MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Superficial Radiation Therapy for Treatment of Skin Cancers**
Policy Number	**6.01.43**
Category	**Technology Assessment**
Original Effective Date	**08/21/14**
Committee Approval Date	**04/16/15, 04/21/16, 04/20/17, 04/19/18**
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Archived Date	**05/16/19**
Archived Review Date	**05/21/20, 08/20/20, 05/20/21, 09/16/21, 09/15/22, 09/21/23**
Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, superficial radiation therapy (SXRT) using a mobile device capable of delivering low energy x-rays, has been medically proven to be effective and, therefore, is considered **medically appropriate** for definitive treatment of basal cell or squamous cell carcinomas when:
   A. The patient is not a surgical candidate; or
   B. The patient declines surgical resection; or
   C. The surgery would be disfiguring; or
   D. The surgery would result in functional compromise.

II. Based upon our criteria and assessment of the peer-reviewed literature, SXRT has been medically proven to be effective, and therefore, is considered **medically appropriate** for the treatment of Kaposi Sarcoma (KS).

III. Based upon our criteria and assessment of the peer-reviewed literature, SXRT has been medically proven to be effective, and therefore, is considered **medically appropriate** for the treatment of Mycosis Fungoides (MF) for:
   A. Definitive treatment of unilesional (i.e. solitary/limited) MF, or
   B. Palliation of individual lesions.

POLICY GUIDELINES

I. Treatment of multiple skin cancers should be performed concurrently, rather than sequentially.

II. Given the rarity and diversity of the condition, patients diagnosed with MF should be treated at specialized centers with expertise in the management of the disease.

DESCRIPTION

SXRT provides an alternative to Mohs micrographic surgery for treatment of basal cell or squamous cell carcinomas. SXRT consists of low energy x-rays that penetrate only superficially, transmitting their energy into the skin, which makes the therapy ideal for treating radiosensitive skin cancers. SXRT differs from traditional external beam radiotherapy (EBRT) in that it has a different energy source, is of smaller size, is based on simpler applied physics and dosimetry; and does not require a linear accelerator. Thus, SXRT is more cost-effective than EBRT. The SRT-100 (Sensus Healthcare, Boca Rattan, FL) and the XStrahl 100, and XStrahl-150 (Gulmay Medical, Buford, GA), are examples of mobile devices developed to deliver low energy x-rays in a physician's office setting. Patients with various skin cancers (e.g., basal cell carcinoma and squamous cell carcinoma), dermatological conditions, or mycosis fungoides who are considered high-risk for surgical procedures due to various disorders, including diabetes and cardiac diseases; and patients with non-melanoma skin cancers on their facial region, can be treated in the dermatology office setting using these devices. The Esteya electronic brachytherapy device received U.S. Food and Drug Administration (FDA) approval in 2013. This mobile device applies radiation directly to the cancerous site using a small high dose rate x-ray source. It concentrates more therapeutic radiation on the disease target and less radiation on surrounding healthy tissue and organs. Electronic brachytherapy features radiation-shielding requirements comparable to low voltage therapeutic x-ray devices, thus, only portable leaded-glass shielding is necessary to provide sufficient protection. Total treatment time per lesion ranges from two to three minutes and multiple lesions can be treated during one session. Some dermatologists offer electronic brachytherapy using the Esteya electronic brachytherapy device as an additional treatment option for treating skin cancers. The Radiant Aura (Xstrahl, Ltd.) is marketed as a combination SXRT and electronic brachytherapy system.

KS is a malignancy derived from endothelial and immune cells infected with human herpes virus type 8. It is most commonly referred to in the treatment of patients with Acquired Immune Deficiency Syndrome (AIDS), however, also appears in transplant cases due to the use of immunosuppressants. It is characterized by numerous vascular tumors of the skin, oral mucosa, lymph nodes or visceral organs, however most patients present with cutaneous disease. The goals of therapy for patients with advanced disease are typically reducing or reversing symptoms, mitigating end organ damage, and slowing disease progression. Multiple methods of treatment are identified depending on the clinical course of the disease, and include highly active antiretroviral therapy (HAART), radiation therapy, cryotherapy, laser therapy, surgical excision, and topic retinoids. Chemotherapy may be added when disease is found in visceral organs and for palliation of symptoms of those with advanced disease or cosmetically unacceptable lesions.

Occurring in approximately 0.4/100,000 persons in the United States, MF is a form of cutaneous T-cell lymphoma, a group of non-Hodgkin lymphomas. It is believed to be caused by the malignant transformation of skin-resident effector memory T cells, and most often presents as flat, red, scaly patches, thicker raised plaque lesions, or more rarely, large nodule tumors of the skin. It typically follows a slow, chronic course but can progress to lymph nodes and internal organs in advanced-stage disease. Treatment is dependent on the stage and the size of the lesion at diagnosis, with the goal being to control the disease with the least amount of toxicity.

RATIONALE

Literature regarding SXRT using mobile devices to deliver low energy radiotherapy as primary, adjuvant or salvage therapy in patients with basal cell carcinoma or squamous cell carcinoma consists of retrospective case series with similar recurrence rates and good cosmesis reported compared to surgical intervention. However large randomized controlled studies are still needed to evaluate the efficacy of this treatment modality.

The American Academy of Dermatology Association Position Statement on Superficial Radiation Therapy for Basal Cell Carcinoma (BCC) or Squamous Cell Carcinoma (SCC) (2014) concluded that, based on current evidence, surgical management remains the most effective treatment for BCC and SCC providing the highest cure rates. SXRT may be considered as a secondary option for the treatment of BCC and SCC in special circumstances, such as, when surgical intervention is contraindicated or refused and after the benefits and risks of treatment alternatives have been discussed with the patient. Additional research is needed on superficial radiation therapy, particularly on long-term outcomes. Dermatologists engaged in providing SXRT must have adequate education and training to administer this therapy safely and effectively.

The National Comprehensive Cancer Network (NCCN) V1.2023 guidelines for KS indicate that for most skin lesions, electrons or superficial x-rays can be used to deliver optimal dosimetry and minimize dose to underlying structures (Category 2A).

Caccialanza,et al (2008) reported on the effectiveness and safety of radiotherapy on KS lesions in a retrospective study of 1482 patients treated with x-ray therapy. The patients were divided by diagnosis of classic KS (n=711) or HIV- related KS. Cure rates were measured for the classic KS group 13.5 years after the end of radiotherapy and complete and partial remission were measured in the HIV-related KS group. Authors reported a cure rate of 98.7% in the classic KS group, and in the HIV-related KS group, a complete remission of 91.4% of lesions, and partial remission of 6.74% at 1 to 46 months from the end of treatment.

The NCCN V2.2023 guidelines for Primary Cutaneous Lymphomas, including mycosis fungoides, indicates that skin-directed therapies, including involved-site radiation therapy, can provide disease control without major cumulative toxicities, and are recommended for patients with early-stage disease and limited skin involvement (stage IA or Stage IB-IIA). NCCN also recommends that given the rarity and complexity of the disease, that it be treated at specialized centers with expertise in the management of cutaneous T-cell lymphoma (Category 2A).

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
77401	Radiation treatment delivery; superficial and/or ortho voltage, per day
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
77427	Radiation treatment management, 5 treatments

HCPCS Codes

Code	Description
No specific code(s)	

ICD10 Codes

Code	Description
C44.0-C44.9	Other and unspecified malignant neoplasm of skin (code range)
C46.0-C46.9	Kaposi's sarcoma (code range)
C84.00-C84.09	Mycosis fungoides (code range)

REFERENCES

American Academy of Dermatology Association. Position Statement on Superficial Radiation Therapy for Basal Cell Carcinoma (BCC) and Squamous Cell Carcinomas (SCC). 2014. Revised 2016 Nov 5.

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*Key Article

KEY WORDS

Superficial x-ray, orthovoltage x-ray, SRT-100, Xstrahl-100, Esteya.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based upon our review, superficial radiation therapy is not addressed in National or Regional Medicare coverage determinations or policies.