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OVERVIEW

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.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

Electronic brachytherapy for the treatment of nonmelanoma skin cancer is considered not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

Electronic brachytherapy for the treatment of nonmelanoma skin cancer is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for not medically necessary benefits/coverage.

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 and 3 million people per year and increasing at a rate of 3% to 8% per year. Other types (e.g., T-cell lymphoma, Merkel cell tumor, basosquamous carcinoma, Kaposi sarcoma) are much less common. 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. 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. 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 and 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 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, 5-year cure rates for basal cell cancer range from 98% to 99%, 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 are range from 80% to 92%, which is lower than that of surgical excision. A 1997 randomized controlled trial by Avril et al 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 NMSC, 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 (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 is constructed of silicone or polymethyl-methacrylate and 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.

For individuals who have NMSC who receive electronic brachytherapy, the evidence includes 2 systematic reviews, a prospective cohort study, 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 Mohs micrographic surgery (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, 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.

CODING

Medicare Advantage Plans and Commercial Products

The following CPT code is considered not covered for Medicare Advantage Plans and not medically necessary for Commercial Products when filed with the ICD-10 diagnosis codes below.

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

ICD-10 Diagnosis Code Range C44.00 - C44.99

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, November 2022

Provider Update, September 2021

Provider Update, July 2020

Provider Update, December 2019

Provider Update, November/December 2018

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