MEDICAL POLICY – 8.01.62

Electronic Brachytherapy for Nonmelanoma Skin Cancer

BCBSA Ref. Policy: 8.01.62

Effective Date: Oct. 1, 2019
Last Revised: Sept. 5, 2019
Replaces: N/A

RELATED MEDICAL POLICIES:
None

Select a hyperlink below to be directed to that section.

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

∞ Clicking this icon returns you to the hyperlinks menu above.

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

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CPT</strong></td>
<td></td>
</tr>
<tr>
<td>0394T</td>
<td>High dose rate electronic brachytherapy, skin surface application, per fraction, includes basic dosimetry, when performed</td>
</tr>
</tbody>
</table>

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. 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\(^1\,\,2\) and increasing at a rate of 3% to 8% per year.\(^2\) 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.\(^2\)

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.\(^3\) 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%,\(^4\) 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 that of 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, a prospective cohort study, and case series. Relevant
outcomes are overall survival, disease-specific survival, change in disease status, and treatment-related morbidity. One trial was identified comparing electronic brachytherapy to Mohs surgery. Only 1 recurrence was reported in the study in the EBT group with no recurrences in the surgery group. Patient satisfaction and cosmesis scores were high in both groups. However, many evidence gaps were identified which limit its ability to support the efficacy and safety of electronic brachytherapy compared with Mohs surgery. 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><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT03024866a</td>
<td>Electronic Brachotherapy: 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 (ongoing)*</td>
</tr>
<tr>
<td>NCT01016899a</td>
<td>Xoft Electronic Brachotherapy Clinical Protocol for the Primary Treatment of Non-Melanoma Skin Cancer</td>
<td>100</td>
<td>Feb 2018 (ongoing)**</td>
</tr>
<tr>
<td>NCT02131805</td>
<td>Electronic Skin Surface Brachotherapy for Cutaneous Basal Cell and Squamous Cell Carcinoma</td>
<td>26</td>
<td>May 2018 (ongoing)***</td>
</tr>
</tbody>
</table>

NCT: national clinical trial

a = Denotes industry-sponsored or cosponsored trial
* = Last updated clinicaltrials.gov January 2019 (status: unknown; preliminary results published but not submitted)
** = Last update posted to clinicaltrials.gov September 2017 (status: active, not recruiting)
*** = Last update to clinicaltrials.gov May 2019 (status: recruiting)
Practice Guidelines and Position Statements

National Comprehensive Cancer Network

National Comprehensive Cancer Network guidelines on basal cell carcinoma (v.1.2018)\textsuperscript{15} (v.1.2019)\textsuperscript{[X]} and squamous cell skin cancer (v.2. 2019)\textsuperscript{16} [X] 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{17} 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® Electronic Brachytherapy System (Nucletron BV) and the Xoft® Axxent® 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.
References


History
<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<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 cancer.</td>
</tr>
<tr>
<td>01/20/16</td>
<td>Coding update. New CPT codes 0394T-0395T, effective 1/1/16, added to policy.</td>
</tr>
<tr>
<td>03/01/19</td>
<td>Coding update, removed CPT code 0395T.</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2019 Premera All Rights Reserved.

**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.
Discrimination Is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
• Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  • Qualified sign language interpreters
  • Written information in other formats (large print, audio, accessible electronic formats, other formats)
• Provides free language services to people whose primary language is not English, such as:
  • Qualified interpreters
  • Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5992. TTY 800-537-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action before a certain date in order to keep your health insurance or fee assistance.

Premera:
• Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  • Qualified sign language interpreters
  • Written information in other formats (large print, audio, accessible electronic formats, other formats)
• Provides free language services to people whose primary language is not English, such as:
  • Qualified interpreters
  • Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5992. TTY 800-537-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at

Oromo (Cushite):

Français (French):

Kreyòl ayisyen (Creole):

Deutsche (German):

Hmoob (Hmong):

Iloko (Ilocano):
Daytoy a Pakdaa ket naglaon iti Napagte nga Impormasjon. Daytoy a pakdaar mabalain nga adda ket naglaon iti napagte nga impormasjon maipanggep iti aplikasyonowo yowo coverage babaen iti Premera Blue Cross. Daytoy ket mabalain dagiti importante a pentsa iti daytoy a pakdaar. Mabalain nga adda rumben nga aramidenyong nga addang sabbay dagiti partikular a naituding nga aldaw tapno mapagtalaineydoy ti coverage ti salun-atoy yowo tulong kadagiti gastos. Adda karbangoyo a mangala iti daytoy nga impormasjon ken tulong iit bukdooy a pagasaaq nga awan ti bayadangyo. Tumawag ti numero nga osawa 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):
Premera Blue Cross (English): This Notice contains important information. Premera Blue Cross has an important message for you. Please read and take note of this important information.

Pourrez-vous arrêter de recevoir ces communications à tout moment en vous dirigeant vers l’adresse Web ci-dessus ou en composant le 800-722-1471 (TTY: 800-842-5357) ?

Primaer Blue Cross (German): Dieses Vermerk enthält eine wichtige Information. Primera Blue Cross möchte Ihnen eine wichtige Mitteilung machen. Bitte lesen Sie sich diese Information bitte ausführlich durch.

Premera Blue Cross (French): Cette avis contient des informations importantes. Premera Blue Cross a une importante information à transmettre. Veuillez la lire attentivement et la prendre en compte.

Premera Blue Cross (Italian): Questo avviso contiene informazioni importanti. Premera Blue Cross ha un messaggio importante per voi. Viene consigliato di leggere attentamente queste informazioni.

Premera Blue Cross (Spanish): Este aviso contiene información importante. Premera Blue Cross tiene una importante noticia para usted. Por favor, lea y tome nota de esta información.

Premera Blue Cross (Portuguese): Este aviso contém informações importantes. Premera Blue Cross tem uma importante mensagem para você. Por favor, leia e note bem essas informações.

Premera Blue Cross (Chinese): 本通知包含了重要的信息。Premera Blue Cross有一条重要信息需要通知您。请您仔细阅读并注意此重要信息。

Premera Blue Cross (Japanese): この通知には重要な情報が含まれています。Premera Blue Crossは、重要なメッセージをお知らせします。詳細をよくご確認ください。

Premera Blue Cross (Korean): 본 통지에는 중요한 정보가 들어 있습니다. Premera Blue Cross는 중요한 메시지를 전달합니다. 자세히 읽고 주의해 주세요.

Premera Blue Cross (Ukrainian): Ця повідомлення містить важливу інформацію. Premera Blue Cross має важливу повідомлення для вас. Будь ласка, прочитайте й зацікавіться усіма деталями.

Premera Blue Cross (Russian): В этом уведомлении содержится важная информация. Premera Blue Cross имеет важное уведомление. Пожалуйста, прочитайте и обратите внимание на все детали.

Premera Blue Cross (Vietnamese): Thông báo này cung cấp thông tin quan trọng. Thông báo này có thể thay đổi trang thái và đơn vị một cách nhanh chóng. Quý vị cần chú ý thông tin này và đọc kỹ.