Medical Policy

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Title: Electronic Brachytherapy

Description/Background

NONMELANOMA SKIN CANCER

Squamous cell carcinoma and basal cell carcinoma are the most common types of nonmelanoma skin cancer (NMSC) in the United States, affecting between 1 million and 3 million people per year[1,2,] respectively, and increasing at a rate of 3% to 8% per year.[2,] Other types (e.g., T-cell lymphoma, Merkel cell tumor, basosquamous carcinoma, Kaposi sarcoma) are much less common. Skin cancer can affect anyone, regardless of skin color; however, the incidence of skin cancer among non-Hispanic White individuals is approximately 30 times higher than that among non-Hispanic Black or Asian/Pacific Islander individuals.[3,] In individuals with darker skin tones, skin cancer is often diagnosed at a later stage when it is more difficult to treat. Additionally, these individuals are prone to skin cancer in areas not commonly exposed to the sun such as the palms of the hands, soles of the feet, the groin, and inside of the mouth.

The primary risk factor for NMSC is sun exposure, with additional risk factors such as toxic exposures, other ionizing radiation exposure, and immunosuppression playing smaller roles.[2] Although these cancers are rarely fatal, they can impact quality of life, functional status, and physical appearance.

Treatment

In general, the most effective treatment for nonmelanoma skin cancer is surgical. If surgery is not feasible or preferred, cryosurgery, topical therapy, or radiotherapy can be considered, though the cure rate may be lower.[3] When considering the most appropriate treatment strategy, recurrence rate, preservation of function, patient expectations, and potential adverse events should be considered.

Surgical

Treatment of nonmelanoma skin cancer is primarily surgical, and the choice of surgical procedure depends on the histologic type, size and location of the lesion. Patient preferences

can also play a factor in surgical decisions due to cosmetic reasons—as well as the consideration of comorbidities and patient risk factors, such as anticoagulation. Local excisional procedures, such as electrodesiccation and curettage or cryotherapy, can be used for low-risk lesions, while surgical excision is indicated for lesions that are not low-risk. Mohs surgery is an excisional procedure that uses microscopic guidance to achieve greater precision and sparing of normal tissue. In patients who meet criteria for Mohs surgery, five-year cure rates for basal cell cancer range from 98% to 99%,[4] making Mohs surgery the preferred procedure for those who qualify.

Radiotherapy

Radiotherapy is indicated for certain nonmelanoma skin cancers not amenable to surgery. In some cases, this is due to the location of the lesion on the eyelid, nose, or other structures that make surgery more difficult and which may be expected to have a less desirable cosmetic outcome. In other cases, surgery may be relatively contraindicated due to clinical factors such as bleeding risk or advanced age. In elderly patients with a relatively large tumor that would require extensive excision, the benefit/risk ratio for radiotherapy may be considered favorable. The 5-year control rates for radiotherapy are range from 80% to 92%, which is lower than for surgical excision.[4] A randomized controlled trial by Avril et al (1997) reported that radiotherapy for basal cell carcinoma resulted in greater numbers of persistent and recurrent lesions compared with surgical excision.[5]

When radiotherapy is used for nonmelanoma skin cancer, the primary modality is external beam radiation. A number of different brachytherapy techniques have also been developed, including low-dose rate systems, iridium-based systems, and high-dose rate systems.[4]

Breast and Endometrial Cancer

Other than skin cancer, breast cancer is the most common cancer among women in the U.S. Some women are at higher risk than others because of their personal or family medical history or because of certain changes in their genes.

When cancer starts in the uterus, it is called uterine cancer. The most common type of uterine cancer is also called endometrial cancer because it forms in the lining of the uterus, called the endometrium.

Treatment

There are 4 basic types of treatment for women with breast and/or endometrial cancer:

- Surgery
- Radiation therapy
- Hormonal therapy
- Chemotherapy

Radiation therapy may be a component of therapy in the treatment of breast and endometrial cancer. Electronic brachytherapy during intraoperative radiotherapy (IORT) are being researched and proposed for the treatment of cancer.

Electronic Brachytherapy

Electronic brachytherapy is a form or radiotherapy delivered locally using a miniaturized electronic x-ray source rather than a radionuclide-based source. A pliable mold is constructed of silicone or polymethyl-methacrylate and fitted to the tumor surface. This mold allows

treatment to be delivered to nonflat surfaces such as the nose or ear. A radioactive source is then inserted into the mold to deliver a uniform radiation dosage directly to the lesion.[4] Multiple treatment sessions within a short time period (typically within a month) are required.

This technique is feasible for well-circumscribed, superficial tumors. It focuses a uniform dose of x-ray source radiation to the lesion with the aid of a shielded surface application. Advantages of this treatment modality compared with standard radiotherapy include a shorter treatment schedule, avoidance of a surgical procedure and hospital stay, less severe side effects because the focused radiation spares healthy tissue and organs, and the avoidance of radioisotopes.[4]

Regulatory Status

Electronic brachytherapy systems for the treatment of nonmelanoma skin cancers are designed to deliver high-dose rate brachytherapy to treat skin surface lesions. This technique focuses a uniform dose of x-ray source radiation to the lesion with the aid of a shielded surface application. The Superficial X-Ray Radiation Therapy System (Sensus Healthcare), Esteya® Electronic Brachytherapy System (Nucletron BV) and the Xoft® Axxent® Electronic Brachytherapy System (iCAD Inc.) are 2 systems that have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. FDA product code: JAD.

Medical Policy Statement

Brachytherapy, when administered through an electronic brachytherapy system is experimental/investigational for all indications (e.g., breast cancer, non-melanoma skin cancer, etc.) because its effectiveness has not been scientifically demonstrated to be as safe and effective as conventional brachytherapy.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.): (commercial)

0394T 0395T

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life,

quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects.

ELECTRONIC BRACHYTHERAPY FOR NONMELANOMA SKIN CANCER

Clinical Context and Test Purpose

The purpose of electronic brachytherapy in individuals who have nonmelanoma skin cancer is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following **PICOs** were used to select literature to inform this review.

Populations

The relevant population of interest are individuals with nonmelanoma skin cancer. Nonmelanoma skin cancer refers to squamous cell carcinoma and basal cell carcinoma. There are other less common types of skin cancer, such as T-cell lymphoma or Merkel cell tumor, which may have specific treatment options that differ from basal and squamous cell carcinomas and may need to be considered on an individual basis.

Interventions

The therapy being considered is electronic brachytherapy. Electronic brachytherapy is a form of radiotherapy delivered locally, using a miniaturized electronic x-ray source rather than a radionuclide-based source. Multiple treatment sessions within a short time period (typically within a month) are required.

Comparators

The following therapies are currently being used: surgery (excision or Mohs surgery), external-beam radiotherapy, and standard brachytherapy.

The diagnosis of nonmelanoma skin cancer involves a detailed review of medical history, a clinical exam, and a skin biopsy. Information from the diagnostic process can assess the risk of recurrence, which informs the choice of treatment. Location and size of the skin cancer are also factors in choosing the treatment strategy. Brachytherapy is considered when lesions are located on anatomic curves or are near critical organs.

Outcomes

The general outcomes of interest are survival, recurrence rates, and treatment-related morbidity.

The follow-up to adequately detect nonmelanoma skin cancer recurrence should be at least five years.

Review of Evidence

Systematic Reviews

Lee et al (2019) published a meta-analysis of 58 studies including 21,371 patients treated with conventional surgical excision (24 studies), Mohs micrographic surgery (MMS; 13 studies), EBRT (19 studies), or high-dose-rate brachytherapy (7 studies) for indolent BCC and SCC of the skin.[7] "Good" cosmesis was reported in 81% (95% confidence interval [CI], 70.6% to 89.6%), 74.6% (95% CI, 63% to 84.6%), and 97.6% (95% CI, 91.3% to 100%) of patients treated with conventional excision, EBRT, and brachytherapy, respectively. This was comparable to the 96% "good" cosmesis grade outcome reported in 1 MMS study. The 5-year local recurrence rate for brachytherapy was 2.5% (95% CI, 0.8% to 5.1%), which was comparable to both MMS (1.8%; 95% CI, 1.1% to 2.7%) and conventional excision (2.1%; 95% CI, 1.0% to 3.5%). The authors concluded that interpretation of results may be limited by selection bias and subjective and heterogeneous cosmesis grading systems, warranting further prospective, comparative studies.

Delishaj et al (2016) published a systematic review of studies on high-dose rate (HDR) brachytherapy, including electronic brachytherapy, for the treatment of nonmelanoma skin cancer.[8] In a literature review, 10 case series with sample sizes of 20 patients or more that reported on nonoverlapping patients were identified. Findings were reported for 1870 patients (N=1870 lesions). The majority of lesions (65%) were basal cell carcinoma and the second largest group (35%) was squamous cell carcinoma. Reviewers did not pool study findings, reporting that the rate of local control ranged from 83% to 100%. After median follow-up rates with range between 9 months to 10 years, recurrence rates ranged from 0% to 17%. Seven of the 10 studies reported recurrence rates of less than 5%, 2 had recurrence rates of 8% to 9%, and 1 study had a recurrence rate of 17%. The 2 studies with recurrence rates in the 8%-to-9% range used Leipzig applicators and the study with a 17% recurrence rate used HDR brachytherapy with surface applicators or custom-made surface molds.

Prospective Cohort Study

Patel et al (2017)[8] published preliminary results from a multi-center prospective matched pair cohort study NCT03024866acomparing clinical outcomes of nonmelanoma skin cancer treated with electronic brachytherapy (EBT) or Mohs micrographic surgery (MMS). Patients from four treatment centers who had already received treatment for NMSC with EBT and met eligibility criteria were invited to participate. A retrospective chart review was used to individually match patients with patients who had received MMS for NMSC based on patient age (±15 years), lesion size, type and location, and treatment dates. All MMS treated subjects treated in the same time-frame were considered for matching and the final pair was selected based on the closest match of demographics and lesion characteristics. A total of 369 patients were included for study representing 208 matched lesion pairs. Additional eligibility criteria included:

- completion of EBT or MMS for NMSC ≥3 years prior
- age > 40 yrs

- diagnosis of squamous cell carcinoma (SCC) or basal cell carcinoma (BCC)
- cancer stage 0-2

Exclusion criteria included:

- target area adjacent to burn scar
- surgical resection of the cancer prior to EBT
- presence of actinic keratosis
- known metastatic disease

Patients were evaluated for follow-up at 2.3 to 5.0 years post-treatment. Treatment with EBT was performed with a miniature, HDR electronic X-ray source using standard surface applicators. A dose of 40.0 Gy in 8 fractions (5 Gy twice weekly) was used to delivered to a depth of 2-3 mm but in some cases a customized dose, depth, or schedule. MMS was performed by clinicians according to guidelines of the American College of Mohs Surgery. Matching of patients based on lesion characteristics was based on histopathology of basal cell carcinoma (BCC) or squamous cell carcinoma (SCC), cancer staging (Stage 0, Stage 1, Stage 2), size (≤ 1 cm, >1 cm and ≤ 2 cm, > 2 cm and ≤ 3 cm), and location (head, ear, eyelid, face/neck, lip, scalp, nose, torso, lower extremity, upper extremity). The mean follow-up length was 3.3 years for the EBT group and 3.5 years for the MMS group. The primary outcome was absence of NMSC recurrence at follow-up. Secondary outcomes included late toxicities, cosmetic outcomes, and patient satisfaction with treatment. All patients completed all evaluations.

Table 1. Prospective Cohort Studies of Electronic Brachytherapy for Nonmelanoma Skin Cancer

Study	**Population**	**N**	**FU**	**Treatment**	**Outcomes**			
Patel et al (2017)	Patients receiving EBT for NMSC	188		EBT				
	Lesions receiving EBT for NMSC (number of lesions, %)	208	Mean 3.3 ± 0.4 y (range 2.6 to 4.3)	EBT	Absence of Local Recurrence at Follow-Up (number of lesions, %, 95% CI)	Cosmesis Grade at Follow-Up (number of lesions, %, 95% CI)[a]	Long-term Toxicities Present at Follow-Up (number of lesions, %)	Results of Patient Satisfaction Questionnaire at Follow-Up (mean ± SD; median, [10-60])[b]
	• Lesions with BCC (113, 54.3%) • Lesions with SCC (95, 45.7%)	208	Mean 3.3 ± 0.4 y (range 3.2; 2.6 to 4.3)	EBT	207 (99.5%, 97.4 to 100%)	Clinician Cosmesis Grade • Excellent/Good (203, 97.6%, 94.5 to 99.2%) • Excellent (133, 63.9%) • Good (70, 33.7%) • Fair (1, 0.5%) • Poor (4, 1.9%) Subject Cosmesis Grade • Excellent (140, 67.3%) • Good (48,	No changes, relatively invisible scar (138, 66.7%) Late toxicities: • Hypopigmentation (124, 59.6%) • Hyperpigmentation (11, 5.3%) • Erythematous scar (6, 2.9%) • Telangiectasia (65, 31.4%) • Hair loss (8, 3.9%) • Fibrosis (3, 1.4%) • Atrophy (12, 5.8%) • Loss of	54.0 ± 9.0; 58.0 Individual Questions • Treatments were convenient (4.3 ± 1.1) • Satisfied with how well treatment worked (4.5 ± 1.1) • Satisfied with appearance of the treated area (4.4 ± 1.0) • If another cancer, would use same treatment (4.1 ± 1.4) • Have not had any

						23.1%) • Fair (15, 7.2%) • Poor (5, 2.4%)	subcutaneous tissue (7, 3.4%) • Hypertrophy (excessive fibrosis) or keloid (0, 0%) • Poor healing, ulceration, erosion (4, 1.9%)	skin problems with treated area (4.5 ± 1.2) • Since treatment, frustrated about appearance of treated site (4.5 ± 1.1) • Since treatment, embarrassed about appearance of treated site (4.6 ± 0.9) • Since treatment, depressed about appearance of treated site (4.5 ± 1.1) • Treatment prevented me from participating in daily activities (4.6 ± 0.9) • Treatment made it hard to work or do what I enjoy (4.7 ± 0.7) • Would recommend treatment to others (4.4 ± 1.3) • Always followed instructions related to care of treated area (4.9 ± 0.4)
	Patients receiving MMS for NMSC	181	---	MMS	Outcomes			
	Lesions receiving MMS for NMSC (number of lesions, %)	208	Mean 3.5 ± 0.5 y (range 2.3 to 5.0)	MMS	Absence of Local Recurrence at Follow-Up (Number of lesions, %, 95% CI)	Cosmesis Grade at Follow-Up (Number of lesions, %, 95% CI)[a]	Long-term Toxicities Present at Follow-Up (Number of lesions, %)	Results of Patient Satisfaction Questionnaire at Follow-Up (mean ± SD; median, [10 to 60])[b]
	• Lesions with BCC (113, 54.3%) • Lesions with SCC (95, 45.7%)	208	Mean 3.5 ± 0.5 y (range 2.3 to 5.0)	MMS	208 (100%, 98.2 to 100%)	Clinician Cosmesis Grade • Excellent/Good (199, 95.7%, 92.0 to 98.0%) • Excellent (142, 68.3%) • Good (57, 27.4%) • Fair (9, 4.3%) • Poor (0, 0.0%) Subject Cosmesis Grade • Excellent (148, 71.1%) • Good (50, 24.0%) • Fair (10, 4.8%)	No changes, relatively invisible scar (143, 68.8%) Late toxicities: • Hypopigmentation (109, 52.4%) • Hyperpigmentation (4, 1.9%) • Erythematous scar (15, 7.2%) • Telangiectasia (23, 11.1%) • Hair loss (7, 3.4%) • Fibrosis (2, 1%) • Atrophy (9, 4.3%) • Loss of subcutaneous tissue (6, 2.9%)	56.0 ± 5.3; 59.0 • Treatments were convenient (4.7 ± 0.6) • Satisfied with how well treatment worked (4.8 ± 0.5) • Satisfied with appearance of the treated area (4.6 ± 0.7) • If another cancer, would use same treatment (4.6 ± 0.7) • Have not had any skin problems with treated area (4.7 ± 0.6)

						• Poor (0, 0.0%)	• Hypertrophy (excessive fibrosis) or keloid (3, 1.4%) • Poor healing, ulceration, erosion (0, 0.0%)	• Since treatment, frustrated about appearance of treated site (4.6 ± 1.0) • Since treatment, embarrassed about appearance of treated site (4.7 ± 0.7) • Since treatment, depressed about appearance of treated site (4.6 ± 0.8) • Treatment prevented me from participating in daily activities (4.6 ± 0.9) • Treatment made it hard to work or do what I enjoy (4.6 ± 0.8) • Would recommend treatment to others (4.7 ± 0.7) • Always followed instructions related to care of treated area (4.7 ± 0.5)
Kuo et al (2022)[10,]	Age ≥60y with AJCC T1N0M0 BCC or SCC	34	12 weeks	EBT	Cosmesis grade at 12 weeks, n (%)	Quality of life, mean (SD)	Adverse events	--
					Clinician • Good: 31 (96.9) • Fair: 1 (3.1) • Bad: 0 • ND: 2 Patient • Good: 31 (93.9) • Fair: 2 (6.1) • Bad: 0 • ND: 1	Skindex-16, baseline (N=34) • Symptoms: 7.4 (17.7) • Emotions: 19.7 (24.0) • Functioning: 4.4 (10.5) • Total: 10.5 (14.9) Skindex-16, 12 weeks (n=33) • Symptoms: 1.6 (3.7) • Emotions: 3.1 (6.0), p≤.006 vs baseline • Functioning: 1.5 (7.0) • Total: 2.1 (4.6), p≤.017 vs baseline Skin Cancer Index, baseline (N=34) • Emotional: 77.7 (22.2) • Social: 90.1	• Most frequent: radiation dermatitis, skin pain, pruritus • Grade 3 adverse events reported in week 3 of treatment (painful skin, 6.6%) and 2 weeks after treatment (radiation dermatitis, 42.4%)	

						(19..1) • Appearance: 67.4 (33.1) • Total: 78.4 (21.9) Skin Cancer Index, 12 weeks (n=33) • Emotional: 86.3 (15.7) • Social: 92.3 (13.4) • Appearance: 87.6 (20.3), p≤.006 vs baseline • Total: 88.7 (13.3)		

MFU: mean follow-up; SD: standard deviation; EBT: electronic brachytherapy; MMS: Mohs micrographic surgery; NMSC: nonmelanoma skin cancer
[a] Standardized scale adapted from Cox et al (1995).[8]
[b] A score of 5 represents the maximum positive or favorable response to each question.

No statistically significant difference was found between EBT (97.6%) and MMS (95.7%) groups for local recurrence absence (p = 1.000). However, one recurrence was reported in the EBT group at 1 year post-treatment. No recurrences occurred in the MMS group. No statistically significant differences were noted for secondary endpoints of cosmesis (p = 0.277) and patient satisfaction with both groups demonstrating predominantly excellent cosmesis grades and high patient satisfaction scores. Late toxicities appeared at similar rates with telangiectiasa being reported slightly more in the EBT vs. MMS group (31.4% vs. 11.1%).

Table 2. EBT Study Relevance Limitations

Study (year)	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-up[e]
Patel et al (2017)	2.Rationale for inclusion and exclusion criteria unclear	2.Version used unclear		6.Clinical significant difference not supported	1.Not sufficient duration for benefit
Kuo et al (2022)		2. Version useduncl ear	5. No comparator	1. Recurrence rates notreported	1. Not sufficient duration for benefit

[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not established and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms

Table 3. EBT Study Design and Conduct Limitations

Study (year)	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]

Patel et al (2017)	3.Allocation concealment unclear in matching procedure	3.Outcome assessed by treating physician	2-3.Evidence of selective reporting and publication	5.Unclear whether patients with metastatic disease should be excluded or whether age exclusion is clinically relevant	1-2.Power calculations not reported or reported for primary outcome	
Kuo et al (2022)	1,2. Open-label single-arm trial	1,2. Open-label 4. Unknown if outcome assessed by treating physician				

[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded to treatment outcome; 3. Outcome assessed by treating physician
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. No intent to treat analysis (per protocol for non-inferiority trials)
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated

Case Series

Evidence consists of uncontrolled studies. The main characteristics and results of published series are summarized in Table 4.

Table 4. Case Series of Electronic Brachytherapy for Nonmelanoma Skin Cancer

Study (Year)	Population	N	MFU, mo	Treatment	Outcomes	
					Recurrence	**Toxicity**
Doggett et al (2023)	Basal or squamous cell carcinoma with ≥5 y follow-up	180	90	• 40 Gy in 8 twice-weekly fractions	1.1%	Hypopigmentation grade 1: 65.9% Telangectasia grade 1: 22.5% Scar grade 1:1.1% Hyperpigmentation grade 1: 1.1% Induration grade 2:0.5%
Pellizzon et al (2020)	Basal or squamous cell carcinoma	71	42.8	• Leipzig applicator • Total dose: 28 to 55 Gy in 7 to 22 fractions	6.9%	Acute: • Grade 1 to 2=100 • Grade 3= 8.9 Late: • Grade 3=3.9 • Grade 4=0
Paravati et al (2015)	Basal, squamous, or basosquamous cell carcinoma	127	16.1	• Axxent Xoft system • 8 fractions delivered 2x/wk	1.2% (2/154)	Acute: • Grade 0-1=53% • Grade 2=34.4%

				• Total dose 40 Gy		• Grade 3=13% Late: • Grade 0-1=94% • Grade 2=6%
Delishaj et al (2015)	Nonmelanoma skin cancer	39	12	Valencia applicator 40 Gy in 8 fractions	0%	Acute: • Grade 1=58% • Grade 2=5% Late: • Grade 1=19% • Grade 2=2%
Tormo et al (2014)	Basal cell carcinoma	32	47	Valencia applicator 42 Gy in 6-7 fractions	3.1%	• Grade 1=NR • Grade 2=0% • Grade 3=0%
Bhatnager et al (2013) (Bhatnager et al [2010])	Nonmelanoma skin cancer	122	10.0	• Axxent Xoft system • 8 fractions delivered 2x/wk • Total dose 40 Gy	0%	• Grade 1=11% • Grade 2=13% • Grade 3=0%
Gauden et al (2013)	Small nonmelanoma skin cancers	200	66[b]	• Leipzig applicator • 12 fractions delivered daily • Total dose 36 Gy	2 % (4/236)	• Grade 1=71% • Grade 2=34% • Grade 3=0%
Giux et al (2000)	Basal or squamous cell carcinoma	136	60	• Brock applicator • Total dose 60-65 Gy in 33-36 fractions	2.2%	NR (“no severe complications”)

Gy: gray; MFU: mean follow-up; NR: not reported
[a] Overlapping case series; results from larger, more recent publication reported.
[b] Median.
[c] Calculated based on number of lesions not patients.

The largest series was published by Gauden et al (2013) and included 200 patients with 236 lesions (121 basal cell, 115 squamous cell).[17] Brachytherapy was the primary treatment modality in 69% of the lesions, while in the remaining 31% (74/236) brachytherapy was used as follow-up treatment to surgery when there were positive margins. Outcomes included treatment efficacy, as measured by local recurrence rate, skin toxicity measured according to the Radiation Therapy Oncologic Group (RTOG) criteria, and cosmetic outcome according to the RTOG Cosmesis scale. After a median follow-up of 66 months, there were recurrences in 2% (4/236) of treated lesions. Cosmetic outcome was judged excellent or good in 88% (208/236) of treated lesions. Grade 1 skin toxicity was common (71% of treated lesions); grade 2 toxicity was less common (34%); and no grade 3 or higher toxicities were noted. Late hypopigmentation of treated skin was reported in 5.5% (13/236) of treated lesions.

Bhatnager published a case series using a commercially available device (Axxent eBx System; Xoft Inc., Sunnyvale, CA).[1] The series included 122 patients with 171 nonmelanoma skin lesions. Most patients had either basal cell carcinoma (53%) or squamous cell carcinoma (41%); there were 10 (5.8%) patients with other types of cancer. Outcome measures included recurrence rates, adverse events using common terminology, and cosmetic results using a standardized Cosmesis scale. After a mean 10-month follow-up, there were no local recurrences. Dermatitis and pruritus were common early adverse events, occurring in 83% and 18% of the treated lesions, respectively. Skin hypopigmentation was the most common late adverse event, occurring in 10.9% of lesions at 1 year. Other late complications included rash (6.5%), alopecia (2.2%), and dry desquamation (2.2%). All patients had their cosmetic outcomes rated as good or excellent.

Section Summary: Nonmelanoma Skin Cancer
For individuals who have nonmelanoma skin cancer who receive electronic brachytherapy, the evidence includes a systematic review and case series. Relevant outcomes are overall survival, disease-specific survival, change in disease status, and treatment-related morbidity. No controlled trials were identified that have compared electronic brachytherapy with alternative treatment options. A 2016 systematic review of case series found local control rates ranging from 83% to 100% and recurrence rates ranging from 0% to 17%. In most studies, the recurrence rate was less than 5%. A 2019 meta-analysis reported brachytherapy cosmesis grades and 5-year local control rates that were comparable to both MMS and conventional excision. Preliminary results from a prospective matched pair cohort study reported no statistically significant difference in outcomes for the use of electronic brachytherapy compared to MMS in NMSC, but confidence in these findings is low due to study design and conduct limitations. In the absence of controlled studies, conclusions cannot be drawn about the efficacy and safety of electronic brachytherapy compared with other treatments for nonmelanoma skin cancer. Controlled trials are needed in defined populations that compare electronic brachytherapy with alternatives, specifically other forms of radiotherapy or surgical approaches. The evidence is insufficient to determine the effects of the technology on health outcomes.

ELECTRONIC BRACHYTHERAPY FOR BREAST CANCER

Clinical Context and Test Purpose
The purpose of electronic brachytherapy in individuals who have breast cancer is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following **PICOs** were used to select literature to inform this review.

Populations
The relevant population of interest are individuals with breast cancer.

Interventions
The therapy being considered is electronic brachytherapy. Electronic brachytherapy is usually administered in a hospital or free-standing facility.

Comparators
The following therapies are currently being used: surgery, external-beam radiotherapy, and standard brachytherapy.

Outcomes
The general outcomes of interest are survival, recurrence rates, and treatment-related morbidity.

The follow-up to adequately detect breast cancer recurrence should be at least yearly for the first five years.

Review of Evidence

Nonrandomized Studies

An observational, nonrandomized, multicenter study by Beitsch et al (2010) evaluated EBT as a post-surgical adjuvant radiation therapy for early stage breast cancer.[23] This study included women aged 50 years or more with invasive carcinoma or ductal carcinoma in situ, tumor size ≤3 cm, negative lymph node status, and negative surgical margins. The endpoints were skin and subcutaneous toxicities, efficacy outcomes, cosmetic outcomes, and device performance. In this interim report, 1-month, 6-month, and 1-year follow-up data are available on 68, 59, and 37 patients, respectively. The EBT device performed consistently, delivering the prescribed 34 Gy to all 69 patients (10 fractions/patient). Most adverse events were Grade 1 and included firmness, erythema, breast tenderness, hyperpigmentation, pruritus, field contracture, seroma, rash/desquamation, palpable mass, breast edema, hypopigmentation, telangiectasia, and blistering, which were anticipated. Breast infection occurred in two (2.9%) patients. No tumor recurrences were reported. Cosmetic outcomes were excellent or good in 83.9%-100% of evaluable patients at 1 month, 6 months, and 1 year.

The conclusion reached was that this observational, nonrandomized, multicenter study demonstrates that this EBT device was reliable and well tolerated as an adjuvant radiation therapy for early stage breast cancer.

Dooley et al (2011) reported on a multicenter, retrospective study of 63 patients to evaluate treatment and clinical outcomes of patients with early stage breast cancer who received adjuvant high-dose rate (HDR) electronic brachytherapy (EBT) treatment post-lumpectomy using the Axxent® EBT system.[27] Dosimetric data from the EBT treatment plans were compared with those based on iridium-192 HDR brachytherapy. This retrospective, multicenter study showed that postsurgical system with similar toxicity outcomes to those reported with iridium-192 brachytherapy, adjuvant radiation therapy for early stage breast cancer can be administered using the EBT.

Patel et al (2013) published updates on the multicenter registry of patients with early-stage breast cancer who bad breast conserving surgery and electronic brachytherapy.[29] Of the 69 enrollees, 62 were evaluated at 1 year and 20 at 2 years post-treatment. 45.2% of patients at 1 year reported adverse events that were “possibly, probably, or definitely related to treatment.” However, most were manageable and typical of treatment with radiation. No recurrences were reported in the patients evaluated at 1 and 2 years. Cosmetic ratings were reported by 93.4% as “good or excellent.” The authors report that longer-follow up is underway.

ELECTRONIC BRACHYTHERAPY FOR ENDOMETRIAL CANCER

Clinical Context and Test Purpose

The purpose of electronic brachytherapy in individuals who have endometrial cancer is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following **PICOs** were used to select literature to inform this review.

Populations

The relevant population of interest are individuals with endometrial cancer.

Interventions

The therapy being considered is electronic brachytherapy. Electronic brachytherapy is usually administered in a hospital or free-standing facility.

Comparators
The following therapies are currently being used: surgery, chemotherapy, external beam radiotherapy and brachytherapy.

Outcomes
The general outcomes of interest are survival, recurrence rates, and treatment-related morbidity.

The follow-up to adequately detect endometrial cancer recurrence should be at a 6 month interval until 5 years.

Dickler et al (2010) reported on a study of 15 patients with stage I or II HDR brachytherapy, Axxent Electronic Brachytherapy.[24,25] The prescribed doses of EBT were successfully delivered in all 15 patients. From the first fraction through 3 months follow-up, there were four CTC Grade 1 adverse events and two CTC Grade II adverse events reported that were EBT related. The mild events reported were dysuria, vaginal dryness, mucosal atrophy and rectal bleeding. The moderate treatment related adverse events included dysuria, and vaginal pain. No Grade III or IV adverse events were reported. The EBT system performed well and was associated with limited acute toxicities.

Section Summary: Breast Cancer and Endometrial Cancer
There is insufficient evidence in peer reviewed scientific literature to support electronic brachytherapy for the treatment of breast cancer or endometrial cancer. Studies are small, mostly case series with limited follow up. Furthermore, studies comparing health outcomes of electronic brachytherapy with health outcomes of standard radioisotope based brachytherapy are lacking. Randomized controlled comparative clinical trials are needed demonstrating improvements in net health outcomes to include the long-term assessment of treatment efficacy and effects. Therefore, electronic brachytherapy is considered experimental/investigational.

SUMMARY OF EVIDENCE
For individuals who have nonmelanoma skin cancer who receive electronic brachytherapy, the evidence includes a systematic review and case series. Relevant outcomes are overall survival, disease-specific survival, change in disease status, and treatment-related morbidity. No controlled trials were identified that compared electronic brachytherapy with alternative treatment options. A 2016 systematic review of case series found local control rates ranging from 83% to 100% and recurrence rates ranging from 0% to 17%. In most studies, the recurrence rate was less than 5%. In the absence of controlled studies, conclusions cannot be drawn about the efficacy and safety of electronic brachytherapy compared with other treatments for nonmelanoma skin cancer. Controlled trials are needed in defined populations that compare electronic brachytherapy with alternatives, either other forms of radiotherapy or surgical approaches. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have breast or endometrial cancer who receive electronic brachytherapy, the evidence includes one observational, nonrandomized trial, one retrospective study and one

prospective multi-center trial. Although electronic brachytherapy appears to be reliable and well tolerated, the evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

National Comprehensive Cancer Network (NCCN)

National Comprehensive Cancer Network guidelines on basal cell carcinoma (v.3.2024)[19] and squamous cell skin cancer (v.1. 2024)[20] both contain the following statement on electronic brachytherapy: "There is insufficient long-term efficacy and safety data to support the routine use of radioisotope or electronic surface brachytherapy."

NCCN does not address electronic brachytherapy for breast cancer (v.3.2024) or endometrial cancers (v.2.2024).

American Brachytherapy Society

The American Brachytherapy Society issued a consensus statement on electronic brachytherapy following a literature review focused on trials, prospective studies, multi-institutional series, and single institution reports addressing clinical outcomes and toxicities.[34] Due to a lack of comparative data to traditional treatments and limited long-term follow-up, prospective studies with a larger number of patients undergoing electronic brachytherapy for nonmelanoma skin cancer are recommended. At this time, the statement recommends that treatment with electronic brachytherapy in this patient population should be performed in the context of a clinical registry or trial.

American Academy of Dermatology (AAD)

The American Academy of Dermatology (2018) published guidelines on the management of basal cell carcinoma[3] and the management of squamous cell carcinoma.[22] Electronic brachytherapy was rated as a C recommendation, with the level of evidence of II and III. By comparison, surgery, cryosurgery, topical therapies, and photodynamic therapies are rated as A and B recommendations.

American Society for Therapeutic Radiology and Oncology (ASTRO)

A 2010 report published by the American Society for Therapeutic Radiology and Oncology (ASTRO) Emerging Technology Committee stated that the "advantages of EBT over existing technologies are as yet unproven in terms of efficacy or patient outcomes."[26]

The report explains the impact of clinical use of electronic brachytherapy could be far-reaching, and if used improperly, potentially harmful to patients. The report explains that electronic brachytherapy is currently an unregulated treatment delivery modality for cancer therapy, with minimal clinical data available from small single institution, studies, none with significant follow-up. It also noted that there are currently no accepted calibration standards for electronic brachytherapy. Thus, there can be large uncertainties associated with absorbed dose measurement at low energies. Furthermore, the report stated that the effects of electronic brachytherapy on tumor and normal tissues are not yet well understood, given the paucity of clinical studies.

Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 5.

Table 5. Summary of Key Ongoing Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01644669	Safety and efficacy study of the Xoft® Axxent® eBx™ IORT system	2000	June 2034
NCT02131805	Electronic skin surface brachytherapy for cutaneous basal cell and squamous cell carcinoma	36	May 2024 (ongoing)
NCT04088435	Xoft® Intraoperative Radiotherapy (IORT) for Patients With Early-Stage Breast Cancer	60	Sep 2027
NCT03561454	An Investigator Initiated Study of Intra-Operative Radiation Therapy (IORT) Using the Xoft® Axxent® eBx System	50	Aug 2029

NCT: national clinical trial
[a] Denotes industry-sponsored or cosponsored trial.

Government Regulations

National

There is no national coverage determination addressing electronic brachytherapy.

Local:

WPS Local Coverage Determination: Category III codes L35490; Effective date: for services performed on or after 03/28/2024.[35]

WPS put the code 0394T and 0395T in the Group I listing of Category III codes; this group lists Category III services determined by WPS Medicare to be reasonable and medically necessary. Coverage will only be allowed when the service is delivered in clinical situations meeting medical necessity. For services addressed in a separate LCD all criteria addressed in that LCD must be met.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Accelerated Breast Irradiation after Breast-Conserving Surgery for Early Stage Breast Cancer and Breast Brachytherapy as Boost with Whole-Breast Irradiation
- Brachytherapy for Clinically Localized Prostate Cancer Using Permanently Implanted Seeds
- Intraoperative Radiation Therapy

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through June 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/07	5/14/07	6/5/07	Joint policy established
5/1/09	2/10/09	2/10/09	Routine maintenance
3/1/12	12/13/11	12/21/11	Updated references; no change in policy status.
5/1/15	2/17/15	2/27/15	Routine maintenance. Added additional FDA-approved devices. No change in policy status.
9/1/15	6/16/15	7/16/15	Added CMS information indicating that 0182T is considered medically necessary for Medicare members effective 2/16/15.
11/1/16	8/16/16	8/16/16	Added codes 0394T and 0395T, deleted 0182T. Added clinical trial information.
11/1/17	8/15/17	8/15/17	Updated background and rational sections. Condensed regulatory section. Added reference #6, studies placed in table format. Updated NCCN guidelines and clinical trials. Policy status remains unchanged.
11/1/18	8/21/18	8/21/18	Routine policy maintenance. No change in policy status.
11/1/19	8/20/19		Routine policy maintenance. No change in policy status.
11/1/20	8/18/20		Routine policy maintenance, updated rationale section, added reference # 7 and 8. No change in policy status.
11/1/21	8/17/21		Routine policy maintenance, no change in policy status.
11/1/22	8/16/22		Updated rationale, added references 7, 11 and 34. No change in policy status.
11/1/23	8/15/23		Routine policy maintenance, no change in policy status. Vendor managed: eviCore. (ds)
11/1/24	8/20/24		Updated rationale added references # 10 & 13. No change in policy

			status. Vendor managed: eviCore (ds)

Next Review Date: 3rd Qtr. 2025

BLUE CARE NETWORK BENEFIT COVERAGE POLICY: ELECTRONIC BRACHYTHERAPY

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	See government section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.