Brachytherapy Policy

Purpose

To describe the CVS Health Radiation Oncology Policy for Brachytherapy.

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 Brachytherapy policy.

Policy

CVS Health considers brachytherapy medically necessary for the treatment of many tumor types. Brachytherapy is a type of radiation in which a radioactive source is placed in close proximity to the treatment site. This technique can be helpful in delivering a high dose to the target area while reducing the amount of radiation to normal surrounding tissue. A variety of radioactive isotopes are employed in brachytherapy. Broadly, brachytherapy can be delivered via intracavitary or interstitial placement. Brachytherapy is a cornerstone of the treatment of gynecologic tumors, including cervical and endometrial cancer. Brachytherapy can be delivered alone combined with external beam radiation therapy (EBRT). Breast brachytherapy treatment delivers radiation via a balloon catheter following lumpectomy to the space left after the cancerous tumor is removed and to the tissue directly surrounding the cavity. Example systems include Mammosite, Contura, and SAVI. In certain clinical scenarios, brachytherapy has been shown to provide superior outcomes compared to external beam radiotherapy. When considering the medical necessity of brachytherapy, CVS Health considers the cancer stage, the treatment intent, extent of disease, if the overall treatment plan incorporates surgery and external beam radiation therapy.

Procedure

CVS Health considers Brachytherapy medically necessary for the following indications:

- Breast cancer, DCIS (Ductal Carcinoma in Situ) and Invasive Breast Cancer (IBC), partial breast radiation delivered via intracavitary treatment
    - Approve 5 fractions delivered daily or 10 fractions delivered twice daily

- Endometrial Cancer, all stages, either with or without external beam radiation therapy
    - In the post-operative setting

a. Stage IA, IB, approve up to 5 fractions intracavitary (vaginal cylinder) brachytherapy
b. Stage II-IV, approve up to 3 fractions intracavitary (vaginal cylinder) if delivered with external beam radiation therapy and up to 5 fractions intracavitary (vaginal cylinder) without external beam radiation therapy

- Cervical Cancer, all stages, either with or without external beam radiation therapy
    - Tandem and ring/ovoid, vaginal cylinder, and interstitial brachytherapy are techniques all applicable
    - Approve up to 8 fractions brachytherapy

- Prostate Cancer, both *HDR and LDR brachytherapy approved, either in the primary setting or boost, where brachytherapy is delivered in conjunction with external beam radiation therapy
    - HDR, in the primary and boost settings, approve up to 6 fractions
    - LDR, in the primary and boost settings, approve

- Skin Cancer, specifically Keratinocyte carcinoma (KC, previously nonmelanoma skin cancer)
    - Approve radionuclide therapy. Electronic brachytherapy is not routinely approved for the treatment of skin cancer.
    - Approve up to 10 fractions

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.

References

The Brachytherapy policy is based on the following references:

1. Bhatnagar A, Loper A. The initial experience of electronic brachytherapy for the treatment of non-melanoma skin cancer. Radiat Oncol. 2010;5:87.
2. Collettini F, Schreiber N, Schnapauff D, et al. CT-guided high-dose-rate brachytherapy of unresectable hepatocellular carcinoma. Strahlenther Onkol. 2015;191(5):405-412.
3. Dickler A, Puthawala MY, Thropay JP, et al. Prospective multi-center trial utilizing electronic brachytherapy for the treatment of endometrial cancer. Radiat Oncol. 2010;5:67.
4. Dou K, Li B, Jacobs M, Laser B. SU-F-P-58: Squamous cell and basal cell carcinoma of the skin treated with a Freiburg flap applicator. Med Phys. 2016;43(6):3371.
5. Eaton DJ. Electronic brachytherapy - current status and future directions. Br J Radiol. 2015;88(1049):20150002.
6. Kee DLC, Gal J, Falk AT, et al. Brachytherapy versus external beam radiotherapy boost for prostate cancer: Systematic review with meta-analysis of randomized trials. Cancer Treat Rev. 2018;70:265-271.
7. Lee A, Givi B, Wu SP, et al. Patterns of care and impact of brachytherapy boost utilization for squamous cell carcinoma of the base of tongue in a large, national cohort. Brachytherapy. 2017;16(6):1205-1212.
8. Likhacheva AO, Devlin PM, Shirvani SM, et al. Skin surface brachytherapy: A survey of contemporary practice patterns. Brachytherapy. 2017;16(1):223-229.
9. Lloyd S, Alektiar KM, Nag S, et al. Intraoperative high-dose-rate brachytherapy: An American Brachytherapy Society consensus report. Brachytherapy. 2017;16(3):446-465.
10. National Comprehensive Cancer Network (NCCN). Basal cell skin cancer. NCCN Clinical Practice Guidelines in Oncology, v.1.2023. Fort Washington, PA: NCCN; 2023.
11. National Comprehensive Cancer Network (NCCN). Pancreatic adenocarcinoma. NCCN Clinical Practice Guidelines in Oncology, v.2.2023. Fort Washington, PA: NCCN; 2023.
12. National Comprehensive Cancer Network (NCCN). Central nervous system cancers. NCCN Clinical Practice Guidelines in Oncology, Version 1.2023. Fort Washington, PA: NCCN; 2023.
13. National Comprehensive Cancer Network (NCCN). Hepatobiliary cancers. NCCN Clinical Practice Guidelines in Oncology, Version 2.2023. Fort Washington, PA: NCCN; 2023.
14. National Comprehensive Cancer Network (NCCN). Squamous cell skin cancer. NCCN Clinical Practice Guidelines in Oncology, v.1.2023. Fort Washington, PA: NCCN; 2023.
15. Park CC, Yom SS, Podgorsak MB, et al; Electronic Brachytherapy Working Group. American Society for Therapeutic Radiology and Oncology (ASTRO) Emerging Technology Committee report on electronic brachytherapy. Int J Radiat Oncol Biol Phys. 2010;76(4):963-972.

16. Shah C, Vicini F, Shaitelman SF, et al. The American Brachytherapy Society consensus statement for accelerated partial-breast irradiation. Brachytherapy. 2018;17(1):154-170.
17. Tom MC, Hepel JT, Patel R, et al. The American Brachytherapy Society consensus statement for electronic brachytherapy. Brachytherapy. 2019;18(3):292-298.
18. Tsang YM, Tharmalingam H, Belessiotis-Richards K, et al. Ultra-fractionated radiotherapy for low- and intermediate risk prostate cancer: High-dose-rate brachytherapy vs stereotactic ablative radiotherapy. Radiother Oncol. 2021 Feb 24 [Online ahead of print].
19. Viswanathan AN, Erickson BA, Ibbott GS, et al. The American College of Radiology and the American Brachytherapy Society practice parameter for the performance of low-dose-rate brachytherapy. Brachytherapy. 2017;16(1):68-74.
20. Xoft Inc. Axxent Electronic Brachytherapy System [website]. Fremont, CA: Xoft; 2023. Available at: http://www.xoftmicrotube.com/. Accessed July 10, 2023.