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MEDICAL POLICY – 8.01.62

Electronic Brachytherapy for Nonmelanoma Skin Cancer

BCBSA Ref. Policy:	8.01.62	
Effective Date:	Oct. 1, 2024	RELATED MEDICAL POLICIES:
Last Revised:	Sept. 9, 2024	None
Replaces:	N/A	

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POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Brachytherapy is a type of radiation therapy. "Brachy-" means "short," so brachytherapy is a way of giving radiation that doesn't travel far through other tissues to reach the cancerous tissue. Electronic brachytherapy is being studied as a treatment for skin cancer other than melanoma. Surgery is usually used to treat nonmelanoma skin cancer. With electronic brachytherapy, a high-dose x-ray is used to deliver radiation directly to the cancerous area. Typically, a mold is made and then placed over the treatment area. A probe — the source of radiation — is inserted into the mold so that the source touches the skin. The radiation is then activated. Once the radiation is delivered, the source is turned off, and the probe and mold are removed. Several sessions are required to complete the treatment. Electronic brachytherapy for nonmelanoma skin cancer is unproven. More studies are needed to see if this treatment is as good as or better than surgery and other types of radiation treatment.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Treatment	Investigational
Electronic brachytherapy (nonmelanoma skin cancer)	**Electronic brachytherapy for the treatment of nonmelanoma skin cancer (e.g., squamous cell and basal cell carcinoma) is considered investigational.**

Coding

Code	Description
CPT	
0394T	High dose rate electronic brachytherapy, skin surface application, per fraction, includes basic dosimetry, when performed

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Benefit Application

Electronic brachytherapy for the treatment of breast cancer is a covered diagnosis.

Evidence Review

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.

Background

Nonmelanoma Skin Cancer

Squamous cell carcinoma and basal cell carcinoma are the most common types of 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 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.[4] When considering the most appropriate treatment strategy, recurrence rate, preservation of function, individual 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. Individual preferences can also play a factor in surgical decisions due to cosmetic reasons, as well as the consideration of comorbidities and individual 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 individuals who meet criteria for Mohs surgery, 5-year cure rates for basal cell cancer range from 98% to 99%,[5] 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 individuals 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.[5] 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.[6]

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.[5]

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.[5] 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.[5]

Summary of Evidence

For individuals who have NMSC who receive electronic brachytherapy, the evidence includes two systematic reviews, two prospective cohort studies, 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, and a more recent single-arm prospective cohort study reported short-term improvements in some measures of quality of life, but confidence in these findings is low due to study design and conduct limitations. In the absence of randomized controlled studies, conclusions cannot be drawn about the efficacy and safety of electronic brachytherapy compared with other treatments for NMSC. 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 that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in **Table 1.**

Table 1. Summary of Key Ongoing Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02131805	A Multicenter Pilot Study of Electronic Skin Surface Brachytherapy for Cutaneous Basal Cell and Squamous Cell Carcinoma	36	May 2024

Unpublished			
NCT01016899[a]	Xoft Electronic Brachytherapy Clinical Protocol for the Primary Treatment of Non-Melanoma Skin Cancer	187 (actual)	Aug 2013 completed

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial

Practice Guidelines and Position Statements

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

Guidelines or position statements will be considered for inclusion 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[4] and the management of squamous cell carcinoma.[20] 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.[21] Due to a lack of comparative data to traditional treatments and limited long-term follow-up, prospective studies with a larger number of individuals undergoing electronic brachytherapy for nonmelanoma skin cancer are recommended. At this time, the statement recommends that treatment with electronic brachytherapy in this individual 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.[22.]

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.[23] 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 four 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.3.2024)[24] and squamous cell skin cancer (v.1.2024)[25] 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."

Medicare National Coverage

There is no national coverage determination.

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 Xoft Axxent Electronic Brachytherapy System (iCAD) are systems that have been cleared for marketing by the US Food and Drug Administration (FDA) through the 510(k) process.

FDA product code: JAD.

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History

Date	Comments
07/14/15	New Policy. Policy created with literature review through April 30, 2015. Electronic brachytherapy is considered investigational for the treatment of nonmelanoma skin cancer.
01/20/16	Coding update. New CPT codes 0394T-0395T, effective 1/1/16, added to policy.
10/01/16	Annual Review, approved September 13, 2016. Policy created with literature review through June 13, 2016; references 9-10 added. Added delete date in coding section. Policy statement unchanged.
09/01/17	Annual Review, approved August 22, 2017. Policy created with literature review through June 6, 2017; reference 6 added. Policy statement unchanged.
10/01/18	Annual Review, approved September 20, 2018. Policy created with literature review through May 2018; references 3 and 15 added. Policy statement unchanged.
03/01/19	Coding update, removed CPT code 0395T.
10/01/19	Annual Review, approved September 5, 2019. Policy updated with literature review through May 2019; references added and updated. Policy statement unchanged.

Date	Comments
10/01/20	Annual Review, approved September 17, 2020. Policy updated with literature review through April 2020; no references added. Policy statement unchanged.
10/01/21	Annual Review, approved September 2, 2021. Policy updated with literature review through June 6, 2021; references added. Policy statement unchanged.
09/01/22	Annual Review, approved August 22, 2022. Policy updated with literature review through May 24, 2022; reference added. Policy statement unchanged.
10/01/23	Annual Review, approved September 11, 2023. Changed the wording from "patient" to "individual" throughout the policy for standardization. Policy updated with literature review through May 18, 2023; references added. Policy statement unchanged.
10/01/24	Annual Review, approved September 9, 2024. Policy updated with literature review through May 30, 2024; Policy statement unchanged.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.