

Corporate Medical Policy

Electronic Brachytherapy for Nonmelanoma Skin Cancer

File Name: electronic_brachytherapy_for_nonmelanoma_skin_cancer
Origination: 7/2015
Last CAP Review: 3/2018
Next CAP Review: 3/2019
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Description of Procedure or Service

Electronic brachytherapy is a form of radiotherapy that is designed to deliver high-dose rate (HDR) brachytherapy for the treatment of 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

Nonmelanoma skin cancer consists primarily of squamous cell carcinoma and basal cell carcinoma, with other types (eg, T-cell lymphoma, Merkel cell tumor, basosquamous carcinoma, Kaposi sarcoma) being much less common. Basal and squamous cell carcinoma are the most common types of malignancy in the United States, affecting between 1 and 3 million people per year and increasing at a rate of 3% to 8% per year. 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. Although these cancers rarely cause mortality, they can impact quality of life, functional status, and physical appearance.

Treatment

In general, the most effective treatment for nonmelanoma skin cancer is surgical. If surgery is not feasible or preferred, cryosurgery, topical therapy or radiotherapy can be considered, although the cure rate may be lower.

Surgical

The choice of surgical procedure depends on the histologic type, and size and location of the lesion. Patient characteristics and preferences may also be part of the decision-making process, with consideration of comorbidities, patient risk factors such as anticoagulation, and cosmetic outcomes. 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 a type of excisional procedure that uses microscopic guidance to achieve greater precision and sparing of normal tissue. In patients who meet criteria for Mohs surgery, five year cure rates for basal cell cancer are in the range of 98% to 99%, making Mohs surgery the preferred procedure for those who qualify.

Radiotherapy

Radiotherapy is indicated for certain nonmelanoma skin cancers that are not amenable to surgery. In some cases, this is due to the location of the lesion on the eyelid, nose, or other structures that make surgery more difficult and which may be expected to have a less desirable cosmetic outcome. In other cases, surgery may be relatively contraindicated due to clinical factors such as bleeding risk or advanced age. In elderly patients with a relatively large tumor that would require extensive excision, the benefit/risk ratio for radiotherapy may be considered favorable. The 5-year control rates for radiotherapy are in the range of 80% to 92%, which is lower than for surgical excision.⁴ A randomized

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controlled trial published in 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 HDR 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 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.

Regulatory Status

Electronic brachytherapy systems for the treatment of nonmelanoma skin cancers are designed to deliver HDR brachytherapy for the treatment of 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 Xofigo® Axxent® Electronic Brachytherapy System (iCAD Inc.) are systems that recently received FDA clearance through the 510(k) process. FDA product code: JAD.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

Electronic brachytherapy for nonmelanoma skin cancer is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Electronic brachytherapy for nonmelanoma skin cancer is covered

Not applicable.

When Electronic brachytherapy for nonmelanoma skin cancer is not covered

Electronic brachytherapy for the treatment of nonmelanoma skin cancer is considered **investigational**.

Policy Guidelines

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

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 0394T, 77767, 77768

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.62, 5/21/15

Medical Director Review 5/2015

Specialty Matched Consultant Advisory Panel 4/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.62, 7/14/16

Specialty Matched Consultant Advisory Panel 3/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.62, 7/13/17

Specialty Matched Consultant Advisory Panel 3/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.62, 7/12/18

Policy Implementation/Update Information

7/28/15 New medical policy issued. Electronic brachytherapy for the treatment of nonmelanoma skin cancer is considered **investigational**. Senior medical director review 5/2015. (lpr)

12/30/15 Added the following CPT codes 0394T, 77767, 77768 and deleted 0182T in Billing/Coding section for effective date 1/1/2016. (lpr)

5/31/16 Specialty Matched Consultant Advisory Panel review 4/27/2016. No change to policy. (lpr)

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- 8/30/16 Updated Policy Guidelines section. Reference added. No change to policy statement. (lpr)
- 4/28/17 Specialty Matched Consultant Advisory Panel review 3/29/2017. No change to policy statement. (lpr)
- 8/25/16 Updated Policy Guidelines section. No change to policy statement. Reference added. (lpr)
- 10/13/17 Corrected date for above note 8/25/16 should read 8/25/17. (lpr)
- 4/27/18 Specialty Matched Consultant Advisory Panel review 3/28/2018. No change to policy statement. (lpr)
- 8/10/18 Updated Description section as well as Regulatory Status. No change to policy statement. Reference added. (lpr)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.