Electronic Brachytherapy for Nonmelanoma Skin Cancer

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

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Investigational</th>
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<tbody>
<tr>
<td><strong>Electronic brachytherapy</strong> <em>(nonmelanoma skin cancer)</em></td>
<td><strong>Electronic brachytherapy for the treatment of nonmelanoma skin cancer (eg, squamous cell and basal cell carcinoma) is considered investigational.</strong></td>
</tr>
</tbody>
</table>

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>CPT</td>
<td>High dose rate electronic brachytherapy, skin surface application, per fraction, includes basic dosimetry, when performed</td>
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</table>

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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. 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 nonmelanoma skin cancer in the United States, affecting between 1 and 3 million people per year\textsuperscript{1,2} and increasing at a rate of 3\% to 8\% per year.\textsuperscript{2} Other types (eg, T-cell lymphoma, Merkel cell tumor, basosquamous carcinoma, Kaposi sarcoma) are much less common. The primary risk factor for nonmelanoma skin cancer is sun exposure, with additional risk factors such as toxic exposures, other ionizing radiation exposure, and immunosuppression playing smaller roles.\textsuperscript{2} Although these cancers are rarely fatal, they can impact the 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.\textsuperscript{3} 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\%,\textsuperscript{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 to be favorable. The 5-year control rates for radiotherapy range from 80% to 92%, which is lower than for surgical excision. 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.

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.

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. 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.

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 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%. 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.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this policy are listed in Table 1.

Table 1. Summary of Key Ongoing Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT03024866²</td>
<td>Electronic Brachytherapy: A Multi-Center Retrospective-Prospective Matched Pairs Cohort Study to Assess Long Term Clinical Outcomes of Nonmelanoma Skin Cancer Patients Treated with eBx Compared to Nonmelanoma Skin Cancer Patients Treated with Mohs Surgery</td>
<td>500</td>
<td>Jan 2018</td>
</tr>
<tr>
<td>NCT01016899²</td>
<td>Xoft Electronic Brachytherapy Clinical Protocol for the Primary Treatment of Non-Melanoma Skin Cancer</td>
<td>100</td>
<td>Feb 2018 (ongoing)</td>
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<tr>
<td>NCT02131805</td>
<td>Electronic Skin Surface Brachytherapy for Cutaneous Basal Cell and Squamous Cell Carcinoma</td>
<td>26</td>
<td>May 2018</td>
</tr>
</tbody>
</table>

NCT: national clinical trial
² Denotes industry-sponsored or cosponsored trial
Practice Guidelines and Position Statements

National Comprehensive Cancer Network

National Comprehensive Cancer Network guidelines on basal cell carcinoma (v.1.2018)\textsuperscript{13} and squamous cell skin cancer (v.2. 2018)\textsuperscript{14} both contain the following statement on electronic brachytherapy: “There is insufficient long-term efficacy and safety data to support the routine use of electronic brachytherapy.”

American Academy of Dermatology

The American Academy of Dermatology (2018) published guidelines on the management of basal cell carcinoma\textsuperscript{3} and the management of squamous cell carcinoma.\textsuperscript{15} 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.

Medicare National Coverage

There is no national coverage determination.

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\textsuperscript{®} Electronic Brachytherapy System (Nucletron BV) and the Xoft\textsuperscript{®} Axxent\textsuperscript{®} 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.

FDA product code: JAD.

History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
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<tbody>
<tr>
<td>07/14/15</td>
<td>New Policy. Policy created with literature review through April 30, 2015. Electronic brachytherapy is considered investigational for the treatment of nonmelanoma skin</td>
</tr>
</tbody>
</table>
### Date | Comments
---|---
01/20/16 | Coding update. New CPT codes 0394T-0395T, effective 1/1/16, added to policy.
03/01/19 | Coding update, removed CPT code 0395T.

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Toll free 855-332-4537, Fax 425-918-5592, TTY 800-842-5357
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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHB Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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