Brachytherapy

Humana®

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Medical Coverage Policy

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Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy

Description

Brachytherapy is a form of treatment, used for both oncologic and non-oncologic conditions, in which radioactive materials are placed inside the body. Radiation sources used during brachytherapy can be implanted either temporarily (via a catheter or tube for a specific time and withdrawn) or permanently (seeds or pellets in or near the tumor which are not removed). These sources can be placed using a variety of different techniques, including but not limited to:

- **Interstitial brachytherapy** is performed by placing the radioactive source directly into or around the tissue to be treated. **GammaTile** is an example of an interstitial brachytherapy device used specifically to treat brain cancers.

- **Intracavity brachytherapy** involves the placement of a radioactive substance in a body cavity near the area to be treated (eg, a tumor).

- **Intraoperative radiation therapy (IORT)** refers to the application of radiation treatment to a surgically exposed site while an individual is in the operating room.

- **Surface brachytherapy**, also known as plaque brachytherapy, is performed when the radiation source is placed directly on an external tumor or target surface (eg, eye, skin cancer).

Based on the technique, either high-dose rate (HDR) or low-dose rate (LDR) brachytherapy can be utilized. LDR brachytherapy is defined as treatment delivered at a rate of 0.4 to 2 Gy per hour, whereas HDR brachytherapy can be delivered at greater than 12 Gy per hour.[111] Additionally, there are a variety of modalities for the delivery of brachytherapy treatment. Depending on the indication, brachytherapy can be delivered using one of several methods including, but may not be limited to:

- **Accelerated partial breast irradiation (APBI)** treatment delivers radiation to the remaining tissue bed after surgery to remove a cancerous tumor. In contrast to conventional whole-breast radiation treatments (WBRT), APBI delivers radiation to the area directly surrounding the original tumor, thus, minimizing radiation exposure to the rest of the breast and other organs. Furthermore, because it is administered in fewer treatments, it allows individuals to return to their normal activities more quickly than WBRT. APBI can be delivered using interstitial brachytherapy, balloon-based applicators, external beam radiotherapy or IORT.

- **Electronic brachytherapy (EBT)** uses an HDR, low-energy X-ray source to apply radiation to the cancerous site. EBT is currently being studied to treat a wide variety of cancers, including, but may not be limited to breast cancer, brain cancer and some skin cancers. Examples of EBT devices include the **Xoft Axxent Electronic Brachytherapy System**, the **Esteya EBT system** and the **INTRABEAM system**. **(Refer to Coverage Limitations section)**

- **Intracoronary brachytherapy** is used to prevent restenosis of an artery after angioplasty or stent placement by delivering a small amount of radiation to the treated area, which may reduce the need for additional angioplasty or bypass surgery. The radiation is intended to discourage the overgrowth of normal tissue as the healing process occurs.

- **Intravascular brachytherapy** has been investigated as an adjunct to angioplasty of the femoropopliteal segment to reduce the risk of restenosis. **(Refer to Coverage Limitations section)**

- **Noninvasive brachytherapy** of the breast involves the use of mammography, which reportedly provides real-time images of the lumpectomy cavity and identifies the size and location needed for the dosing applicators. Noninvasive HDR brachytherapy applicators are positioned on opposite sides of the breast and radiation is delivered directly to the target site. An example of a noninvasive brachytherapy device is the **Accuboost system**. **(Refer to Coverage Limitations section)**

- **Selective internal radiation therapy (SIRT)**, also known as **transarterial radioembolization (TARE)**, is a procedure in which tiny radiation-filled (eg, yttrium-90) beads, called microspheres, are delivered directly to the tumor. The microspheres are delivered through a catheter placed in the femoral artery and threaded through the hepatic artery to the tumor site. There are two devices approved by the US Food and Drug Administration (FDA) for use in SIRT/TARE therapy. **SIR-Spheres** are resin spheres that are

indicated for the treatment of unresectable metastatic liver tumors from primary colorectal cancer (CRC). **Theraspheres** are spheres made of glass, which are indicated for unresectable primary hepatocellular carcinoma (HCC).

Prostate rectal spacers, also known as **transperineal biodegradable spacers (eg, Barrigel Hyaluronic Spacer, SpaceOAR)** can be placed in individuals with prostate cancer to position the anterior (frontal) section of the rectal wall away from the prostate during radiotherapy treatments with the goal of limiting radiation exposure to the anterior rectum. Because this material is biodegradable, it is absorbed by the body over time.

Coverage Determination

Brachytherapy
Humana members may be eligible under the Plan for **brachytherapy** when the following criteria are met:

- Brain cancer for the following indications:
  - Treatment with GammaTile in an individual with newly diagnosed or recurrent intracranial neoplasms[116]; **OR**
- Breast cancer (**refer to Coverage Limitations section for noncovered types of brachytherapy of the breast**):
  - Accelerated partial breast irradiation (APBI) when the following criteria are met:
    - 45 years of age or older[12,38]; **AND**
    - *BRCA* negative[38]; **AND**
    - Invasive carcinoma or ductal carcinoma in situ (DCIS)[12,38]; **AND**
    - Node negative[12]; **AND**
    - Total tumor size less than or equal to 3 cm[12,38]; **AND**
    - Tumor removed with negative surgical margins[12,38]; **OR**
  - Adjunctive boost to the tumor bed in an individual receiving whole breast radiation therapy (WBRT) following breast conserving surgery (eg, lumpectomy)[21,63]; **OR**
- Extrahepatic cholangiocarcinoma for the following indications:
  - Palliation of obstructive jaundice (eg, recurrent stent occlusion) in individuals with unresectable disease; **OR**
  - Treatment in combination with external beam radiation therapy (EBRT) for unresectable, nonmetastatic disease[113]; **OR**
- Esophageal cancer for the following indications:

  - Palliative treatment for obstructive dysphagia[21,24,66,75,89,106]; **OR**
  - Unresectable, nonmetastatic disease[24]; **OR**

- Gynecologic cancer (cervical,[5,6,7,21,33,66,70,88] endometrial/uterine[19,21,66,100] or vaginal[21,66,84]); **OR**

- Head and neck cancer (eg, lip, nasopharyngeal, oral cavity, salivary gland)[21,66,90]; **OR**

- Intracoronary application for in-stent restenosis following angioplasty or stent placement[15,67,114]; **OR**

- Intraocular cancer for the following indications:

  - As a secondary treatment for retinoblastoma after local treatment failure (eg, cryoablation, EBRT, laser therapy, local or systemic chemotherapy)[8,80]; **OR**

  - Uveal melanoma[8,93]; **OR**

- Lung cancer for the following indications:

  - Endobronchial treatment of the central airway in an individual who is not a candidate for surgical resection[17,21]; **OR**

  - Palliative treatment for an individual with unresectable disease and symptomatic airway obstruction[17,31,78,81]; **OR**

- Nonmelanoma skin cancer for the following indications:

  - Definitive treatment for individuals in which surgery would be disfiguring or compromise function; **OR**
  - Definitive treatment for individuals who cannot undergo or decline surgical treatment[1,2,30,66]; **OR**

- Penile cancer when the following criteria are met:

  - Node negative; **AND**
  - T1 or T2 disease; **AND**
  - Tumors less than 4 cm confined to the glans and prepuce[66,79,96]; **OR**

- Prostate cancer for the following indications:

  - Monotherapy for low-risk or favorable intermediate-risk disease[11,21,29,40,45,97]; **OR**

  - As a boost following EBRT for unfavorable intermediate-risk, high-risk or very high-risk disease[11,21,29,40,45,97]; **OR**

  - Salvage therapy for local recurrence after prior radiotherapy[21,46,66]; **OR**

- Soft tissue sarcoma when the following criteria are met:

- Postoperatively, as either monotherapy or a boost following EBRT for individuals with positive surgical margins; **OR**

- As a postoperative boost following EBRT in individuals with negative surgical margins[98]; **OR**

- Vulvar cancer for the following indications:

  - As a boost following EBRT; **OR**
  - Monotherapy for primary disease[101]

Prostate Rectal Spacers

Humana members may be eligible under the Plan for implantation of **prostate rectal spacers (eg, SpaceOar, Barrigel)** when the following criteria are met:

- Individual undergoing radiation treatment for prostate cancer; **AND**
- No grossly apparent posterior extraprostatic extension[57,97]

Selective Internal Radiation Therapy

Humana members may be eligible under the Plan for treatment using **SIRT** when the following criteria are met:

- Intrahepatic cholangiocarcinoma for the following indications:

  - Individual is not a candidate for surgical resection (eg, unresectable mass or medical comorbidities prohibiting surgery); **OR**

  - Treatment is being used to downstage disease in preparation for other curative treatments[86]; **OR**

- Treatment of a solitary tumor using TheraSpheres in an individual with unresectable hepatocellular carcinoma (HCC)[122] when the following criteria are met:

  - Tumor measuring 1-8 cm in diameter; **AND**

  - Child-Turcotte-Pugh Score A cirrhosis; **AND**

  - Eastern Cooperative Oncology Group (ECOG) Performance Status of 0-2; **AND**

  - No macrovascular invasion; **AND**

  - Well-compensated liver function (eg, no signs or symptoms of decompensation such as ascites, hepatic encephalopathy, jaundice or variceal hemorrhage); **OR**

- Treatment of unresectable metastatic liver tumors from primary colorectal cancer (CRC) using SIR-Spheres in conjunction with adjuvant intra-hepatic artery chemotherapy[121]; **OR**

- Unresectable liver metastases from primary neuroendocrine tumors for **ANY** of the following:

    - Symptomatic on a somatostatin analogue (SSA) or following another form of systemic therapy; **OR**
    - Progressive on a SSA or following another form of systemic therapy; **OR**
    - Used as debulking therapy for bulky liver disease[20,94]

AND absence of ALL of the following:

- Abnormal vascular anatomy that would result in significant reflux of hepatic arterial blood to the stomach, pancreas or bowel

- Ascites

- Clinical liver failure

- Disseminated extra-hepatic malignant disease

- Greater than 20% shunting of the hepatic artery blood flow to the lungs

- Portal vein thrombosis

- Previous EBRT to the liver

- Treatment with capecitabine within 2 months prior to or any time after treatment with SIR-Spheres[121,122]

Coverage Limitations

Humana members may **NOT** be eligible under the Plan for **brachytherapy** for any indications other than those listed above including, but may not be limited to:

- Age-related macular degeneration; **OR**
- Bladder cancer; **OR**
- Intravascular brachytherapy following femoropopliteal angioplasty; **OR**
- Pancreatic cancer

These are considered experimental/investigational as they are not identified as widely used and generally accepted for any other proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the Plan for the following types of **brachytherapy** for **ANY** indications including, but may not be limited to, breast cancer:

- Electronic brachytherapy (0394T, 0395T) and placement of the radiation therapy applicator (0735T); **OR**
- Noninvasive brachytherapy (eg, Accuboost)

These are considered experimental/investigational as they are not identified as widely used and generally accepted for any other proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Robotic-assisted brachytherapy and/or the use of software in planning brachytherapy treatment (eg, Clarity System, Vitesse HDR Treatment Planning System) are considered integral to the primary procedure and not separately reimbursable.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
19296	Placement of radiotherapy afterloading expandable catheter (single or multichannel) into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; on date separate from partial mastectomy	
19297	Placement of radiotherapy afterloading expandable catheter (single or multichannel) into the breast for interstitial radioelement application following partial mastectomy, includes imaging guidance; concurrent with partial mastectomy (List separately in addition to code for primary procedure)	
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	
19499	Unlisted procedure, breast	**Not Covered if used to report any treatment outlined in Coverage Limitations section**

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)	
31643	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of catheter(s) for intracavitary radioelement application	
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	
55860	Exposure of prostate, any approach, for insertion of radioactive substance;	
55862	Exposure of prostate, any approach, for insertion of radioactive substance; with lymph node biopsy(s) (limited pelvic lymphadenectomy)	
55865	Exposure of prostate, any approach, for insertion of radioactive substance; with bilateral pelvic lymphadenectomy, including external iliac, hypogastric and obturator nodes	
55874	Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed	
55875	Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy	
55876	Placement of interstitial device(s) for radiation therapy guidance (eg, fiducial markers, dosimeter), prostate (via needle, any approach), single or multiple	
55920	Placement of needles or catheters into pelvic organs and/or genitalia (except prostate) for subsequent interstitial radioelement application	
57155	Insertion of uterine tandem and/or vaginal ovoids for clinical brachytherapy	
57156	Insertion of a vaginal radiation afterloading apparatus for clinical brachytherapy	
58346	Insertion of Heyman capsules for clinical brachytherapy	
61770	Stereotactic localization, including burr hole(s), with insertion of catheter(s) or probe(s) for placement of radiation source	
76873	Ultrasound, transrectal; prostate volume study for brachytherapy treatment planning (separate procedure)	
76965	Ultrasonic guidance for interstitial radioelement application	

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)	**Not Covered if used to report any treatment outlined in Coverage Limitations section**
77424	Catheter, brachytherapy seed administration	
77425	Intraoperative radiation treatment delivery, electrons, single treatment session	
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	**Not Covered if used to report any treatment outlined in Coverage Limitations section**
77771	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 2-12 channels	**Not Covered if used to report any treatment outlined in Coverage Limitations section**
77772	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; over 12 channels	**Not Covered if used to report any treatment outlined in Coverage Limitations section**
77778	Interstitial radiation source application, complex, includes supervision, handling, loading of radiation source, when performed	
77789	Surface application of low dose rate radionuclide source	
77790	Supervision, handling, loading of radiation source	

77799	Unlisted procedure, clinical brachytherapy	**Not Covered if used to report any treatment outlined in Coverage Limitations section**
92974	Transcatheter placement of radiation delivery device for subsequent coronary intravascular brachytherapy (List separately in addition to code for primary procedure)	
CPT® Category III Code(s)	**Description**	**Comments**
0394T	High dose rate electronic brachytherapy, skin surface application, per fraction, includes basic dosimetry, when performed	**Not Covered**
0395T	High dose rate electronic brachytherapy, interstitial or intracavitary treatment, per fraction, includes basic dosimetry, when performed	**Not Covered**
0735T	Preparation of tumor cavity, with placement of a radiation therapy applicator for intraoperative radiation therapy (IORT) concurrent with primary craniotomy (List separately in addition to code for primary procedure)	**Not Covered**
HCPCS Code(s)	**Description**	**Comments**
A9527	Iodine I-125, sodium iodide solution, therapeutic, per mCi	
C1715	Brachytherapy needle	
C1716	Brachytherapy source, nonstranded, gold-198, per source	
C1717	Brachytherapy source, nonstranded, high dose rate iridium-192, per source	**Not Covered if used to report any treatment outlined in Coverage Limitations section**
C1719	Brachytherapy source, nonstranded, nonhigh dose rate iridium-192, per source	
C1728	Catheter, brachytherapy seed administration	
C2616	Brachytherapy source, nonstranded, yttrium-90, per source	
C2634	Brachytherapy source, nonstranded, high activity, iodine-125, greater than 1.01 mCi (NIST), per source	
C2635	Brachytherapy source, nonstranded, high activity, palladium-103, greater than 2.2 mCi (NIST), per source	
C2636	Brachytherapy linear source, nonstranded, palladium-103, per 1 mm	
C2637	Brachytherapy source, nonstranded, ytterbium-169, per source	
C2638	Brachytherapy source, stranded, iodine-125, per source	
C2639	Brachytherapy source, nonstranded, iodine-125, per source	

C2640	Brachytherapy source, stranded, palladium-103, per source	
C2641	Brachytherapy source, nonstranded, palladium-103, per source	
C2642	Brachytherapy source, stranded, cesium-131, per source	
C2643	Brachytherapy source, nonstranded, cesium-131, per source	
C2644	Brachytherapy source, cesium-131 chloride solution, per mCi	
C2645	Brachytherapy planar source, palladium-103, per sq mm	
C2698	Brachytherapy source, stranded, not otherwise specified, per source	
C2699	Brachytherapy source, nonstranded, not otherwise specified, per source	
C7533	Percutaneous transluminal coronary angioplasty, single major coronary artery or branch with transcatheter placement of radiation delivery device for subsequent coronary intravascular brachytherapy	
C9725	Placement of endorectal intracavitary applicator for high intensity brachytherapy	
C9726	Placement and removal (if performed) of applicator into breast for intraoperative radiation therapy, add-on to primary breast procedure	
C9728	Placement of interstitial device(s) for radiation therapy/surgery guidance (e.g., fiducial markers, dosimeter), for other than the following sites (any approach): abdomen, pelvis, prostate, retroperitoneum, thorax, single or multiple	
G0458	Low dose rate (LDR) prostate brachytherapy services, composite rate	
Q3001	Radioelements for brachytherapy, any type, each	
S2095	Transcatheter occlusion or embolization for tumor destruction, percutaneous, any method, using yttrium-90 microspheres	

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Appendix

Appendix A
Child-Turcotte-Pugh Classification[108]

CTP classification: Child A: score of 5-6; Child B: score of 7-9; Child C: score of 10-15

	Points Ascribed		
Parameters	**1**	**2**	**3**
Ascites	None	Grade 1-2 (or easy to treat)	Grade 3-4 (or refractory)
Hepatic Encephalopathy	None	Grade 1-2 (or induced by a precipitant)	Grade 3-4 (or spontaneous)
Bilirubin (mg/dL)	Less than 2	2-3	Greater than 3
Albumin (g/dL)	Greater than 3.5	2.8-3.5	Less than 2.8
Prothrombin time (seconds greater than control) **OR** INR	Less than 4 Less than 1.7	4-6 1.7-2.3	Greater than 6 Greater than 2.3

Appendix B
Eastern Cooperative Oncology Group (ECOG) Performance Status

Performance status	Definition
0	Fully active; no performance restrictions.
1	Strenuous physical activity restricted; fully ambulatory and able to carry out light work.
2	Capable of all self-care but unable to carry out any work activities. Up and about >50% of waking hours.
3	Capable of only limited self-care; confined to bed or chair >50% of waking hours.
4	Completely disabled; cannot carry out any self-care; totally confined to bed or chair.

Appendix C
Initial Risk Stratification and Staging for Clinically Localized Prostate Cancer[97]

Risk Group	Clinical/Pathologic Features
Very Low	Has all of the following: • cT1c • Grade Group 1 • PSA <10 ng/mL • Fewer than 3 prostate biopsy fragments/cores positive, ≤50% cancer in each fragment/coreg • PSA density <0.15 ng/mL/g

Low	Has all of the following but does not qualify for very low risk: • cT1–cT2a • Grade Group 1 • PSA <10 ng/mL
Intermediate	Has all of the following: • No high-risk group features • No very-high-risk group features • Has one or more intermediate risk factors (IRFs): ○ cT2b–cT2c ○ Grade Group 2 or 3 ○ PSA 10–20 ng/mL
Favorable Intermediate	Has all of the following: • 1 IRF • Grade Group 1 or 2 • <50% biopsy cores positive (eg, <6 of 12 cores)
Unfavorable Intermediate	Has one or more of the following: • 2 or 3 IRFs • Grade Group 3 • ≥ 50% biopsy cores positive (eg, ≥ 6 of 12 cores)
High	Has no very-high-risk features and has exactly one high-risk feature: • cT3a OR • Grade Group 4 or Grade Group 5 OR • PSA >20 ng/mL
Very High	Has at least one of the following: • cT3b–cT4 • Primary Gleason pattern 5 • 2 or 3 high-risk features • >4 cores with Grade Group 4 or 5

Appendix D

Tumor staging for Penile Cancer (TNM staging)[123]

T category	T criteria
TX	Primary tumor cannot be assessed
T0	No evidence of primary tumor
Tis	Carcinoma *in situ* (penile intraepithelial neoplasia [PeIN])
Ta	Noninvasive localized squamous cell carcinoma
T1	Glans: Tumor invades lamina propria. Foreskin: Tumor invades dermis, lamina propria, or dartos fascia. Shaft: Tumor invades connective tissue between epidermis and corpora regardless of location. All sites with or without lymphovascular invasion or perineural invasion and is or is not high grade.
T1a	Tumor is without lymphovascular invasion or perineural invasion and is not high grade (eg, grade 3 or sarcomatoid)

T1b	Tumor exhibits lymphovascular invasion and/or perinerual invasion or is high grade (eg, grade 3 or sarcomatoid)
T2	Tumor invades into corpus spongiosum (either glans or ventral shaft) with or without urethral invasion
T3	Tumor invades into corpora cavernosum (including tunica albuginea) with or without urethral invasion
T4	Tumor invades into adjacent structures (eg, scrotum, prostate, pubic bone)

Change Summary

- 07/25/2024 Annual Review, Coverage Change.