MEDICAL POLICY

MEDICAL POLICY DETAILS

<table>
<thead>
<tr>
<th>Medical Policy Title</th>
<th>Superficial Radiation Therapy for Treatment of Skin Cancers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy Number</td>
<td>6.01.43</td>
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<tr>
<td>Category</td>
<td>Technology Assessment</td>
</tr>
<tr>
<td>Effective Date</td>
<td>08/21/14</td>
</tr>
<tr>
<td>Revised Date</td>
<td>04/16/15, 04/21/16, 04/20/17, 04/19/18</td>
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<tr>
<td>Archived Date</td>
<td>05/16/19</td>
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<tr>
<td>Edited Date</td>
<td>05/21/20</td>
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</tbody>
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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 product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.
- If a Medicare 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.

POLICY STATEMENT

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 not been medically proven to be effective and, therefore, 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

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 do not penetrate very deeply or penetrate 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; 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’s office setting. Patients with various skin cancers (e.g., basal cell carcinoma and squamous cell carcinoma), dermatological conditions, or mycosis fungoides in patients 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 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.

Proprietary Information of Excellus BlueCross BlueShield
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 safely and effectively administer this therapy.

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.

CPT Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>77401</td>
<td>Radiation treatment delivery; superficial and/or ortho voltage, per day</td>
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<tr>
<td>77336</td>
<td>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</td>
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<tr>
<td>77427</td>
<td>Radiation treatment management, 5 treatments</td>
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REFERENCES


Medical Policy: Superficial Radiation Therapy for Treatment of Skin Cancers
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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 review, superficial or orthovoltage radiosurgery is not addressed in a Regional or a National coverage determination or policy.