

## Brachytherapy

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**All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member’s condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual [\\*](#).**

### Purpose:

This policy addresses the medical necessity of - Brachytherapy.

### Description & Definitions:

Brachytherapy utilizes radioactive seeds which are surgically placed next to a tumor. These allow a physician to use higher total dose of radiation to treat a small area.

### Criteria:

Brachytherapy may be indicated for **1 or more of the following**:

- Breast cancer as indicated by **1 or more of the following**:
  - Localized disease characterized as low-risk, after treatment with lumpectomy, as indicated by **1 or more of the following**:
    - Invasive ductal carcinoma with **ALL of the following**:
      - BRCA negative
      - Estrogen receptor positive
      - Negative surgical margin width of 2 mm or greater
      - No lymphovascular invasion
      - Individual age 50 years or older
      - Tumor size 2 cm or less (stage T1)
    - Low or intermediate grade ductal carcinoma in situ with **ALL of the following**:
      - Negative surgical margin width of 3 mm or greater
      - Tumor size 2.5 cm or less

- Localized disease characterized as high-risk, after treatment with lumpectomy, as indicated by **ALL of the following**:
  - Administered in conjunction with whole breast radiation.
  - Individual at higher risk of recurrence as indicated by **1 or more of the following**:
    - Age younger than 50 years
    - Focally positive surgical margins
    - High-grade (poorly differentiated) disease
  - Stage I, IIA, or IIB disease, or T3, N1, M0 disease
- Cervical cancer
- Cholangiocarcinoma, as indicated by **ALL of the following**:
  - As adjuvant treatment after surgery for individuals with 1 or more of the following:
    - R1 resection (positive margin)
    - R2 resection (gross residual disease after resection)
    - Carcinoma in situ found at the surgical specimen margin.
- Esophageal cancer, as indicated by **1 or more of the following**:
  - To treat a gross residual tumor or unresectable luminal lesion
  - Palliative treatment needed for dysphagia.
- Head and neck cancer
- Lung cancer, as indicated by **1 or more of the following**:
  - Non-small cell lung cancer, and symptomatic recurrent disease as indicated by **1 or more of the following**:
    - Endobronchial obstruction
    - Symptomatic hemoptysis
  - After local treatment failure with external beam radiation therapy, and recurrent symptoms as indicated by **1 or more of the following**:
    - Atelectasis
    - Cough
    - Dyspnea
    - Hemoptysis
    - Post-obstructive pneumonia
- Ocular melanoma without evidence of distant metastasis (ie, confined to the globe)
- Penile cancer
- Prostate cancer, as indicated by **1 or more of the following**:
  - Localized disease characterized as low-risk, as indicated by **ALL of the following**:
    - International Society of Urological Pathology (ISUP) Grade Group 1 (Gleason score of 6 or less)
    - Life expectancy 10 years or greater
    - Pretreatment PSA less than 10 ng/mL (mcg/L)
    - Stage T1 or T2a prostate cancer
    - No active inflammatory bowel disease
  - Localized disease characterized as intermediate-risk or high-risk, as indicated by **ALL of the following**:
    - Administered in conjunction with external beam radiation.
    - ISUP Grade Group 2 to 5 (Gleason score of 7 to 10)
    - Life expectancy greater than 5 years

- Pretreatment PSA of 10 ng/mL (mcg/L) or greater
  - Stage T2b/T2c or T3a prostate cancer
- Local recurrence after primary radiation therapy and **ALL of the following**:
  - Pretreatment PSA of 10 ng/mL (mcg/L) or less
  - No prior pelvic lymph node dissection
- Rectal cancer, as indicated by **1 or more of the following**:
  - Stage II or III disease that is medically operable, and **ALL** of the following:
    - Concurrent chemoradiation planned.
    - Individual refuses abdominoperineal resection
    - Tumor is less than 5 cm from the anal verge.
  - Stage II or III disease that is medically inoperable, and **1 or more of the following**:
    - Administered with chemoradiation, as indicated by **1 or more of the following**:
      - Tumor 10 cm or less from anal verge, and Eastern Cooperative Oncology Group (ECOG) performance status 0 to 1
      - Tumor 10 cm or less from anal verge, Eastern Cooperative Oncology Group (ECOG) performance status 2 or higher, and local symptoms present
      - Tumor less than 5 cm, Eastern Cooperative Oncology Group (ECOG) performance status 2 or higher, and local symptoms absent
    - Tumor 5 cm or less from anal verge, Eastern Cooperative Oncology Group (ECOG) performance status 0 to 1 and local symptoms absent
    - Tumor 10 cm or less from anal verge and local symptoms present
- Retinoblastoma, as indicated by **ALL of the following**:
  - After local treatment failure with **1 or more of the following**:
    - Chemotherapy
    - Cryotherapy
    - External beam radiation therapy
    - Laser therapy
  - Clinical staging demonstrates no evidence of metastases.
- Soft tissue sarcoma
- Skin Cancer (Basal Cell and Squamous Cell), as indicated by **1 or more** of the following:
  - To treat a skin cancer which is not amenable to surgery or external beam radiation.
  - To treat a previously irradiation field
- Squamous cell cancer of the eye as indicated by **ALL of the following**:
  - Only other option available is removal of the eye.
- Uterine Neoplasms (Endometrial Cancer, Uterine sarcoma, Uterine Cancer)
- Vulvar/Vaginal cancer

Brachytherapy is considered not medically necessary for any use other than those indicated in clinical criteria, to include but not limited to:

- High dose electronic brachytherapy (e.g. Xofig Axxent)
- Non-invasive brachytherapy (e.g. AccuBoost)

## Coding:

Medically necessary with criteria:

Coding	Description

19298	Placement of radiotherapy after loading brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes imaging guidance.
20555	Placement of needles or catheters into muscle and/or soft tissue for subsequent interstitial radioelement application (at the time of or subsequent to the procedure).
41019	Placement of needles, catheters, or other device(s) into the head and/or neck region (percutaneous, transoral, or transnasal) for subsequent interstitial radioelement application.
55875	Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy.
55920	Placement of needles or catheters into pelvic organs and/or genitalia (except prostate) for subsequent interstitial radioelement application.
57156	Insertion of a vaginal radiation afterloading apparatus for clinical brachytherapy.
77316	Brachytherapy isodose plan; simple (calculation[s] made from 1 to 4 sources, or remote afterloading brachytherapy, 1 channel), includes basic dosimetry calculation(s).
77317	Brachytherapy isodose plan; intermediate (calculation[s] made from 5 to 10 sources, or remote afterloading brachytherapy, 2-12 channels), includes basic dosimetry calculation(s).
77318	Brachytherapy isodose plan; complex (calculation[s] made from over 10 sources, or remote afterloading brachytherapy, over 12 channels), includes basic dosimetry calculation(s).
77750	Infusion or instillation of radioelement solution (includes 3-month follow-up care).
77761	Intracavitary radiation source application; simple.
77762	Intracavitary radiation source application; intermediate.
77763	Intracavitary radiation source application; complex.
77767	Remote afterloading high dose rate radionuclide skin surface brachytherapy, includes basic dosimetry, when performed; lesion diameter up to 2.0 cm or 1 channel.
77768	Remote afterloading high dose rate radionuclide skin surface brachytherapy, includes basic dosimetry, when performed; lesion diameter over 2.0 cm and 2 or more channels, or multiple lesions.
77770	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 1 channel.
77771	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 2-12 channels.

77772	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; over 12 channels.
77778	Interstitial radiation source application, complex, includes supervision, handling, loading of radiation source, when performed
77790	Supervision, handling, loading of radiation source
77799	Unlisted procedure, clinical brachytherapy (need to put for cardiovascular brachytherapy see mcg).

Considered Not Medically Necessary:

Coding	Description
0394T	High dose rate electronic brachytherapy, skin surface application, per fraction, includes basic dosimetry, when performed.
0395T	High dose rate electronic brachytherapy, interstitial or intracavitary treatment, per fraction, includes basic dosimetry, when performed.

U.S. Food and Drug Administration (FDA) - approved only products only.

## Document History:

Revised Dates:

- 2021: March
- 2020: April
- 2019: December
- 2015: June, July, October
- 2014: June, December
- 2013: April, May, June
- 2012: January, June, July, September
- 2011: June, December
- 2010: March, July
- 2009: June
- 2008: January, June

Reviewed Dates:

- 2023: March
- 2022: March
- 2019: March
- 2018: November
- 2017: November
- 2016: March, July, August
- 2010: February, June
- 2005: October

Effective Date:

- February 2001

## References:

Including but not limited to: Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

Federal Register. The Daily Journal of the United States Government. Rubidium-82 Generators, Emerging Technologies, and Other Medical Use of Byproduct Material. 7.3.2023. Retrieved 2.23.24. <https://www.federalregister.gov/documents/2023/07/03/2023-14018/rubidium-82-generators-emerging-technologies-and-other-medical-use-of-byproduct-material>

U.S. Department Of Health And Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Radiological Devices Branch, Division of Reproductive, Abdominal, and Radiological Devices. Photon-Emitting Brachytherapy Sources. Retrieved 2.23.24. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-submission-premarket-notifications-photon-emitting-brachytherapy-sources-guidance-industry>

Hayes. A symplr Company. Health Technology Assessment. Apr 30, 2021. Accelerated Partial Breast Irradiation For Breast Cancer Using Brachytherapy. Retrieved 3.1.24. <https://evidence.hayesinc.com/report/dir.brachytherapybreast521>

Hayes. A symplr Company. Clinical Research Response, Jun 16, 2023. GammaTile (GT Medical Technologies Inc.) for Brain Tumors. Retrieved 3.1.24. <https://evidence.hayesinc.com/report/crr.gamma5639>

Centers for Medicare & Medicaid Services. CMS.gov. Intraoperative Radiation Therapy. L37779. 7.29.2021. Retrieved 3.1.24. <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=37779&ver=16>

Commonwealth of Virginia. Department of Medical Assistance Services. Provider Manual. 2024. Retrieved 3.1.24. [https://vamedicaid.dmas.virginia.gov/pdf\\_chapter/practitioner#gsc.tab=0&gsc.q=brachytherapy&gsc.sort=](https://vamedicaid.dmas.virginia.gov/pdf_chapter/practitioner#gsc.tab=0&gsc.q=brachytherapy&gsc.sort=)

National Comprehensive Cancer Network. NCCN.org. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Version 4.2023, Prostate Cancer Version 4.2023 — September 7, 2023. Retrieved 3.1.24. [https://www.nccn.org/professionals/physician\\_gls/pdf/prostate\\_blocks.pdf](https://www.nccn.org/professionals/physician_gls/pdf/prostate_blocks.pdf)

Anderson, E., Kim, S, Sandler, H, Kamrava, M. High-dose-rate fractionated brachytherapy monotherapy for localized prostate cancer: a systematic review and meta-analysis. Journal of Contemporary Brachytherapy. 8.13.2021. Retrieved 3.1.24. doi: 10.5114/jcb.2021.108590

National Comprehensive Cancer Network. NCCN.org. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Basal Cell Skin Cancer. Version 2.2024.- September 14, 2023. Retrieved 3.1.2024. [https://www.nccn.org/professionals/physician\\_gls/pdf/nmsc\\_blocks.pdf](https://www.nccn.org/professionals/physician_gls/pdf/nmsc_blocks.pdf)

National Comprehensive Cancer Network. NCCN.org. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) CCN Guidelines Version 1.2024 Invasive Breast Cancer – January 25, 2024. Retrieved 3.1.24. [https://www.nccn.org/professionals/physician\\_gls/pdf/breast\\_blocks.pdf](https://www.nccn.org/professionals/physician_gls/pdf/breast_blocks.pdf)

National Comprehensive Cancer Network. NCCN.org. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Version 1.2024, 09/20/23 Cervical Cancer Version 1.2024 — September 20, 2023. Retrieved 3.4.24. [https://www.nccn.org/professionals/physician\\_gls/pdf/cervical\\_blocks.pdf](https://www.nccn.org/professionals/physician_gls/pdf/cervical_blocks.pdf)

National Comprehensive Cancer Network. NCCN.org. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). NCCN Guidelines Version 4.2023 Esophageal and Esophagogastric Junction Cancers - January 26, 2024. Retrieved 3.5.2024. [https://www.nccn.org/professionals/physician\\_gls/pdf/esophageal\\_blocks.pdf](https://www.nccn.org/professionals/physician_gls/pdf/esophageal_blocks.pdf)

National Comprehensive Cancer Network. NCCN.org. NCCN Clinical Practice Guidelines in Oncology (NCCNGuidelines®). Small Cell Lung Cancer Version 1.2024 — September 5, 2023. Retrieved 3.5.2024. [https://www.nccn.org/professionals/physician\\_gls/pdf/sclc\\_blocks.pdf](https://www.nccn.org/professionals/physician_gls/pdf/sclc_blocks.pdf)

National Comprehensive Cancer Network. NCCN.org. NCCN Clinical Practice Guidelines in Oncology (NCCNGuidelines®). Melanoma: Uveal Version 1.2023 — May 4, 2023. Retrieved 3.5.2024. [https://www.nccn.org/professionals/physician\\_gls/pdf/uveal\\_blocks.pdf](https://www.nccn.org/professionals/physician_gls/pdf/uveal_blocks.pdf)

National Comprehensive Cancer Network. NCCN.org. NCCN Clinical Practice Guidelines in Oncology (NCCNGuidelines®). Penile Cancer Version 1.2024 — October 25, 2023, Retrieved 3.5.24. [https://www.nccn.org/professionals/physician\\_gls/pdf/penile\\_blocks.pdf](https://www.nccn.org/professionals/physician_gls/pdf/penile_blocks.pdf)

National Comprehensive Cancer Network. NCCN.org. NCCN Clinical Practice Guidelines in Oncology (NCCNGuidelines®). Rectal Cancer Version 1.2024 — March 4, 2024. Retrieved 3.5.2024. [https://www.nccn.org/professionals/physician\\_gls/pdf/rectal\\_blocks.pdf](https://www.nccn.org/professionals/physician_gls/pdf/rectal_blocks.pdf)

National Comprehensive Cancer Network. NCCN.org. NCCN Clinical Practice Guidelines in Oncology (NCCNGuidelines®). Soft Tissue Sarcoma Version 3.2023 — December 12, 2023 . Retrieved 3.5.24 [https://www.nccn.org/professionals/physician\\_gls/pdf/sarcoma\\_blocks.pdf](https://www.nccn.org/professionals/physician_gls/pdf/sarcoma_blocks.pdf)

National Comprehensive Cancer Network. NCCN.org. NCCN Clinical Practice Guidelines in Oncology (NCCNGuidelines®). Uterine Neoplasms Version 1.2024 — September 20, 2023. Retrieved 3.5.24. [https://www.nccn.org/professionals/physician\\_gls/pdf/uterine\\_blocks.pdf](https://www.nccn.org/professionals/physician_gls/pdf/uterine_blocks.pdf)

National Comprehensive Cancer Network. NCCN.org. NCCN Clinical Practice Guidelines in Oncology (NCCNGuidelines®). Vulvar Cancer . Version 3.2024 — December 21, 2023. Retrieved 3.5.24. [https://www.nccn.org/professionals/physician\\_gls/pdf/vulvar\\_blocks.pdf](https://www.nccn.org/professionals/physician_gls/pdf/vulvar_blocks.pdf)

Carelon Medical Benefits Management clinical appropriateness guidelines and cancer treatment pathways. Radiation Therapy (excludes Proton) 2023-04-09. Retrieved 3.8.2024. <https://guidelines.carelonmedicalbenefitsmanagement.com/radiation-therapy-excludes-proton-2023-04-09/>

MCG, 27th Edition. Informed Care Strategies. Brachytherapy. ACG: A-0270 (AC). Retrieved 3.8.2024. <https://careweb.careguidelines.com/ed27/index.html>

National Cancer Institute. Brachytherapy to Treat Cancer. 1.29.2019. Retrieved 3.8.24. <https://www.cancer.gov/about-cancer/treatment/types/radiation-therapy/brachytherapy>

### Special Notes: \*

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to “correct or ameliorate” (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member’s condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

### Keywords:

Brachytherapy, shp medical 71, radioactive seeds, Xofigo, accubox, Radioactive seed localization, RSL, breast cancer, lumpectomy, BRCA, ductal carcinoma in situ, Cervical cancer, Endometrial cancer, Esophageal cancer, Head and neck cancer, Lung cancer, penile cancer, prostate cancer, Ocular melanoma, rectal cancer, retinoblastoma, Respiratory and digestive tract cancers, Soft tissue sarcoma, Vaginal cancer, ebrt