

similar or non-inferior to conventionally fractionated IMRT, with one trial showing fewer treatment failures with a moderately fractionated regimen. Toxicity was similar between moderately hypofractionated and conventional regimens in some but not all of the trials. In addition, efficacy results varied among the trials, with some showing noninferiority or similar efficacy and others showing that hypofractionation may be less effective than conventional fractionation schemes. These safety and efficacy differences are likely a result of differences in fractionation schedules. In addition, a large cohort study showed no differences in QOL or urinary or bowel function between those that received fractionated versus conventional regimens. Overall, the panel believes that hypofractionated IMRT techniques, which are more convenient for patients, can be considered as an alternative to conventionally fractionated regimens when clinically indicated. Fractionation schemes that have shown acceptable efficacy and toxicity can be found on PROS-I 4 of 8. An ASTRO/ASCO/AUA evidence-based guideline regarding the use of hypofractionated radiation in patients with localized prostate cancer concluded that moderately fractionated regimens are justified for routine use in this setting and provides mor detail on the topic (MS-26).

An analysis of the National Cancer Database found that dose escalation (75.6-90 Gy) resulted in a dose-dependent improvement in overall survival (OS) for patients with intermediate- or high-risk prostate cancer. In light of these findings, the conventional 70 Gy dose is no longer considered adequate. A dose of 75.6 to 79.2 Gy in conventional fractions to the prostate (with or without seminal vesicles) is appropriate for patients with low-risk cancers. Patients with intermediate -risk and high risk disease should receive doses of up to 81 Gy (MS-27).

Department of Veterans Affairs Systematic Review of Radiation Therapy for Definitive Treatment of Selected Cancers (Landsteiner et al., 2023)

To date, the comparative effectiveness and harms of hypofractionation versus conventional radiation for definitive therapy have not been summarized for many cancer types; only breast and prostate cancers have been summarized by recent systematic reviews. The U.S. Veterans Department (Landsteiner et al., 2023) conducted a systematic review of the available randomized trial evidence on the comparative efficacy and harms of hypofractionation versus conventional or long-course radiation as definitive therapy among adults with breast, prostate, lung, rectal, head and neck, bladder, pancreas, melanoma, and non-melanoma skin cancers. The cancers captured in this review were prioritized by the Operational Partners and where radiotherapy was likely to be used as definitive treatment.

In an effort to assess the highest quality evidence, this review focused on data from randomized controlled trials (RCTs). The reviewers searched MEDLINE and Embase from inception to January 5, 2022. A total of 106 publications were included, comprising 71 trials across the cancers of interest. Of the 46 trials rated low or some concerns for risk of bias, most compared moderate hypofractionation to conventional radiotherapy (n= 35). The majority of the trials evaluated breast (n = 17) or prostate (n = 18) cancers; while fewer trials looked at lung (n = 5), head and neck (n = 4) or rectal (n = 2) cancers. No randomized controlled trials were identified for pancreatic, melanoma, or non-melanoma skin cancers. A third of the studies enrolled less than 500 participants. The included trials evaluating lung, head and neck, and rectal cancers all had sample sizes less than 500. All trials enrolled populations with a median or mean age of ≥45. Studies varied in tumor and treatment regimen characteristics. The majority of trials conducted in the breast or prostate populations tended to have longer follow-up times (> 5 years), whereas the lung, head and neck, and rectal cancer trials tended to have shorter durations (< 5 years). Few were designed to adequately assess overall or disease specific survival.

Of the 8 cancers initially prioritized for this review, this review found no RCTs enrolling individuals with bladder, pancreatic, melanoma, and non-melanoma cancers. Only 1 or 2 RCTs rated as low risk of bias or as having some bias concerns were available for rectal and head and neck. Breast and prostate cancers both had a number of RCTs identified, as well as several prior systematic reviews related to hypofractionation. Previously published reviews in the other cancer types were primarily comprised of retrospective non-RCTs which have important limitations in outcome assessment.

Similar to other reviews among individuals with breast cancer, findings in this review suggest overall survival, local regional recurrence, and harms outcomes may not differ between hypofractionation and conventional radiotherapy. While there was greater variation in the harms outcomes, none of the analyses suggested a clinically meaningful difference in toxicity, based on a priori consensus derived thresholds, between hypofractionation and conventional radiotherapy. However, evidence certainty for acute and late harms was very low or low, in part due to a limited number of trials capturing the harm of interest as well as down rating for imprecision.

In men with prostate cancer, previous reviews found that overall survival and harms were similar between hypofractionation regimens compared to conventional radiotherapy. The findings is this review also support those results. Several review authors cited the need for longer follow-up periods and additional trials to provide clearer evidence regarding harms. While evidence certainty was low to moderate, many of the outcomes demonstrated little to no difference between hypofractionation and conventional radiotherapy. Such findings for survival are not unexpected given the indolent course of most localized prostate cancers even if treated expectantly.

For individuals with non-small cell lung cancer, evidence certainty for hypofractionation versus conventional therapy and SABR/SBRT versus conventional radiotherapy was either low or very low for all outcomes, making assessment challenging. Similarly, for individuals with small cell lung cancer, the evidence certainty for hypofractionation versus hyperfractionation was either low or very low for all outcomes. The included studies captured populations with variation in stage and location of disease. This variation in population coupled with smaller trial population sizes and short follow up periods were some of the noted concerns that led to a reduction in the certainty of evidence.

Hypofractionation results in fewer treatment days and thus may improve treatment access and reduce patient and caregiver burden. RCTs are needed in all cancers but particularly among patients with pancreatic, melanoma, non-melanoma, head and neck, rectal, bladder, and lung cancer. There is little to no evidence to address whether comparative effectiveness and harms vary by tumor or patient characteristics (Landsteiner et al., 2023).

Analysis of Evidence (Rational for Determination)

Intensity Modulated Radiation Therapy (IMRT) is a technology for delivering highly conformal external beam radiation to specified targets with radiation beams whose intensity varies throughout the individual treatment fields. IMRT is particularly useful for delivering highly conformal radiation dose to targets positioned near sensitive normal tissues.

The maturation and dissemination of IMRT capabilities with improved clinical outcomes has expanded to the point that for some anatomical sites such as head and neck malignancies, prostate, anus, central nervous system and thoracic malignancies, IMRT is commonly performed. However, it is important to note that normal tissue dose volume histograms (DVHs) or dosimetry must be demonstrably improved with an IMRT plan to validate coverage. In all cases, documentation of the medical necessity is required.

Coding

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

When medical necessity criteria for IMRT of the prostate are met, a hydrogel spacer (CPT 55874) would be considered medically necessary as well.

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

References

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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), 08/25/2025 (annual review, adopted ASTRO Model Policy for IMRT Indications,

Instructions for Use

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).

Fallon Health generally 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.

For plan members enrolled in NaviCare, Fallon Health first follows 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.

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.

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.