MEDICAL POLICY

SUBJECT: SUPERFICIAL RADIATION THERAPY FOR TREATMENT OF SKIN CANCERS

POLICY NUMBER: 6.01.43
CATEGORY: Technology Assessment

EFFECTIVE DATE: 08/21/14
REVISED DATE: 04/16/15

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- If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.
- Medical policies apply to commercial and Safety Net products only when a contract benefit for the specific service exists.
- Medical policies only apply to Medicare products when a contract benefit exists and where there is no national or local Medicare coverage decision for the specific service.

POLICY STATEMENT:

Based upon our criteria and assessment of peer-reviewed literature, Superficial Radiation Therapy (SXRT) using a mobile device capable of delivering low energy x-rays has not been medically proven to be effective and is considered not medically necessary for the treatment of basal cell or squamous cell carcinomas.

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Superficial radiotherapy or orthovoltage radiotherapy (SXRT) provides an alternative to Mohs micrographic surgery for treatment of basal cell or squamous cell carcinomas. SXRT consists of low energy x-rays which do not penetrate very deeply or only superficially and transmits their energy into the skin, making the therapy ideal for treating radiosensitive skin cancers. SXRT differs from external beam radiotherapy (EBRT) by having a different energy source, smaller size, simpler applied physics and dosimetry, and a linear accelerator is not required. Thus, SXRT is more cost-effective than traditional EBRT. The SRT-100™ (Sensus Healthcare, Boca Rattan, FL) and the XStrahl 100 and 150 (Gulmay Medical, Buford, GA) are two mobile devices developed to deliver low energy x-rays in a physician office setting. Treatment of various skin cancers (e.g., basal cell carcinoma and squamous cell carcinoma), dermatological conditions and mycosis fungoides in patients who are considered high risk for surgical procedures due to various disorders, diabetic and cardiac diseases, or for patients with non-melanoma skin cancers on their facial region can be performed in the dermatology office setting using these devices. The Esteya® electronic brachytherapy device received FDA approval in 2013. This mobile device applies radiation directly to the cancerous site using a small high dose rate x-ray source and concentrates more therapeutic radiation on the disease target and less radiation to 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 2-3 minutes and multiple lesions can be treated during 1 session. Electronic brachytherapy using the Esteya electronic brachytherapy device is advertised as an additional treatment option by a dermatologist for treating skin cancers.

RATIONALE:

Literature regarding superficial radiation therapy 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.
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.

CPT:
- 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 (once weekly, irrespective of the number of treatment sites)

REFERENCES:


KEY WORDS:
Superficial x-ray, orthovoltage x-ray, SR-100, Xstrahl-100, Esteya.

**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

Based upon review, superficial or orthovoltage radiosurgery is not addressed in a Regional or a National coverage determination or policy.