Brachytherapy, Noncoronary

Policy Number:
MM.05.004
Line(s) of Business:
HMO; PPO; QUEST Integration
Section:
Radiology
Place(s) of Service:
Outpatient

Original Effective Date:
05/10/2005
Current Effective Date:
8/29/2018

I. Description

Brachytherapy is a form of radiation treatment used to stop the growth of cancer cells and involves placing radioactive material directly into or near a tumor. This allows the tumor to receive a dose of radiation while reducing the exposure to surrounding tissue. Treatment time varies, depending upon the method of treatment, the type of radioactive material, and the cancer site.

There are currently three basic clinical brachytherapy formats: interstitial, intracavitary and intraluminal. Brachytherapy is either temporary or permanent and may be referred to as low-dose rate (LDR) brachytherapy or high-dose rate (HDR) brachytherapy. It may be used independently as the sole treatment or as an adjunctive treatment in combination with external beam therapy and/or other modalities such as surgery or chemotherapy.

- LDR: In a temporary LDR implant, the radiation dose is delivered continuously over one to several days in a hospital setting, with the patient managed under radiation safety precautions with limits to nursing and visitor time in order to protect them from low-level radiation exposure. A permanent LDR implant uses permanently implanted sources, and can be performed as either an ambulatory or in-patient procedure. The permanent implant continuously delivers radiation as the isotope decays.
- HDR: is performed by using a remote afterloading device to transport the radioactive source(s) to the target. . HDR allows the dose to be delivered in minutes. It is often given in a series of multiple fractions and can be performed either on an outpatient or inpatient basis.

In breast cancer, balloon brachytherapy allows for the positioning of a single, high dose liquid radiation source within the surgical cavity, delivering a uniform dose to the cavity walls. This type of brachytherapy is an alternative to whole breast irradiation.

Radioembolization also referred to as selective internal radiotherapy (SIRT), is the intra-arterial delivery of small beads (microspheres) impregnated with yttrium-90 via the hepatic artery. The microspheres, which become permanently embedded, are delivered to tumor preferentially to normal liver, as the hepatic circulation is uniquely organized, whereby tumors greater than 0.5 cm rely on the hepatic artery for blood supply while normal liver is primarily perfused via the portal vein. RE has been proposed as a therapy for multiple types of primary and metastatic liver tumors.

Y90 microspheres are available in two forms, resin and glass. Resin Y90 microspheres (SIR-Spheres) were FDA approval through the PMA process in 2002 for the treatment of unresectable hepatic metastases from colorectal cancer. Glass Y90 microspheres (Theraspheres), were approved by humanitarian device exemption (HDE), for radiation treatment or as a neoadjuvant to surgery or transplantation in patients with unresectable HCC who can have placement of appropriately positioned hepatic arterial catheters.

II. Criteria/Guidelines

A. Brachytherapy is covered (subject to Limitations and Administrative Guidelines) for the following conditions:

1. Head and neck cancer:
   a. When used as monotherapy for the treatment of small primary tumors; or
   b. For recurrent disease used in conjunction with external beam radiotherapy (EBRT)
2. Uveal melanoma and small Retinoblastoma when all of the following criteria are met:
   a. Unilateral disease has been confirmed
   b. Largest diameter is 5-18mm and thickness 10mm or less
   c.
3. Soft tissue sarcoma when used as combination therapy. See the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines on Soft Tissue Sarcoma for detailed patient selection criteria.
4. Prostate cancer
   Definitive Radiation Therapy by Risk Group
   Very low risk
   Men with NCCN very low risk prostate cancer are encouraged to pursue active surveillance.
   Low Risk
   Prophylactic lymph node radiation should NOT be performed routinely. ADT or antiandrogen therapy should NOT be used routinely
   Favorable Intermediate Risk
   Prophylactic lymph node radiation is not performed routinely, and ADT or antiandrogen therapy is not used routinely. Prophylactic lymph node radiation and/or ADT use is reasonable if additional risk assessments suggest aggressive tumor behavior.
   Unfavorable Intermediate Risk
   Prophylactic nodal radiation can be considered if additional risk assessments suggest aggressive tumor behavior. ADT should be used unless additional risk assessments suggest less-aggressive tumor behavior or if medically contraindicated. The duration of ADT can be reduced when combined with EBRT and brachytherapy. Brachytherapy combined with ADT (without EBRT), or SBRT combined with ADT can be considered when delivering longer courses of EBRT would present medical or social hardship.
   High Risk

Prophylactic nodal radiation can be considered. ADT is required unless medically contraindicated. The duration of ADT may be reduced when EBRT is combined with brachytherapy. Brachytherapy combined with ADT (without EBRT), or SBRT combined with ADT, can be considered when delivering longer courses of EBRT would present a medical or social hardship.

Very High Risk

Prophylactic nodal radiation should be considered. ADT is required unless medically contraindicated.

Regional Disease

Nodal radiation should be performed. Clinically positive nodes should be dose-escalated as Dose-Volume Histogram parameters allow. ADT is required unless medically contraindicated, and the addition of abiraterone and prednisone to ADT can be considered.

Salvage Brachytherapy

Permanent LOR or temporary HDR brachytherapy is a treatment option for pathologically confirmed local recurrence after EBRT or brachytherapy. Subjects should have restaging imaging according to the NCCN high-risk stratification group to rule out regional nodal or metastatic disease. Patients should be counselled that salvage brachytherapy significantly increases the probability

of urologic, sexual, and bowel toxicity compared to brachytherapy, as primary treatment previously.

Prostate cancer risk is often defined using the following criteria (Epstein):

- Low risk: PSA [prostate-specific antigen] level of 10 ng/mL or less, Gleason score of 6 or less, and clinical stage T1c (very low risk) or T1-T2a.
- Intermediate risk: PSA level greater than 10 ng/mL but 20 ng/mL or less, or Gleason score of 7, or clinical stage T2b-T2c.
- High risk: PSA level greater than 20 ng/mL or Gleason score of 8 to 10, or clinical stage T3a for clinically localized disease and T3b-T4 for locally advanced disease.

Table 1. NCCN Risk Stratification

Risk group	Clinical/pathologic features	Imaging[i,j]	Molecular testing of tumor
Very low[g]	• T1c AND • Gleason score ≤6/grade group 1 AND • PSA <10 ng/mL AND • Fewer than 3 prostate biopsy fragments/cores positive, ≤50% cancer in each fragment/core[h] AND • PSA density <0.15 ng/mL/g	Not indicated	Not indicated
Low[g]	• T1-T2a AND • Gleason score ≤6/grade group 1 AND • PSA <10 ng/mL	Not indicated	Consider if life expectancy ≥10y[l]
Favorable intermediate[g]	• T2b-T2c OR • Gleason score 3+4=7/grade group 2 OR • PSA 10–20 ng/mL AND • Percentage of positive biopsy cores <50%	• Bone imaging[k]: not recommended for staging • Pelvic ± abdominal imaging: recommended if nomogram predicts >10% probability of pelvic lymph node involvement	Consider if life expectancy ≥10y[l]
Unfavorable intermediate[g]	• T2b-T2c OR • Gleason score 3+4=7/grade group 2 or Gleason score 4+3=7/grade group 3 OR • PSA 10–20 ng/mL	• Bone imaging[k]: recommended if T2 and PSA >10 ng/mL • Pelvic ± abdominal imaging: recommended if nomogram predicts >10% probability of pelvic lymph node involvement	Not routinely recommended
High	• T3a OR • Gleason score 8/grade group 4 or Gleason score 4+5=9/grade group 5 OR • PSA >20 ng/mL	• Bone imaging[k]: recommended • Pelvic ± abdominal imaging: recommended if nomogram predicts >10% probability of pelvic lymph node involvement	Not routinely recommended
Very high	• T3b-T4 OR • Primary Gleason pattern 5 OR • >4 cores with Gleason score 8–10/ grade group 4 or 5	• Bone imaging[k]: recommended • Pelvic ± abdominal imaging: recommended if nomogram predicts >10% probability of pelvic lymph node involvement	Not routinely recommended
Regional	Any T, N1, M0	Already performed	Consider tumor testing for homologous recombination gene mutations and for microsatellite instability (MSI) or mismatch repair deficiency (dMMR)[m,n]
Metastatic	Any T, Any N, M1	Already performed	Consider tumor testing for homologous recombination gene mutations and for MSI or dMMR[m,n]

5. Endobronchial tumors:
   a. For primary endobronchial tumors that cannot be excised surgically or cannot be treated by EBRT due to co-morbidities or location of the tumor
   b. As palliative therapy for airway obstruction or severe hemoptysis in patients with primary, metastatic or recurrent malignant endobronchial tumors
   c. Stenotic obstruction post lung transplantation refractory to other treatments such as balloon dilation, laser debridement, or stent placement.
6. Cervical cancer:
   a. As monotherapy for inoperable stage IA1 and IA2
   b. Used in conjunction with EBRT and/or chemotherapy for inoperable stage IB1 and IIAI
   c. After chemoradiation for clinical stage IB2-IVA
   d. As a palliative therapy with or without EBRT for stage IVB to decrease the risk of severe hemorrhage or other life-threatening symptoms
7. Uterine neoplasms:
   a. Brachytherapy can be delivered to an intact uterus, either preoperatively or definitively; or

b. To the vagina after hysterectomy. See NCCN's Clinical Practice Guidelines on Uterine neoplasms for detailed patient selection criteria.

8. Breast cancer:
   a. As an adjunctive boost to the tumor bed in patients undergoing initial treatment for stage I or II breast cancer who have received whole breast radiation therapy after prior breast conserving surgery; or
   b. Accelerated Partial Breast Irradiation (APBI) as an alternative to whole breast irradiation in patients meeting the American Society of Breast Surgeon's patient selection criteria:
      i. 45 years of age or older for invasive cancer and age 50 years or older for ductal carcinoma in situ (DCIS)
      ii. The patient has Invasive ductal carcinoma or DCIS
      iii. Total tumor size (invasive and DCIS) is less than or equal to 3cm in size
      iv. Negative microscopic surgical margins of excision
      v. Sentinel lymph node negative

9. Skin cancer, where surgical resection and photon or electron beam techniques are contraindicated.

B. Intrahepatic radioembolization is covered (subject to Limitations and Administrative Guidelines) to treat the following conditions:
   1. Primary hepatocellular carcinoma that is unresectable and limited to the liver
   2. Primary hepatocellular carcinoma as a bridge to liver transplantation.
   3. Primary intrahepatic cholangiocarcinoma in patients with unresectable tumors.
   4. Hepatic metastases from neuroendocrine tumors (carcinoid and noncarcinoid) with diffuse and symptomatic disease when systemic therapy has failed to control symptoms.
   5. Unresectable hepatic metastases from colorectal carcinoma, melanoma (ocular or cutaneous), or breast cancer that are both progressive and diffuse, in patients with liver-dominant disease who are refractory to chemotherapy or are not candidates for chemotherapy or other systemic therapies.

   Note: Symptomatic disease from metastatic neuroendocrine tumors refers to symptoms related to excess hormone production.

C. This list of indications is not exhaustive and while brachytherapy is not indicated in the routine management for other cancers, brachytherapy is often a reasonable and necessary treatment for other sites. There is no definitive list of "approved sites" nor is it possible to preclude some cancers solely on the basis of the primary site of origin.

III. Limitations

A. Electronic brachytherapy is not covered for breast cancer and all other indications (e.g., non-melanoma skin cancer) because it has not been shown to improve health outcomes.
B. Intrahepatic radioembolization for all other indications has not been known to be effective in improving health outcomes except for the conditions listed in II.B. 1-4**.**

IV. Administrative Guidelines

A. Precertification is required for all conditions listed above with the exception of prostate cancer. To precertify, please complete HMSA's Pre-certification Request and mail or fax the form as indicated. Submit clinical documentation that supports the criteria listed above. In addition, HMSA reserves the right to perform retrospective reviews of all services rendered. The following documentation must be kept in the patient's medical record and made available upon request:

1. A written, signed and dated prescription or treatment plan
2. Designation of the treatment site, isotope, number of source positions and the planned dose to each point

B. The following CPT codes are specific to brachytherapy:

CPT	Description
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	intermediate (calculation[s] made from 5 to 10 sources, or remote afterloading brachytherapy, 2-12 channels), includes basic dosimetry calculation(s)
77318	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 three months follow-up care)
77761	Intracavitary radiation source application; simple
77762	intermediate
77763	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
77776	Interstitial radiation source application; simple
77777	intermediate
77778	complex
77789	Surface application of radiation source
77790	Supervision, handling, loading of radiation source
HCPCS	**Description**
Q3001	Radioelements for brachytherapy, any type, each

C. Applicable CPT codes for breast brachytherapy:

CPT	**Description**
19296	Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement applications following partial mastectomy, includes imaging guidance on date separate from partial mastectomy
19297	concurrent with partial mastectomy (List separately in addition to code for primary procedure)
19298	multiple tube or button type catheters, performed at the same session or subsequent session

D. Applicable CPT codes for prostate brachytherapy (**Precertification is not required):**

CPT	**Description**
55860	Exposure of prostate, any approach, for insertion of radioactive substance
55875	Transperitoneal 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 (e.g., fiducial markers, dosimeter), prostate (via needle, any approach), single or multiple
76001	Fluoroscopy, physician time more than one hour, assisting a non-radiologic physician (e.g., nephrostolithotomy, ERCP, bronchoscopy, transbronchial biopsy)
76873	Ultrasound, transrectal; prostate volume study for brachytherapy treatment planning (separate procedure)
76965	Ultrasonic guidance for interstitial radioelement application

E. Applicable CPT codes for endobronchial brachytherapy:

CPT	Description
31643	Bronchoscopy (rigid or flexible); with placement of catheter(s) for intracavitary radioelement application

F. Applicable CPT codes for gynecologic brachytherapy:

CPT	Description
57155	Insertion of uterine tandem and/or vaginal ovoids for clinical brachytherapy
57156	Insertion of vaginal radiation afterloading apparatus for clinical brachytherapy
58346	Insertion of heyman capsules for clinical brachytherapy

G. Applicable CPT code for head and/or neck brachytherapy:

CPT	Description
41019	Placement of needles, catheters, and other devices into the head and/or neck region

H. Applicable CPT code for ocular brachytherapy**:**

CPT	Description
67218	Destruction of localized lesion of retina (e.g., macular edema, tumors), one or more sessions; radiation by implantation of source (includes removal of source)

I. Applicable CPT code for soft tissue sarcoma brachytherapy:

CPT	Description
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)

J. Applicable HCPCS for intrahepatic radioembolization :

HCPCS	Description
C2616	Brachytherapy source, nonstranded, Yttrium-90, per Source

S2095	Transcatheter occlusion or embolization for tumor destruction, percutaneous, any method, using yttrium-90 microspheres

K. Codes that do not meet payment determination criteria**:**

HCPCS	**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

Documentation requirements:

- Documentation supporting the medical necessity of these services, such as ICD-9-CM codes, must be submitted with each claim.
- The treatment goal (curative, palliative or tumor control) must be documented in the medical record.
- The record must contain documentation of the patient's informed consent to treatment
- A written, signed and dated prescription or treatment plan designed by the radiation oncologist must be on file. The prescription must include all of the following information: designation of the·treatment site, designation of the isotope, designation of the number of source positions, and the planned dose to selected points described during dosimetry.
- Given the multiplicity of services that are inherent in brachytherapy, it is essential that the medical records reflect each service in a clear linear and temporally logical form. Flow charts, where helpful, are recommended. All procedures should be documented with a procedural note. A treatment summary should be prepared.
- Since HDR treatments are typically given as a series (often twice daily, over a period of days or weeks) they should be individually documented.

V. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii's Patients' Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. Medicare defines medical necessity as health care services or supplies needed to diagnose or treat an illness, injury, condition, disease, or its symptoms and that meet accepted standards of medicine. This definition applies only to Medicare Advantage (PPO and HMO) plans.

HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA's determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VI. References

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