

## Clinical Policy: Radiation Therapy for Skin Cancer

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### Description

Although surgical excision remains the primary treatment for skin cancer, radiation therapy serves an integral role in both definitive and adjuvant contexts.<sup>1</sup> Radiation therapy is a fundamental treatment modality for skin cancers, offering curative potential in members/enrollees who are not candidates for surgery and reducing the risk of recurrence and metastasis when used as adjuvant therapy.<sup>2</sup>

*Note: For information regarding medical necessity for intensity-modulated radiotherapy (IMRT), please refer to CP.MP.69 Intensity-Modulated Radiotherapy.*

### Policy/Criteria

- I. It is the policy of health plans affiliated with Centene Corporation® that treatment for skin cancer with radiation therapy (e.g., electron beam radiation, proton beam radiation, high-dose rate brachytherapy, three-dimensional conformal radiation therapy) is **medically necessary** for the treatment of *non-melanoma skin cancer*, when one of the following is met:
  - A. Basal cell carcinoma (BCC), one of the following:
    1. Definitive radiation therapy, all of the following:
      - a. Member/enrollee is not a surgical candidate, declines surgical resection, or surgery would compromise function or cosmesis due to anatomical location of tumor;
      - b. One of the following:
        - i. Low-risk or high-risk BCC;
        - ii. Advanced BCC (i.e., locally advanced, nodal, or metastatic BCC);
    2. Adjuvant radiation therapy, one of the following:
      - a. Positive margins and further resection is not feasible;
      - b. High-risk BCC with extensive perineural spread or large-nerve involvement and resection is not feasible after negative margins;
      - c. Nodal disease;
  - B. Cutaneous squamous cell carcinoma (cSCC), one of the following:
    1. Definitive radiation therapy, all of the following:
      - a. Member/enrollee is not a surgical candidate, declines surgical resection, or surgery would compromise function or cosmesis due to anatomical location of tumor;
      - b. One of the following:
        - i. Low-risk, high-risk, or very high-risk cSCC;
        - ii. Advanced cSCC (i.e., locally advanced cSCC, nodal disease, or in-transit metastasis);
    2. Adjuvant radiation therapy, one of the following:
      - a. Close or positive margins and re-excision is not feasible;

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- b. High-risk cSCC, very high-risk cSCC, or locally advanced cSCC and negative margins with extensive perineural spread or large-nerve involvement or if other poor prognostic features are present;
- c. Recurrence after a prior margin-negative resection;
- d. Stage T3 or T4 tumors;
- e. Desmoplastic or infiltrative tumors in the setting of chronic immunosuppression;
- f. cSCC has metastasized to clinically apparent regional lymph nodes and one of the following:
  - i. One positive node  $\leq$  3 cm with no extranodal extension (ENE);
  - ii.  $\geq$  two positive nodes or one node  $>$  3 cm with no ENE;
  - iii. Any node with ENE;
  - iv. Incompletely excised nodal disease;

#### Note:

- For BCC and cSCC definitive radiation is not recommended in members/enrollees with genetic conditions predisposing them to heightened radiosensitivity, such as ataxia telangiectasia, nevoid basal cell carcinoma syndrome (Gorlin syndrome), or LiFraumeni syndrome.
- For BCC and cSCC radiation therapy is not routinely repeated for recurrent disease in a previously radiated field.

#### C. Merkel cell carcinoma (MCC), one of the following:

1. Definitive radiation therapy, all of the following:
  - a. Member/enrollee is not a surgical candidate, declines surgical resection, or surgery would compromise function or cosmesis due to anatomical location of tumor;
  - b. One of the following:
    - i. Nodal disease;
    - ii. Draining nodal basin with positive lymph node biopsy and no distant metastasis;
    - iii. Distant metastasis detected on clinical and/or radiologic examination;
    - iv. In-transit disease;
    - v. Recurrence of MCC (local, locally advanced, or regional);
2. Adjuvant radiation therapy, one of the following:
  - a. Local MCC with no lymph node involvement and tumor is surgically resectable, one of the following:
    - i. Clear margins with  $\geq$  one adverse risk factor;
    - ii. Microscopically positive margins;
    - iii. Narrow clinical margin ( $<$  1 cm) excision or adverse risk factors;
    - iv. Sentinel lymph node (SLN) positive and one of the following:
      - a) Radiation therapy to the nodal basin;
      - b) Node dissection with adjuvant radiation therapy for multiple involved nodes and/or the presence of ENE;
      - c) SLN negative in high-risk clinical scenarios;
  - b. In-transit disease.

**II.** It is the policy of health plans affiliated with Centene Corporation that treatment for skin cancer with radiation therapy (e.g., electron beam, superficial photon radiation, three-

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dimensional conformal radiation therapy) is **medically necessary** for the treatment of *malignant cutaneous melanoma*, when any of the following criteria are met:

- A. Definitive radiation therapy for melanoma in situ (MIS), lentigo maligna in medically inoperable members/enrollees or those in whom surgical morbidity of complete resection would be prohibitive;
- B. Definitive or palliative intent radiation for one of the following:
  1. Unresectable nodal, satellite, or in-transit disease;
  2. Residual local, satellite, or in-transit disease after prior treatment;
- C. Adjuvant radiation, one of the following:
  1. High-risk resected regional disease with any of the following risk factors for regional recurrence:
    - a. Extranodal extension in clinically involved nodes;
    - b.  $\geq$  one parotid lymph node of any size;
    - c.  $\geq$  two cervical or axillary nodes of any size;
    - d.  $\geq$  three inguinofemoral nodes of any size;
    - e.  $\geq$  3 cm cervical or axillary node;
    - f.  $\geq$  4 cm inguinofemoral node;
  2. Distant metastatic disease that is widely disseminated with or without brain metastases;
  3. Desmoplastic melanoma when there is a high risk of local recurrence.

**III.** It is the policy of health plans affiliated with Centene Corporation that the following procedures are considered **not medically necessary** in the treatment of any skin cancer, as there is insufficient data on long-term safety and efficacy:

- A. Electronic surface brachytherapy;
- B. Image guided superficial radiation therapy (IGSRT).

### Background

Skin cancer is the most prevalent cancer type in the United States with an incidence rate of over five million cases annually. Basal cell carcinoma (BCC) and cutaneous squamous cell carcinoma (cSCC) account for the majority of all skin cancer diagnoses and are the most treatable if caught early.<sup>3</sup> Merkel cell carcinoma (MCC) is a less common skin cancer that can be aggressive and spread rapidly, making it more difficult to treat.<sup>4</sup> Melanoma is a less common type of skin cancer, but it has a higher mortality rate and is considered particularly dangerous because it is much more likely to spread to other parts of the body if not detected and treated early.<sup>5</sup> The primary treatment modality for skin cancer is surgical excision, but radiation therapy plays a key role for treatment in the definitive and adjuvant settings. Definitive radiation therapy, also called curative or primary radiation therapy, is used as the main treatment to eliminate cancer with curative intent. Adjuvant radiation therapy is a type of radiotherapy given after surgery to eliminate any remaining cancer cells that may not be visible but could still be present.<sup>6</sup>

#### *Basal Cell Carcinoma (BCC)*

Surgery remains the standard and most effective treatment for BCC, however, primary radiation therapy can serve as an alternative in situations where surgery is not feasible, contraindicated, or refused by the patient following an informed discussion of risks and benefits. Primary or adjuvant radiation therapy represents an effective treatment option for selected patients with

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BCC, providing satisfactory tumor control and cosmetic outcomes, though cure rates might be lower. Adverse events following radiation therapy include acute radiation-induced skin toxicity, possible alterations to underlying tissues, and greater challenges in managing recurrences within the irradiated area. Late adverse effects may include alopecia, cartilage necrosis, pigmentary alterations of the skin, as well as an increased risk of secondary malignancies. The National Comprehensive Cancer Network (NCCN) offers guidance on both primary and adjuvant radiation therapy for BCC and cSCC, including dosing recommendations. It also advises consulting the American Society for Radiation Oncology (ASTRO) guideline on definitive and postoperative radiation therapy for basal and squamous cell cancers of the skin for general indications and dose recommendations.<sup>1,7</sup>

#### *Cutaneous Squamous Cell Carcinoma (cSCC)*

Although cSCC rarely metastasizes, it is the second most common skin cancer and can cause extensive local tissue damage, disfigurement, and invasion into soft tissue, cartilage, and bone. Treatment options are continually advancing to prevent disease recurrence and improve quality of life. While surgery remains the primary local treatment for cSCC, factors such as patient preference may lead to the selection of radiation therapy as the main treatment approach. The NCCN notes that when determining the appropriateness of radiation therapy, the decision should be made together with a radiation oncologist. Radiation as a primary therapy may be considered for patients who are not surgical candidates due to comorbidities, the extent of the disease, or risk of compromising function or cosmesis due to anatomical location of the tumor.<sup>8</sup>

#### *Merkel cell carcinoma (MCC)*

MCC is a rare form of non-melanoma skin cancer that tends to grow quickly, metastasize early, and has a mortality rate higher than that of melanoma. Surgical excision is the principal therapeutic approach for most MCC and is essential for precise pathological assessment and staging of the primary tumor and regional involvement. Because of its propensity for rapid expansion, surgery has been the predominant approach for treating primary MCC tumors and has demonstrated improved outcomes relative to nonsurgical primary treatment. According to the NCCN, data on the effectiveness of definitive radiation therapy is limited; however, for patients with localized or regional MCC who are not surgical candidates or decline surgery, definitive radiation is likely to offer favorable outcomes.<sup>3</sup> Additionally, if surgery is not feasible, definitive radiation therapy can be considered for nodal MCC in cases where there is a positive lymph node biopsy in the draining nodal basin without distant metastasis, when distant metastases are detected on clinical or radiologic evaluation, or when in-transit metastases are present.<sup>9</sup> In-transit metastasis refers to the spread of skin cancer cells through lymphatic vessels, forming secondary tumors more than two centimeters from the primary site but before reaching the regional lymph nodes.<sup>10</sup> The NCCN offers recommendations on the use of adjuvant radiation therapy for MCC, aiming to lower the risk of local or regional recurrence after surgical removal.<sup>9</sup>

#### *Cutaneous Melanoma*

The American Academy of Dermatology reports that over one million Americans are currently living with melanoma, and an estimated 212,200 new cases are expected to be diagnosed in the U.S. in 2025.<sup>11</sup> While surgical excision is the standard of care for in situ melanoma, it may not be feasible in cases involving comorbidities or tumors located in cosmetically sensitive areas. In certain cases, radiotherapy has also been utilized for the treatment of lentigo maligna.<sup>12</sup>

Adjuvant radiation therapy is rarely indicated after complete excision of a primary melanoma. However, an exception may be desmoplastic neurotropic melanoma (DNM), due to its tendency to be locally aggressive. Adjuvant radiation therapy may also be appropriate for select patients with clinically positive lymph nodes and risk factors associated with a high likelihood of nodal basin recurrence. The NCCN panel extensively reviewed the role of adjuvant radiation therapy in patients at high risk of recurrence and reached a consensus that strong evidence supports its effectiveness in delaying or preventing nodal relapse. However, certain institutions contended that the higher risk of late toxicities associated with radiation therapy may outweigh the advantages of reducing nodal basin recurrence. Careful selection of patients, based on factors such as location, size, nodal involvement, and gross extramural extension instead of histologic assessment, is essential. Overall, when considering adjuvant radiation therapy, the potential benefits must be carefully weighed against the increased risk of chronic skin and regional side effects that can impair quality of life.<sup>12</sup>

**Coding Implications**

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2024, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

<b>CPT® Codes</b>	<b>Description</b>
77261	Therapeutic radiology treatment planning; simple
77262	Therapeutic radiology treatment planning; intermediate
77263	Therapeutic radiology treatment planning; complex
77280	Therapeutic radiology simulation-aided field setting; simple
77285	Therapeutic radiology simulation-aided field setting; intermediate
77290	Therapeutic radiology simulation-aided field setting; complex
77295	3-dimensional radiotherapy plan, including dose-volume histograms
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
77301	Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications
77316	Brachytherapy isodose plan; simple (calculation[s] made from 1 to 4 sources, or remote afterloading brachytherapy, 1 channel), includes basic dosimetry calculation(s)

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<b>CPT® Codes</b>	<b>Description</b>
77317	Brachytherapy isodose plan; intermediate (calculation[s] made from 5 to 10 sources, or remote afterloading brachytherapy, 2-12 channels), includes basic dosimetry calculation(s)
77318	Brachytherapy isodose plan; complex (calculation[s] made from over 10 sources, or remote afterloading brachytherapy, over 12 channels), includes basic dosimetry calculation(s)
77332	Treatment devices, design and construction; simple (simple block, simple bolus)
77333	Treatment devices, design and construction; intermediate (multiple blocks, stents, bite blocks, special bolus)
77334	Treatment devices, design and construction; complex (irregular blocks, special shields, compensators, wedges, molds or casts)
77385	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple
77386	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex
77401	Radiation treatment delivery, superficial and/or ortho voltage, per day
77402	Radiation treatment delivery, => 1 MeV; simple
77407	Radiation treatment delivery, => 1 MeV; intermediate
77412	Radiation treatment delivery, => 1 MeV; complex
77427	Radiation treatment management, 5 treatments
77470	Special treatment procedure (eg, total body irradiation, hemibody radiation, per oral or endocavitary irradiation)
77771	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 2-12 channels
77772	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; over 12 channels

<b>HCPCS Codes</b>	<b>Description</b>
G6001	Ultrasonic guidance for placement of radiation therapy fields
G6003-14	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: up to 5 mev [to 20 mev or greater]
G6015	Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session
G6016	Compensator-based beam modulation treatment delivery of inverse planned treatment using three or more high resolution (milled or cast) compensator, convergent beam modulated fields, per treatment session

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed. Reviewed by external specialist.	08/25	08/25

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### **Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering

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benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note: For Medicaid members/enrollees**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**Note: For Medicare members/enrollees**, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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