

<b>8.01.62</b>		<b>Electronic Brachytherapy for Nonmelanoma Skin Cancer</b>	
<b>Original Policy Date:</b>	September 30, 2015	<b>Effective Date:</b>	September 1, 2023
<b>Section:</b>	8.0 Therapy	<b>Page:</b>	Page 1 of 20

**Policy Statement**

- I. Electronic brachytherapy for the treatment of nonmelanoma skin cancer (see Policy Guidelines section) is considered **investigational**.

**NOTE:** Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

**Policy Guidelines**

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.

**Coding**

The following category III CPT code is specific for application of electronic brachytherapy to the skin surface:

- **0394T:** High dose rate electronic brachytherapy, skin surface application, per fraction, includes basic dosimetry, when performed

The following CPT code is specific for application of interstitial or intracavitary electronic brachytherapy:

- **0395T:** High dose rate electronic brachytherapy, interstitial or intracavitary treatment, per fraction, includes basic dosimetry, when performed

Any of the following codes may be used, and are considered not medically necessary: 0394T, 0395T, 77014, 77261-77263, 77280, 77285, 77290, 77295, 77300-77301, 77306-77307, 77321, 77331-77334, 77338, 77370-77373, 77385-77387, 77401, 77402, 77407, 77412, 77417, 77424-77425, 77432, 77435, 77469-77470, 77770-77772, 77778, 77790, G0339-G0340, G6001-G6017

**Description**

Electronic brachytherapy is a form of radiotherapy designed to deliver high-dose rate radiation to treat nonmelanoma skin cancer (NMSC). This technique focuses a uniform dose of X-ray source radiation to the lesion with the aid of a shielded surface application.

**Related Policies**

- Radiation Oncology

**Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

## Regulatory Status

Electronic brachytherapy systems for the treatment of NMSCs 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 SRT-100 Vision™ System (Sensus Healthcare), Esteya® Electronic Brachytherapy System (Nucletron BV), and the Xofigo® Axcent® Electronic Brachytherapy System (iCAD) are systems that have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process.

U.S. Food and Drug Administration product code: JAD.

## Rationale

### 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<sup>1,2</sup> respectively, and increasing at a rate of 3% to 8% per year.<sup>2</sup> 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.<sup>3</sup> 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.<sup>2</sup> 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 NMSC is surgical. If surgery is not feasible or preferred, cryosurgery, topical therapy, or radiotherapy can be considered, though the cure rate may be lower.<sup>4</sup> When considering the most appropriate treatment strategy, recurrence rate, preservation of function, patient expectations, and potential adverse events should be considered.

### Surgical

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, 5-year cure rates for basal cell cancer range from 98% to 99%,<sup>5</sup> making Mohs surgery the preferred procedure for those who qualify.

## Radiotherapy

Radiotherapy is indicated for certain NMSCs 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 range from 80% to 92%, which is lower than that of surgical excision.<sup>5</sup> 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.<sup>6</sup>

When radiotherapy is used for NMSC, the primary modality is external-beam radiotherapy. A number of different brachytherapy techniques have also been developed, including low-dose rate systems, iridium-based systems, and high-dose rate systems.<sup>5</sup>

## Electronic Brachytherapy

Electronic brachytherapy is a form of radiotherapy delivered locally, using a miniaturized electronic X-ray source rather than a radionuclide-based source. A pliable mold, constructed of silicone or polymethyl-methacrylate, is 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.<sup>5</sup> Multiple treatment sessions within a short time period (typically within a month) are required.

This technique is feasible for well-circumscribed, superficial tumors because it focuses a uniform dose of X-ray source radiation on 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.<sup>5</sup>

## Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are 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 to 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 a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 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 (RCT) 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. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these

groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

## Electronic Brachytherapy for Nonmelanoma Skin Cancer

### Clinical Context and Therapy Purpose

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

The following PICO was used to select literature to inform this review.

### *Populations*

The relevant population of interest is individuals with NMSC. Nonmelanoma skin cancer refers to squamous cell carcinoma (SCC) and basal cell carcinoma (BCC). 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 SCC and BCC 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 (EBRT), and standard brachytherapy.

The diagnosis of NMSC 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. Follow-up to adequately detect NMSC recurrence should be at least 5 years.

### Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

### 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.<sup>7</sup> "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 brachytherapy, including electronic brachytherapy, for the treatment of NMSC.<sup>8</sup> A literature review conducted through May 2019 identified 10 case series with sample sizes of 20 patients or more that reported on nonoverlapping patients. Findings were reported for 1870 patients (N=1870 lesions). Most lesions (65%) were BCC and the second largest group (35%) was SCC. Reviewers did not pool study findings, reporting that the rates of local control ranged from 83% to 100%. After a median follow-up ranging from 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 high-dose rate brachytherapy with surface applicators or custom-made surface molds.

### Prospective Cohort Study

Patel et al (2017)<sup>9</sup> published preliminary results from a multi-center prospective matched pair cohort study (NCT03024866) comparing clinical outcomes of NMSC treated with electronic brachytherapy or MMS. Patients from 4 treatment centers who had already received treatment for NMSC with electronic brachytherapy 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 ( $\pm 15$  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 electronic brachytherapy or MMS for NMSC  $\geq 3$  years prior
- age  $> 40$  yrs
- diagnosis of SCC or BCC
- cancer stage 0 to 2

Exclusion criteria included:

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

Patients were evaluated for follow-up at 2.3 to 5.0 years post-treatment. Treatment with electronic brachytherapy was performed with a miniature, high dose rate 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 to 3 mm but in some cases a customized dose, depth, or schedule was used. Mohs micrographic surgery was performed by clinicians according to guidelines of the American College of Mohs Surgery. Matching of patients on lesion characteristics was based on the histopathology of BCC or SCC, cancer staging (Stage 0, Stage 1, Stage 2), size ( $\leq 1$  cm,  $> 1$  cm and  $\leq 2$  cm,  $> 2$  cm and  $\leq 3$  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 electronic brachytherapy 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.

The main characteristics and results are summarized in Table 1.

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

Study	Population N	FU	Treatment	Outcomes
<b>Patel et al (2017)<sup>a</sup></b>	Patients receiving EBT for NMSC	188	EBT	Absence of Local Recurrence at Follow-Up (number of lesions, %, 95% CI)
	Lesions receiving EBT for NMSC (number of lesions, %)	Mean 3.3 ± 0.4 y (range 2.6 to 4.3)	EBT	Cosmesis Grade at Follow-Up (number of lesions, %, 95% CI) <sup>a</sup>
				Long-term Toxicities Present at Follow-Up (number of lesions, %)
				Results of Patient Satisfaction Questionnaire at Follow-Up (mean ± SD; median, [10-60]) <sup>b</sup>
				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 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
	• Lesions with BCC (113, 54.3%)	Mean 3.3 ± 0.4 y	EBT	207 (99.5%, 97.4 to 100%)
	• Lesions with SCC (95, 45.7%)	3.2; 2.6 to 4.3)		
				Clinician Cosmesis Grade
				• No changes, relatively invisible scar (138, 66.7%)
				Late toxicities:
				• 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, 23.1%)
				• Fair (15, 7.2%)
				• Poor (5, 2.4%)
				• 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 subcutaneous tissue (7, 3.4%)
				• Hypertrophy (excessive fibrosis) or keloid (0, 0%)
				• Poor healing, ulceration, erosion (4, 1.9%)

Study	Population N	FU	Treatment Outcomes					
						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) <sup>a</sup>	Long-term Toxicities Present at Follow-Up (Number of lesions, %)	Results of Patient Satisfaction Questionnaire at Follow-Up (mean ± SD; median, [10 to 60]) <sup>b</sup>	
• Lesions with BCC (113, 54.3%)	208	Mean 3.5 ± 0.5 y (range 2.3 to 5.0)	MMS	208 (100%, 98.2 to 100%)	• Excellent (199, 95.7%, 92.0 to 98.0%) • Excellent (142, 68.3%) • Good (57, 27.4%) • Fair (9, 4.3%) • Poor (0, 0.0%)	• 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%)	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%) • Hypertrophy (excessive fibrosis) or keloid (3, 1.4%) • Poor healing,	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) • Since
• Lesions with SCC (95, 45.7%)					• Excellent (148, 71.1%) • Good (50, 24.0%) • Fair (10, 4.8%) • Poor (0, 0.0%)	• Excellent (148, 71.1%) • Good (50, 24.0%) • Fair (10, 4.8%) • Poor (0, 0.0%)	• Hypertrophy (excessive fibrosis) or keloid (3, 1.4%) • Poor healing,	• Satisfied with appearance of the treated area (4.6 ± 0.7) • Have not had any skin problems with treated area (4.7 ± 0.6) • Since

Study	Population	N	FU	Treatment	Outcomes
					ulceration, erosion (0, 0.0%) 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)
<b>Kuo et al (2022)<sup>10</sup></b>	Age ≥60y with AJCC TNOMO BCC or SCC	34	12 weeks	EBT	<p>Cosmesis grade at 12 weeks, n (%)</p> <p>Quality of life, mean (SD)</p> <p>Adverse events</p> <p>--</p> <p>Clinician • Good: 31 (96.9) • Fair: 1 (3.1) • Bad: 0 • ND: 2</p> <p>Skindex-16, baseline (N=34) • Symptoms: 7.4 (17.7) • Emotions: 19.7 (24.0)</p> <p>• 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%)</p> <p>Patient • Good: 31 (93.9) • Fair: 2 (6.1) • Bad: 0 • ND: 1</p> <p>• Functioning: 4.4 (10.5) • Total: 10.5 (14.9)</p> <p>Skindex-16, 12 weeks (n=33)</p>



Study	Population N	FU	Treatment Outcomes
			<ul style="list-style-type: none"> <li>• Symptoms: 1.6 (3.7)</li> <li>• Emotions: 3.1 (6.0), <math>p \leq .006</math> vs baseline</li> <li>• Functioning: 1.5 (7.0)</li> <li>• Total: 2.1 (4.6), <math>p \leq .017</math> vs baseline</li> </ul>
			Skin Cancer Index, baseline (N=34) <ul style="list-style-type: none"> <li>• Emotional: 77.7 (22.2)</li> <li>• Social: 90.1 (19.1)</li> <li>• Appearance: 67.4 (33.1)</li> <li>• Total: 78.4 (21.9)</li> </ul>
			Skin Cancer Index, 12 weeks (n=33) <ul style="list-style-type: none"> <li>• Emotional: 86.3 (15.7)</li> <li>• Social: 92.3 (13.4)</li> <li>• Appearance: 87.6 (20.3), <math>p \leq .006</math> vs baseline</li> <li>• Total: 88.7 (13.3)</li> </ul>

AJCC: American Joint Committee on Cancer; BCC: basal cell carcinoma; CI: confidence interval; EBT: electronic brachytherapy; FU : follow-up; MMS: Mohs micrographic surgery; ND: no data; NMSC: nonmelanoma skin cancer; SCC: squamous cell carcinoma; SD: standard deviation.

<sup>a</sup> Standardized scale adapted from Cox et al (1995).<sup>11</sup>

<sup>b</sup> A score of 5 represents the maximum positive or favorable response to each question.

No statistically significant difference was found between electronic brachytherapy (97.6%) and MMS (95.7%) groups for local recurrence absence ( $p=1.000$ ). However, 1 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 ( $p=.277$ ) and patient satisfaction with both groups demonstrating predominantly excellent cosmesis grades and high patient satisfaction scores. Late toxicities appeared at similar rates with telangiectasia being reported slightly more in the electronic brachytherapy versus MMS group (31.4% vs. 11.1%).

A summary of study relevance limitations is provided in Table 2.

### Table 2. Study Relevance Limitations

Study (year)	Population <sup>a</sup>	Intervention <sup>b</sup>	Comparator <sup>c</sup>	Outcomes <sup>d</sup>	Follow-Up <sup>e</sup>
Patel et al (2017) <sup>9</sup>	2. Rationale for inclusion and exclusion criteria unclear	2. Version used unclear		6. Clinically significant difference not supported	1. Not sufficient duration for benefit
Kuo et al (2022) <sup>10</sup>		2. Version used unclear	5. No comparator	1. Recurrence rates not reported	1. Not sufficient duration for benefit

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

<sup>a</sup> Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.

<sup>b</sup> Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5. Other.

<sup>c</sup> Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.

<sup>d</sup> Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.

<sup>e</sup> Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

A summary of study design and conduct limitations is provided in Table 3.

**Table 3. Study Design and Conduct Limitations**

Study (year)	Allocation <sup>a</sup>	Blinding <sup>b</sup>	Selective Reporting <sup>c</sup>	Data Completeness <sup>d</sup>	Power <sup>e</sup>	Statistical <sup>f</sup>
Patel et al (2017) <sup>9</sup>	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 for primary outcome	
Kuo et al (2022) <sup>10</sup>	1,2. Open-label single-arm trial	1,2. Open-label 4. Unknown if outcome assessed by treating physician				

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

<sup>a</sup> Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.

<sup>b</sup> Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.

<sup>c</sup> Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.

<sup>d</sup> 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. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.

<sup>e</sup> Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.

<sup>f</sup> 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; 5. Other.

### Case Series

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

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

Study	Population	N	MFU, mo	Treatment	Outcomes	
					Recurrence	Toxicity, %
Doggett et al (2023) <sup>12</sup>	Basal or squamous cell carcinoma with $\geq 5$ y follow-up	180	90	<ul style="list-style-type: none"> <li>40 Gy in 8 twice-weekly fractions</li> </ul>	1.1%	<ul style="list-style-type: none"> <li>Hypopigmentation grade 1: 65.9%</li> <li>Telangiectasia grade 1: 22.5%</li> <li>Scar grade 1: 1.1%</li> <li>Hyperpigmentation grade 1: 1.1%</li> <li>Induration grade 2: 0.5%</li> </ul>
Pellizzon et al (2020) <sup>13</sup>	Basal or squamous cell carcinoma	71	42.8	<ul style="list-style-type: none"> <li>Leipzig applicator</li> <li>Total dose: 28 to 55 Gy in 7 to 22 fractions</li> </ul>	6.9%	Acute: <ul style="list-style-type: none"> <li>Grade 1 to 2=100</li> <li>Grade 3= 8.9</li> </ul> Late: <ul style="list-style-type: none"> <li>Grade 3=3.9</li> <li>Grade 4=0</li> </ul>
Paravati et al (2015) <sup>14</sup>	Basal, squamous, or basosquamous cell carcinoma	127	16.1	<ul style="list-style-type: none"> <li>Axxent Xoft system</li> <li>Total dose: 40 Gy in 8 fractions delivered 2 times weekly</li> </ul>	1.2% <sup>c</sup> (2/154)	Acute: <ul style="list-style-type: none"> <li>Grade 0 to 1=53</li> <li>Grade 2=34.4</li> <li>Grade 3=13</li> </ul> Late: <ul style="list-style-type: none"> <li>Grade 0 to 1=94</li> <li>Grade 2=6</li> </ul>
Delishaj et al (2015) <sup>15</sup>	Nonmelanoma skin cancer	39	12	<ul style="list-style-type: none"> <li>Valencia applicator</li> <li>Total dose: 40 Gy in 8 fractions</li> </ul>	0%	Acute: <ul style="list-style-type: none"> <li>Grade 1=58</li> <li>Grade 2=5</li> </ul> Late: <ul style="list-style-type: none"> <li>Grade 1=19</li> <li>Grade 2=2</li> </ul>
Tormo et al (2014) <sup>16</sup>	Basal cell carcinoma	32	47	<ul style="list-style-type: none"> <li>Valencia applicator</li> <li>Total dose: 42 Gy in 6 to 7 fractions</li> </ul>	3.1%	<ul style="list-style-type: none"> <li>Grade 1=NR</li> <li>Grade 2=0</li> <li>Grade 3=0</li> </ul>
Bhatnagar et al (2013) <sup>1</sup> ; Bhatnagar & Loper (2010) <sup>17,a</sup>	Nonmelanoma skin cancer	122	10.0	<ul style="list-style-type: none"> <li>Axxent Xoft system</li> <li>Total dose: 40 Gy in 8 fractions delivered twice weekly</li> </ul>	0%	<ul style="list-style-type: none"> <li>Grade 1=11</li> <li>Grade 2=13</li> <li>Grade 3=0</li> </ul>

Study	Population	N	MFU, mo	Treatment	Outcomes
Gauden et al (2013) <sup>18</sup>	Small nonmelanoma skin cancers	200	66 <sup>b</sup>	<ul style="list-style-type: none"> <li>Leipzig applicator</li> <li>Total dose: 36 Gy in 12 fractions delivered daily</li> </ul>	2% <sup>c</sup> (4/236) <ul style="list-style-type: none"> <li>Grade 1=71</li> <li>Grade 2=34</li> <li>Grade 3=0</li> </ul>
Giux et al (2000) <sup>19</sup>	Basal or squamous cell carcinoma	136	60	<ul style="list-style-type: none"> <li>Brock applicator</li> <li>Total dose: 60 to 65 Gy in 33 to 36 fractions</li> </ul>	2.2% NR ("no severe complications")

MFU: mean follow-up; NR: not reported.

<sup>a</sup> Overlapping case series; results from larger, more recent publication reported.

<sup>b</sup> Median.

<sup>c</sup> Calculated based on number 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).<sup>18</sup> Brachytherapy was the primary treatment modality in 69% of the lesions, while in the remaining 31% (74/236) brachytherapy was a follow-up treatment to surgery when there were positive margins. Outcomes included treatment efficacy, as measured by local recurrence rate, skin toxicity measured using Radiation Therapy Oncologic Group criteria, and cosmetic outcome using the Radiation Therapy Oncologic Group Cosmesis Scale. After a median follow-up of 66 months, there were recurrences in 2% (4/236) of treated lesions. Cosmetic outcome was judged to be 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 instances of grade 3 or higher toxicities were noted. Late hypopigmentation of treated skin was reported in 5.5% (13/236) of treated lesions.

Bhatnager (2013) published a case series using a commercially available device (Axxent eBx System).<sup>1</sup> The series included 122 patients with 171 nonmelanoma skin lesions. Most patients had either BCC (53%) or SCC (41%); 10 (5.8%) patients had other types of cancer. Outcome measures included recurrence rates, adverse events using version 3.0 of the Common Terminology Criteria for Adverse Events, 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.

### Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

### Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### American Academy of Dermatology

In 2018, the American Academy of Dermatology published guidelines on the management of basal cell carcinoma<sup>4</sup>, and the management of squamous cell carcinoma.<sup>20</sup> Electronic brachytherapy was rated as a C recommendation, with a level of evidence of II and III. By comparison, surgery, cryosurgery, topical therapies, and photodynamic therapies are rated as A and B recommendations.

### 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.<sup>21</sup> 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. This recommendation was reaffirmed in a 2020 American Brachytherapy Society consensus statement on skin brachytherapy.<sup>22</sup>

### American Society for Radiation Oncology

The American Society for Radiation Oncology (ASTRO) issued clinical practice guidelines regarding definitive and postoperative radiation therapy for basal and squamous cell cancers of the skin.<sup>23</sup> Key questions were addressed by a systematic literature review and recommendations were developed via consensus with a modified Delphi approach. Consensus recommendations for specific dose-fractionation schemes are detailed for the definitive and post-operative settings. The guideline also states that appropriate use of any of the 4 major radiation modalities, including electronically-generated low energy sources such as electronic brachytherapy, result in similar local control and cosmetic outcomes. Therefore, "the decision of which modality and fractionation scheme to use should be based on both tumor characteristics (e.g., shape, contour, depth, and location) and normal tissue considerations."

### National Comprehensive Cancer Network

The National Comprehensive Cancer Network guidelines on basal cell carcinoma (v.1.2023)<sup>24</sup>, and squamous cell skin cancer (v.1.2023)<sup>25</sup>, both contain the following statement on brachytherapy: "There is insufficient long-term efficacy and safety data to support the routine use of electronic surface brachytherapy."

### U.S. Preventive Services Task Force Recommendations

Not applicable.

### Medicare National Coverage

There is no national coverage determination. In the absence of national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

### Ongoing and Unpublished Clinical Trials

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

**Table 5. Summary of Key Ongoing Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT02131805	A Multicenter Pilot Study of Electronic Skin Surface Brachytherapy for Cutaneous Basal Cell and Squamous Cell Carcinoma	36	May 2024
<i>Unpublished</i>			
NCT01016899 <sup>a</sup>	Xoft Electronic Brachytherapy Clinical Protocol for the Primary Treatment of Non-Melanoma Skin Cancer	100	Aug 2013 (completed)

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

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### Documentation for Clinical Review

- No records required

### Coding

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.*

Type	Code	Description
CPT®	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
	77261	Therapeutic radiology treatment planning; simple
	77262	Therapeutic radiology treatment planning; intermediate
	77263	Therapeutic radiology treatment planning; complex
	77280	Therapeutic radiology simulation-aided field setting; simple
	77285	Therapeutic radiology simulation-aided field setting; intermediate
	77290	Therapeutic radiology simulation-aided field setting; complex
	77295	3-dimensional radiotherapy plan, including dose-volume histograms
77300	Basic radiation dosimetry calculation, central axis depth dose calculation, TDF, NSD, gap calculation, off axis factor, tissue inhomogeneity factors, calculation of non-ionizing radiation surface and	

Type	Code	Description
		depth dose, as required during course of treatment, only when prescribed by the treating physician
	77301	Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications
	77306	Teletherapy isodose plan; simple (1 or 2 unmodified ports directed to a single area of interest), includes basic dosimetry calculation(s)
	77307	Teletherapy isodose plan; complex (multiple treatment areas, tangential ports, the use of wedges, blocking, rotational beam, or special beam considerations), includes basic dosimetry calculation(s)
	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)
	77321	Special teletherapy port plan, particles, hemibody, total body
	77331	Special dosimetry (e.g., TLD, microdosimetry) (specify), only when prescribed by the treating physician
	77332	Treatment devices, design and construction; simple (simple block, simple bolus)
	77333	Treatment devices, design and construction; intermediate (multiple blocks, stents, bite blocks, special bolus)
	77334	Treatment devices, design and construction; complex (irregular blocks, special shields, compensators, wedges, molds or casts)
	77338	Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan
	77370	Special medical radiation physics consultation
	77401	Radiation treatment delivery, superficial and/or ortho voltage, per day
	77402	Radiation treatment delivery, => 1 MeV; simple
	77407	Radiation treatment delivery, => 1 MeV; intermediate
	77412	Radiation treatment delivery, => 1 MeV; complex
	77417	Therapeutic radiology port image(s)
	77470	Special treatment procedure (e.g., total body irradiation, hemibody radiation, per oral or endocavitary irradiation)
HCPCS	G6001	Ultrasonic guidance for placement of radiation therapy fields
	G6002	Stereoscopic x-ray guidance for localization of target volume for the delivery of radiation therapy
	G6003	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: up to 5 mev
	G6004	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: 6-10 mev
	G6005	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: 11-19 mev
	G6006	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: 20 mev or greater



Type	Code	Description
	G6007	Radiation treatment delivery, two separate treatment areas, three or more ports on a single treatment area, use of multiple blocks: up to 5 mev
	G6008	Radiation treatment delivery, two separate treatment areas, three or more ports on a single treatment area, use of multiple blocks: 6-10 mev
	G6009	Radiation treatment delivery, two separate treatment areas, three or more ports on a single treatment area, use of multiple blocks: 11-19 mev
	G6010	Radiation treatment delivery, two separate treatment areas, three or more ports on a single treatment area, use of multiple blocks: 20 mev or greater
	G6011	Radiation treatment delivery, three or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; up to 5 mev
	G6012	Radiation treatment delivery, three or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 6-10 mev
	G6013	Radiation treatment delivery, three or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 11-19 mev
	G6014	Radiation treatment delivery, three or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 20 mev or greater
	G6015	Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session
	G6016	Compensator-based beam modulation treatment delivery of inverse planned treatment using three or more high resolution (milled or cast) compensator, convergent beam modulated fields, per treatment session
	G6017	Intra-fraction localization and tracking of target or patient motion during delivery of radiation therapy (e.g., 3D positional tracking, gating, 3D surface tracking), each fraction of treatment

## Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
09/30/2015	BCBSA Medical Policy adoption
01/01/2016	Coding update
09/01/2016	Policy revision without position change
09/01/2017	Policy revision without position change
09/01/2018	Policy revision without position change
09/01/2019	Policy revision without position change
10/01/2020	Annual review. No change to policy statement. Literature review updated. Coding update.
11/20/2020	No change to policy statement. Policy guidelines updated.
06/01/2021	No change to policy statement. Policy guidelines updated. Coding update.
08/01/2021	Annual review. No change to policy statement.

Effective Date	Action
12/01/2021	Administrative update. No change to policy statement. Literature review updated.
08/01/2022	Annual review. No change to policy statement.
09/01/2022	Administrative update. No change to policy statement. Literature review updated.
09/01/2023	Annual review. No change to policy statement. Literature review updated.

## Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

## Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: [MedPolicy@blueshieldca.com](mailto:MedPolicy@blueshieldca.com)

*Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must*

**8.01.62 Electronic Brachytherapy for Nonmelanoma Skin Cancer**

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*be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.*

**Appendix A**

POLICY STATEMENT (No changes)	
BEFORE	AFTER
<p>Electronic Brachytherapy for Nonmelanoma Skin Cancer 8.01.62</p> <p><b>Policy Statement:</b></p> <ul style="list-style-type: none"> <li>I. Electronic brachytherapy for the treatment of nonmelanoma skin cancer (see Policy Guidelines section) is considered <b>investigational</b>.</li> </ul>	<p>Electronic Brachytherapy for Nonmelanoma Skin Cancer 8.01.62</p> <p><b>Policy Statement:</b></p> <ul style="list-style-type: none"> <li>I. Electronic brachytherapy for the treatment of nonmelanoma skin cancer (see Policy Guidelines section) is considered <b>investigational</b>.</li> </ul>