Electronic Brachytherapy: Understanding the Technology; Identifying Appropriate Use

The following information is for dermatology practices concerning Appropriate Use Criteria (AUC) for Electronic Brachytherapy.

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Electronic Brachytherapy (eBt) is an established treatment option for the management of nonmelanoma skin cancers. EBT may employ either X-rays from a non-isotopic source or X-rays from an isotopic source. Dermatologists have partnered with appropriate physics and/or radiation oncology services to apply eBt that employs X-rays from a non-isotopic source in a private practice environment. Together, they have devised Appropriate Use Criteria (AUC) for eBt. This is distinguished from eBt, executed by dermatologists using X-rays from an isotopic source.

AUC are part of the “risks, benefits, and alternatives” discussion between the patient and physician. This requires informed consent and is dependent on understanding the availability and ability of technology, patient needs, physician expertise, regulatory approval, and economic coverage. This AUC covers non-isotopic eBt applied to basal cell and squamous cell skin cancers of no more than 4cm in extent and 5mm in depth at the time of the procedure. Regulatory approval and reimbursement are separate issues.

It is worth noting that any dermatology group practice, by permission of the in-office ancillary exception under the Stark Law, may offer this health benefit to patients in their private office setting.

**AUC for eBt**

The FDA gave clearance of the first eBt device in 2009. These X-rays emitted from a non-isotopic source—and distinguished from technology employing X-rays from an isotopic source—have separate CMS recognition and billing codes.

Dermatologists who use non-isotopic eBt understand there are no limits to applying this technology to body surface other than appropriate judgment and best medical practices. They also realize that a subsequent radiation oncologist evaluation is necessary to approve the patient for therapy.

While dermatologists and radiation oncologists have different approaches to medical care, they are aligned concerning eBt. Ebt can be conducted by a dermatologist with input from physics for commissioning the devices and consultation with radiation oncologist per clinical judgement. Therefore, AUC pertaining to the dermatologist proceeds and is separate from the radiation oncologist. And while a dermatologist may feel the patient meets AUC, the radiation oncologist may reject the referral because the case does not meet their AUC.

Dermatologists who have identified basal cell or squamous cell tumors by proven biopsy sampling, must consult with the patient to determine care options. This includes providing risks, benefits, and alternatives for destroying the lesion by all available methods.

The patient must also receive an unbiased presentation. This is often problematic, since physicians do not always
offer all alternatives, nor does each patient’s insurance cover all options. However, best medical practice includes communicating all care choices and physicians can be held accountable for an incomplete presentation.

As with many medical advances, it is often one field expanding into another to bring about change. Once initial investigation has undergone appropriate review and acceptance, this change usually remains with the field of endeavor.

Ajay Bhatnagar, a radiation oncologist investigator, extended his field to identify patients amenable to eBt. This has now been accepted as a standard of care for removing basal cell and squamous cell cancers in the field of dermatology, with over 5,500 patients treated and over 28,000 patient visits.

Neither Dr. Bhatnagar, nor any other radiation oncologist, suggests that these non-melanoma skin cancers are ensconced in their field. These lesions, removed by dermatologists and other specialties, are mainly the purview of dermatologists. Since Bhatnagar’s original work, all eBt cases must now go through dermatology review first.

The following AUC for non-isotope eBt strictly concerns dermatologists and must be formulated by dermatologists who employ this treatment approach. (AUC for Radiation Oncologists is separate and must be determined by those physicians as well.) They know the field best, and in proper formulation of criteria, avoid interference from other physicians and unrelated industry. This is not to eliminate input from related fields and industry as AUC are formulated. Instead, dermatologists should gather input and relevant data from as many sources as appropriate.

The list of AUC is dynamic. Currently, appropriate use includes, but is not limited to the following:

- Where surgical distortion is inevitable
- Concern for considerable disfigurement or scar
- Concern for keloidal formation
- Patients and physicians concerned with coagulation/anticoagulant regimens
- Immunocompromised conditions
- Histories of undesirable or poor outcomes from prior skin cancer removals including but not limited to septicemias, hospitalizations, osteomyelitis, and graft sloughing
- Diabetic and non-diabetic patients with wound care issues
- Patients with risks of surgical problems where their support system could not tolerate anything but a good postoperative course (such as the subsequent need for a wound care center which the patient would be unable to attend)
- Inability of the patient to withstand surgical procedures either through their length, breathe, or disabilities
- Over bony prominences with risk of contractors
- Risks of grafts if they are necessary for closure
- Back of the hands
- Genitalia
- Lower legs
- The need to decrease risks of likely wound care issues for the physician
- Failure of MMS or other interventions
- Superficial/multi centric basal cell carcinomas.

**SUMMARY**

EBr is an evolving technology that is physician-inspired and driven, rather than derived from academic medical centers. Consequently, there has been more interest and adoption from the community.

Elektra, which manufactures Esteya and Xoft (including Axxent), has responded to physician interest in removing tumors without surgical intervention. And while these companies may be leading and creating the field, they do not establish AUC.

AUC is a reasoning process for correct action using best medical practice as the only goal. For any new and evolving technology, that process expands and contracts with the application of data.

AUC must be determined and approved by medical governing boards and societies. Paramount to this approval requires that AUC are presented by honest researchers who work in the specific field, publish in the specific field and use the technology in FDA and industry-approved recommendations. Governing bodies and boards review the material in an unbiased fashion by individuals who endeavor specifically in this field and possess no conflicts of interest.

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Appropriate Use Criteria (AUC) specify when it is appropriate to use a procedure. An “appropriate” procedure is one for which the expected health benefits exceed the expected health risks by a wide margin. Often, sound data is not available or does not provide evidence that is detailed enough to apply to the full range of patients seen in everyday clinical practice. Nevertheless, physicians must make daily decisions about when to use or not use a particular procedure. AUCs facilitate these decisions by combining the best available scientific evidence with the collective judgment of physicians in order to determine the appropriateness of performing a procedure.