KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Superficial Radiation Therapy (Electronic Brachytherapy for Non-Melanoma Skin Cancer)

- "Xoft" Skin Treatments

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Noridian retired LCD Brachytherapy: Non-intracoronary (L34065). These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for "medical judgment" which could be based on our commercial criteria or literature search.
Local Coverage Article	None

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Nonmelanoma skin cancer (NMSC) is the most common malignancy in the Caucasian population and its incidence continues to rise. It is estimated that more than two million Americans are affected by NMSC each year. Due to ultraviolet light exposure, over 95% of cancers are located in the head and neck region (nose, ears, eyelids, and lips). Basal cell carcinoma (BCC) represents approximately 75-80% of NMSCs and squamous cell carcinoma (SCC) 20-25%. It is reported that half of the patients with NMSC are over 65 years of age and that almost 50% of them may develop a second primary NMSC within 5 years. These cancers have a low mortality

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rate and are rarely life threating, but they represent a significant burden on global health care services due to their increasing incidence (Alam 2011, Bhatnagar 2010 & 2013, Benkhaled, 2022).

Treatment options for NMSC include surgery, radiation therapy, chemotherapy, and photodynamic therapy. Surgery is considered the gold standard treatment; it provides the highest cure rates and has satisfactory cosmetic results. Surgical techniques include excision, curettage with electrodessication, and Mohs micrographic surgery (MMS). The choice of procedure depends on the histologic type, size, and location of the lesion. Some patients, however, are not suitable candidates for surgery because of their age, health condition, potential disfigurement, or functional defects when the cancer is located in high-risk areas. Radiation therapy has been used for selected skin cancers, typically reserved as a second-line therapy for patients with surgical contraindications or as adjuvant therapy for high-risk lesions. It is also an alternative to surgery for lesions located in areas where surgery may be more difficult, lead to disfigurement, or affect structural function e.g., eyelid, ear, or nose. Radiation therapy techniques used for NMSC include superficial x-rays, orthovoltage x-rays and megavoltage photons, electron beam irradiation, radionuclide-based brachytherapy (BT). (Bhatnagar 2010 & 2013, Frakulli 2015, Linos 2015, Safigholi 2015, Patel 2017, Ramachandran 2017).

Electronic brachytherapy (eBT, EBT, or EBX) is a relatively newer technology administering high-dose-rate brachytherapy (HDR-BT) with the use of a low energy miniaturized electronic X-ray source rather than a radionuclide-based source x-ray source. Potential advantages of EBT over traditional BT include isotope-free delivery, relatively reduced need for shielding, optimal sparing of normal tissues, shorter time of treatment, reduced dose to treating staff, and no radioactive waste. In addition. the EBT systems can be operated in a standard treatment room with minimal shielding due to low energy and no radiation leakage when off (Bhatnagar 2013, Safigholi 2015, Ouhib, 2015, Ramachandran 2017, Goyal 2021, Tang 2022).

Several types of EBT systems are currently available. The main component is a miniature X-ray tube that produces bremsstrahlung (electromagnetic) radiation using electron energies ranging from 20-70keV. Treatment of skin cancers is performed using conical applicators developed by the manufacturers and provided in different sizes (1cm, 2 cm, 3.5 cm, and 5 cm) to ensure adequate coverage of the clinical and planning target volume. Patients are treated with different fractionation regimens depending on the location and depth of the lesion with the most frequent regimen being 40 Gy/8 fx. The therapy is typically delivered twice weekly over 4 weeks (Bhatnagar 2013, Safigholi 2015, Goyal 2021).

Medical Technology Assessment Committee (MTAC)

Electronic Brachytherapy for Non-Melanoma Skin Cancer

04/21/2014: MTAC REVIEW

Evidence Conclusion: There is insufficient published evidence to determine the safety and efficacy of EBT for the treatment of NMSC. There is an ongoing clinical trial “Electronic Brachytherapy for the Treatment of NMSC” (NLM Identifier NCT01016899) with the objective of recording the recurrence in patients treated for nonmelanoma (basal cell and squamous cell carcinomas) skin cancer using the Xoft Axxent Electronic Brachytherapy System. The trial will also evaluate the cosmetic outcomes and skin toxicities related to the treatment.

Articles: The literature search for EBT for the treatment of NMSC identified only one study on the use of electronic brachytherapy for the treatment of NMSC. The initial results were reported in 2010 (Bhatnagar A, and Loper A, 2010) and 1-year results were published in 2013 (Bhatnagar A 2013). Bhatnagar A. Nonmelanoma skin cancer treated with electronic brachytherapy: results at 1 year. Brachytherapy. 2013; 12(2):134-140. See **Evidence Table.** Bhatnagar A, Loper A. The initial experience of electronic brachytherapy for the treatment of non-melanoma skin cancer. Radiat Oncol. 2010; 5:87. doi: 10.1186/1748-717X-5-87 See **Evidence Table.**

The use of electronic brachytherapy for non-melanoma skin cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

03/21/2016: MTAC REVIEW

Electronic Brachytherapy (EBT) for the treatment of non-melanoma skin cancer (NMSC)

Evidence Conclusion: There is insufficient published evidence to determine whether the safety and efficacy outcomes of electronic brachytherapy for NMSC are as good or superior to the outcomes of alternative treatment options. There are no published randomized or non-randomized controlled trials that compared EBT to an alternative therapy for the treatment of NMSC. The available published evidence consists of case series that used different systems for the delivery of HDR. The largest series (Bhatnagar 2010 & 2013) that used one of the three commercially available devices (the Axxent system, Xoft Inc. Sunnyvale, CA) was reviewed by MTAC earlier in 2014, and did not provide sufficient evidence on the long-term efficacy or safety of the procedure.

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The more recent case series identified by the search were small retrospective series with no comparison groups, and do not provide additional evidence to support the use of EBT for NMSC. In a recently published article, Linos and colleagues (2015), expressed their concern regarding the increase in the use of EBT for skin cancer. The authors analyzed Medicare claims data and found that EBT use for skin cancer is increasing rapidly in the Medicare population. They indicated this may be attributable to marketing by the manufacturers, and that there is insufficient long-term data on the efficacy and safety of the therapy to cover the period during which recurrence and radiation sequelae would be expected (Linos, 2015).

Articles: The updated literature search for the use of electronic brachytherapy in the treatment of NMSC did not identify any controlled trial that compared the therapy with an alternative mode of treatment. The search only identified a number of small retrospective case series and a systematic review of the observational studies reporting on the outcomes of low-dose or high-dose brachytherapy used for the treatment of NMSC of the eyelid (Frakulli 2015).

The use of electronic brachytherapy for non-melanoma skin cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Per NCCN Guidelines Version 1.2017 Basal Cell Skin Cancer. P. 11
"There is insufficient long-term efficacy and safety data to support the routine use of electronic surface brachytherapy."

07/08/2024: MTAC REVIEW

Evidence Conclusion

- There is insufficient published evidence to determine the comparatives safety and efficacy of electronic brachytherapy and Moh's surgery in treating patients with NMSC.
- There is insufficient published evidence to determine the net health outcomes of electronic brachytherapy in patients with NMSC.
- Randomized controlled trials with sufficient follow-up duration are needed to determine the comparative long-term safety and efficacy of EBT and MMS in patients with NMSC.

Articles: The literature search for studies published after the 2016 MTAC review of the technology, did not identify any RCT that compared electronic brachytherapy to Mohs Surgery for the treatment of patients with nonmelanoma skin cancer. The search only revealed a matched pair cohort study that compared EBT vs. Mohs micrographic surgery for the treatment of early stage NMSC (Patel, et al 2017); a systematic review with meta-analysis of studies evaluating different treatment modalities used for indolent skin cancer (Lee, et al 2019); a small (N=34) prospective study reporting on short term cosmesis and QoL with electronic skin surface brachytherapy for keratinocyte carcinoma (Kuo et al, al 2023): two year outcomes of a small pilot single arm observational study with incomplete follow-up of 26 patients (Ballester-Sánchez, et al, 2017) , retrospective chart reviews; and case series of patients with NMSC treated with EBT. See **Evidence Table**

Patel, et al's 2017 matched pair cohort study was selected for critical appraisal. Lee, et al's meta-analysis was not selected for the current review as the authors excluded studies that used electronic brachytherapy due to the lack of long-term data.

The use of electronic brachytherapy for non-melanoma skin cancer does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Hayes Technology Brief

Hayes, Inc. Hayes Technology Brief. Superficial Radiation Therapy for Treatment of Nonmelanoma Skin Cancer. Lansdale, PA: Hayes, Inc.; 3/2018

Applicable Codes

Effective until September 1, 2024

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met

Non-Medicare - Considered Not Medically Necessary

CPT® Codes	Description

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

Effective September 1, 2024
Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare - Considered Not Medically Necessary

CPT® Codes	Description
0394T	High dose rate electronic brachytherapy, skin surface application, per fraction, includes basic dosimetry, when performed
77280	Therapeutic radiology simulation-aided field setting; simple
77285	Therapeutic radiology simulation-aided field setting; intermediate
77300	Basic radiation dosimetry calculation, central axis depth dose calculation, TDF, NSD, gap calculation, off axis factor, tissue inhomogeneity factors, calculation of non-ionizing radiation surface and depth dose, as required during course of treatment, only when prescribed by the treating physician
77336	Continuing medical physics consultation, including assessment of treatment parameters, quality assurance of dose delivery, and review of patient treatment documentation in support of the radiation oncologist, reported per week of therapy
77370	Special medical radiation physics consultation
77401	Radiation treatment delivery, superficial and/or ortho voltage, per day
G6001	Ultrasonic guidance for placement of radiation therapy fields
With diagnosis Code	
C44.01	Basal cell carcinoma of skin of lip
C44.02	Squamous cell carcinoma of skin of lip
C44.1121	Basal cell carcinoma of skin of right upper eyelid, including canthus
C44.1122	Basal cell carcinoma of skin of right lower eyelid, including canthus
C44.1191	Basal cell carcinoma of skin of left upper eyelid, including canthus
C44.1192	Basal cell carcinoma of skin of left lower eyelid, including canthus
C44.1221	Squamous cell carcinoma of skin of right upper eyelid, including canthus
C44.1222	Squamous cell carcinoma of skin of right lower eyelid, including canthus
C44.1291	Squamous cell carcinoma of skin of left upper eyelid, including canthus
C44.1292	Squamous cell carcinoma of skin of left lower eyelid, including canthus
C44.212	Basal cell carcinoma of skin of right ear and external auricular canal
C44.219	Basal cell carcinoma of skin of left ear and external auricular canal
C44.222	Squamous cell carcinoma of skin of right ear and external auricular canal
C44.229	Squamous cell carcinoma of skin of left ear and external auricular canal
C44.311	Basal cell carcinoma of skin of nose
C44.319	Basal cell carcinoma of skin of other parts of face
C44.321	Squamous cell carcinoma of skin of nose
C44.329	Squamous cell carcinoma of skin of other parts of face
C44.41	Basal cell carcinoma of skin of scalp and neck
C44.42	Squamous cell carcinoma of skin of scalp and neck
C44.510	Basal cell carcinoma of anal skin
C44.511	Basal cell carcinoma of skin of breast
C44.519	Basal cell carcinoma of skin of other part of trunk
C44.520	Squamous cell carcinoma of anal skin
C44.521	Squamous cell carcinoma of skin of breast
C44.529	Squamous cell carcinoma of skin of other part of trunk

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C44.612	Basal cell carcinoma of skin of right upper limb, including shoulder
C44.619	Basal cell carcinoma of skin of left upper limb, including shoulder
C44.622	Squamous cell carcinoma of skin of right upper limb, including shoulder
C44.629	Squamous cell carcinoma of skin of left upper limb, including shoulder
C44.712	Basal cell carcinoma of skin of right lower limb, including hip
C44.719	Basal cell carcinoma of skin of left lower limb, including hip
C44.722	Squamous cell carcinoma of skin of right lower limb, including hip
C44.729	Squamous cell carcinoma of skin of left lower limb, including hip
D04.0	Carcinoma in situ of skin of lip
D04.111	Carcinoma in situ of skin of right upper eyelid, including canthus
D04.112	Carcinoma in situ of skin of right lower eyelid, including canthus
D04.121	Carcinoma in situ of skin of left upper eyelid, including canthus
D04.122	Carcinoma in situ of skin of left lower eyelid, including canthus
D04.21	Carcinoma in situ of skin of right ear and external auricular canal
D04.22	Carcinoma in situ of skin of left ear and external auricular canal
D04.39	Carcinoma in situ of skin of other parts of face
D04.4	Carcinoma in situ of skin of scalp and neck
D04.5	Carcinoma in situ of skin of trunk
D04.61	Carcinoma in situ of skin of right upper limb, including shoulder
D04.62	Carcinoma in situ of skin of left upper limb, including shoulder
D04.71	Carcinoma in situ of skin of right lower limb, including hip
D04.72	Carcinoma in situ of skin of left lower limb, including hip
D04.8	Carcinoma in situ of skin of other sites
D07.1	Carcinoma in situ of vulva
D07.4	Carcinoma in situ of penis

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
08/02/2024	05/06/2014[MPC], 03/03/2015[MPC], 01/05/2016[MPC], 11/01/2016[MPC], 09/05/2017[MPC], 08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC], 08/07/2023[MPC], 04/02/2024[MPC]	08/06/2024

[MPC] Medical Policy Committee

Revision History	Description of Change
04/05/2016	Added MTAC review
04/25/2017	Added NCCN Guideline
04/17/2018	Added Hayes Guideline
08/04/2020	Removed deactivated CPT code 0182Tand CPT code 77401
04/26/2024	Updated applicable codes by adding: 77280, 77285, 77300, 77336, 77370, 77401 and G6001 with applicable skin cancer diagnosis.
08/02/2024	Added the July 2024 MTAC Review
08/06/2024	MPC approved MTAC's recommendation of insufficient evidence and maintain the policy of non-coverage.

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