

Intensity Modulated Radiation Therapy (IMRT) Policy

Purpose

To describe the CVS Health Radiation Oncology Policy for Intensity Modulated Radiation Therapy (IMRT).

Scope

The scope of this document applies to CVS Health clients who have signed up for the CVS Radiation Oncology program under CVS Health Solutions. This document includes the details for the IMRT policy.

Policy

CVS Health considers intensity modulated radiation therapy (IMRT) medically necessary for the curative treatment of many tumor types. IMRT is a type of radiation that uses modulation of the radiation beams to shape around the target volumes and avoid the organs-at-risk. In the curative treatment of some cancers, IMRT has been shown to be superior in sparing normal tissue compared to 3D or 2D radiotherapy. When considering the medical necessity of IMRT, CVS Health considers the cancer stage, the treatment intent, if the overall treatment plan incorporates surgery or chemotherapy, margin status, and performance status.

Procedure

CVS Health considers IMRT medically necessary for the following indications when there is a concern about damage to surrounding critical structures with the use of 3D conformal radiation therapy, and after consideration of cancer stage, the treatment intent, if the overall treatment plan incorporates surgery or chemotherapy, margin status, and performance status:

Re-irradiation of an in-field or marginal recurrence being treated with curative intent, where other radiotherapy approaches would exceed acceptable constraints

- Adrenal gland cancer; or

CVS Health considers a maximum of 30 fractions with definitive intent and 20 fractions with palliative intent as medically necessary. CVS Health considers a maximum of 20 fractions for stage IV secondary malignancy neoplasm as medically necessary.

- Anal cancer; or

CVS Health considers a maximum of 33 fractions with definitive intent for stages 2 and 3 and 30 fractions for stage 1 as medically necessary. CVS Health recommends 3DCRT or 2D for members in Stage 4 with palliative intent.

- Anaplastic thyroid cancer; *or*

CVS Health considers a maximum of 33 fractions for stages 1-3 thyroid cancer as medically necessary

- Bladder cancer; *or*

CVS Health considers a maximum of 28 fractions with definitive intent for members with stages 3 or 4 bladder cancer that have undergone resection surgery and 36 fractions for all stages if they have not undergone resection surgery as medically necessary. CVS Health considers a maximum of 20 fractions with palliative intent as medically necessary.

- Brain tumors in close proximity to critical structures; *or*

CVS Health considers a maximum of 33 fractions for members with benign and malignant primary brain tumors in proximity to critical structures as medically necessary.

- Breast cancer; *or*

CVS Health considers IMRT not medically necessary for the treatment of breast cancer with the exception of the following scenarios where IMRT is medically necessary:

- a. Whole Breast Hypofractionation regimen (maximum of 24 fractions; up to 16 treatments and up to an additional 8 boost treatments)
 - i. left-sided breast cancer AND
 - ii. the following cardiac doses cannot be, using 3D, including after the use of complex positioning and breath hold technique: mean heart dose > 3.2 Gy AND can be less than that with IMRT
- b. Whole Breast Standard fractionation regimen (maximum of 33 fractions; up to 25 treatments and up to an additional 8 boost treatments)
 - i. Breast size >500 cc
 - ii. 3D CRT results in hotspots >110% AND can be avoided with IMRT
 - iii. 3D CRT, with positioning and breath hold optimization, yields a mean heart dose > 4 Gy AND can be less than that with IMRT
- c. Accelerated Partial breast irradiation
 - i. CVS Health considers a maximum of 10 fractions delivered twice daily or 5 fractions delivered daily for stages 0, I, and II as medically necessary.

- d. Bilateral breast irradiation (maximum of 33 fractions; up to 25 treatments and up to an additional 8 boost treatments)
- e. Postmastectomy radiation therapy (maximum of 33 fractions; up to 25 treatments and up to an additional 8 boost treatments)
- i. 3D CRT results in hotspots >110% AND can be avoided with IMRT OR
- ii. 3D CRT with positioning and breath hold optimization yields a mean heart dose > 4 Gy AND can be less than that with IMRT
- Cervical cancer; or

CVS Health considers a maximum of 25 fractions for members with stage 1 cervical cancer who have brachytherapy planned with definitive intent and a maximum of 35 fractions when no brachytherapy is planned as medically necessary. CVS Health considers a maximum of 30 fractions for members with stage 2 or 3 cervical cancer who have brachytherapy planned with definitive intent and a maximum of 35 fractions when no brachytherapy is planned as medically necessary. Stage 4 cervical cancer treated with definitive intent will require further oncologist review. CVS Health recommends 3DCRT or 2D for members with stage 4 disease with palliative intent.

- Cutaneous melanoma; or

CVS Health considers a maximum of 35 fractions for any cutaneous melanoma cancer stage with definitive intent as medically necessary and a maximum of 20 fractions with palliative intent as medically necessary.

- Endometrial cancer; or

CVS Health considers a maximum of 30 fractions for any endometrial cancer stage with definitive intent for members that have undergone surgery and a maximum of 35 fractions for members who have not undergone surgery as medically necessary. CVS Health recommends 3DCRT or 2D for members with palliative intent.

- Esophageal cancer; or

CVS Health considers a maximum of 35 fractions for members with cervical esophageal cancer with definitive intent and a maximum of 28 fractions for members with non-cervical esophageal with definitive intent as medically necessary. CVS Health considers a maximum of 10 fractions for members with treated with palliative intent as medically necessary.

- Gastric cancer; or

CVS Health considers a maximum of 30 fractions with definitive intent as medically necessary and a maximum of 10 fractions with palliative intent as medically necessary.

- Gallbladder cancer or

CVS Health considers a maximum of 30 fractions in the treatment of gallbladder cancer with definitive intent as medically necessary and a maximum of 10 fractions with palliative intent as medically necessary.

- Head and neck cancer excluding T1 and T2 glottic cancer; *or*

CVS Health considers a maximum of 37 fractions for members who have undergone surgery and are receiving chemotherapy with definitive intent as medically necessary. CVS Health considers a maximum of 68 fractions with BID dosing for members who have not had surgery or chemotherapy with definitive intent as medically necessary. CVS Health considers a maximum of 20 fractions with palliative intent as medically necessary.

- Hepatobiliary cancer; *or*

CVS Health considers a maximum of 30 fractions with definitive intent as medically necessary. CVS Health considers a maximum of 10 fractions with palliative intent as medically necessary.

- Hodgkin's Lymphoma; *or*

CVS Health considers a maximum of 24 fractions with definitive intent and complete response as medically necessary. CVS Health considers a maximum of 30 fractions with partial response as medically necessary. CVS Health recommends 3DCRT or 2D for members treated with palliative intent.

- Malignant Pleural Mesothelioma; *or*

CVS Health considers a maximum of 30 fractions with definitive intent and complete resections after surgery as medically necessary. CVS Health considers a maximum of 33 fractions with definitive intent and with no complete resection after surgery as medically necessary. CVS Health considers a maximum of 10 fractions with palliative intent as medically necessary.

- Merkel cell carcinoma; *or*

CVS Health considers a maximum of 33 fractions with definitive intent as medically necessary. CVS Health considers a maximum of 20 fractions with palliative intent as medically necessary.

- Metastatic disease to the brain

CVS Health considers a maximum of 10 fractions of hippocampal avoidance- whole brain radiation therapy (HA-WBRT) medically necessary when ALL of the following criteria are met: 1) the member has a better prognosis (≥ 4 months) and 2) no metastases within 5 mm of the hippocampi, and 3) no leptomeningeal metastases.

- Metastatic disease (non-brain)

CVS Health considers a maximum of 20 fractions as medically necessary when the following criteria are met:

Metastatic Breast, Non-Small Cell Lung, Colorectal, Renal Cell, and Prostate Cancers, Sarcoma, and Melanoma who meet the following criteria:

- 1-3 total metastases
- primary tumor has been or will be definitively addressed and is currently controlled
- all sites of metastases are being treated in this course of radiation
- radiation treatment cannot be safely delivered with SBRT
- Non-small cell lung cancer; or

CVS Health considers a maximum of 35 fractions for stages II and above with definitive intent as medically necessary. CVS Health recommends 3DCRT or 2D for members with palliative intent and stage 1 definitive intent.

- Non-melanoma skin cancer; or

CVS Health considers a maximum of 33 fractions with definitive intent in the head and neck area as medically necessary. CVS Health considers a maximum of 20 fractions with palliative intent as medically necessary.

- Pancreatic cancer; or

CVS Health considers a maximum of 30 fractions with definitive intent as medically necessary. CVS Health considers a maximum of 20 fractions with palliative intent as medically necessary.

- Penile cancer; or

CVS Health considers a maximum of 35 fractions for stages I to III with definitive intent as medically necessary. CVS Health recommends 3DCRT or 2D for members treated with palliative intent.

- Prostate cancer; or

CVS Health considers a maximum of 28 fractions as medically necessary in the treatment of prostate cancer unless the patient has ANY of the following:

1. High-risk or node-positive disease
2. History of inflammatory bowel disease
3. Previous pelvic radiation,
4. Prior TURP (transurethral resection of the prostate), cryotherapy, or HIFU (high-intensity focused ultrasound)

In Palliative intent, 20 maximum fractions will be approved.

- Non-Hodgkin's Lymphoma (NHL)

CVS Health considers a maximum of 30 fractions as medically necessary for the following histologies of NHL:

- a. Follicular
 - b. Marginal Zone
 - c. Mantle Cell
 - d. Diffuse large B-cell
 - e. Chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL)
 - f. Primary Cutaneous Lymphomas
 - g. T-cell lymphoma
 - h. Burkitt's lymphoma
 - i. PTLD (post-transplant lymphoproliferative disorder)
- Rectal cancer * see note

CVS Health considers a maximum of 30 fractions with definitive intent as medically necessary. CVS Health recommends 3DCRT or 2D for members with palliative intent with the exception of T4 tumors requiring treatment of the external iliac or inguinal lymph nodes.

- Small-bowel cancer; or

CVS Health considers a maximum of 30 fractions for stages I, II and III as medically necessary. CVS Health recommends 3DCRT or 2D for members treated with palliative intent.

- Small-cell lung cancer; or

CVS Health considers a maximum of 35 fractions daily (or 30 fractions twice daily) in the definitive treatment as medically necessary.

- Soft tissue sarcoma; or

CVS Health considers a maximum of 30 fractions with definitive intent for members who have surgery and complete resection. CVS Health considers a maximum of 40 fractions when surgery is not a treatment modality as medically necessary. CVS Health considers a maximum of 20 fractions necessary when the intent is palliative.

- Solitary Plasmacytoma; or

CVS Health considers a maximum of 28 fractions necessary in the treatment of solitary plasmacytoma of the head and neck as medically necessary.

- Testicular cancer; or

CVS Health considers IMRT not necessary in the treatment of testicular cancer.

- Thymic cancer/thymoma; or

CVS Health considers a maximum of 27 fractions (35 fractions for R2 resection) post-surgically as medically necessary. In the inoperable setting, CVS Health considers a maximum of 35 fractions as medically necessary. CVS Health considers a maximum of 15 fractions with palliative intent as medically necessary.

- Uveal melanoma; or

CVS Health considers a maximum of 5 fractions (30 fractions for R2 resection) in the treatment of uveal melanoma post-surgically medically necessary. CVS Health considers a maximum of 30 fractions in the inoperable setting as medically necessary. CVS Health considers a maximum of 10 fractions with palliative intent as medically necessary.

- Vulvar cancer

CVS Health considers a maximum of 30 in the treatment of vulvar cancer post-surgically as medically necessary. In the inoperable setting, a maximum of 36 fractions is considered medically necessary.

The final medical necessity will be determined based on the terms of the member's benefit plan. Please check benefit plan descriptions.

Related CMS Coverage Guidance

This Clinical Policy supplements but does not replace, modify, or supersede existing Medicare Regulations or applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). The supplemental medical necessity criteria in this policy further define those indications for services that are proven safe and effective where those indications are not fully established in applicable NCDs and LCDs. These supplemental medical necessity criteria are based upon evidence-based guidelines and clinical studies in the peer-reviewed published medical literature. While there is a possible risk of reduced or delayed care with any coverage criteria, CVS Health believes that the benefits of these criteria – ensuring patients receive services that are appropriate, safe, and effective – substantially outweigh any clinical harms.

Code of Federal Regulations (CFR):

42 CFR 417; 42 CFR 422; 42 CFR 423.

Internet-Only Manual (IOM) Citations:

CMS IOM Publication 100-02, Medicare Benefit Policy Manual; CMS IOM Publication 100-03 Medicare National Coverage Determination Manual.

Medicare Coverage Determinations:

Centers for Medicare & Medicaid Services (CMS), Medicare Coverage Database [Internet]. Baltimore, MD: CMS; updated periodically. Available at: Medicare Coverage Center. Accessed November 7, 2023.

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The IMRT policy is based on the following references:

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