

A CMS Medicare Administrative Contractor
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Key Questions

1. According to NCCN guidelines, surgical excision with margins and/or Mohs is considered first line therapy for patients with high risk BCCA and high risk and very high risk SCCA.
 - a. Is there sufficient evidence to support that superficial radiation therapy is equivalent for non-surgical candidates?
 - b. Is there any advantage to add HRUS (high resolution ultrasound) to SRT, versus standard SRT alone or using the newer SRT machines/protocols without HRUS; If so, why?
 - c. How do you define a nonsurgical candidate?
2. Does the literature support that low risk BCCA or low risk SCCA should be treated with non-surgical or alternative means or standard excision or Mohs? If so, what literature supports this approach?
3. Is there sufficient evidence to treat any patient with a nonmelanoma skin cancer (NMSC) including ones that are very small and easily treated in a single session by other means?
 - a. If yes, is this supported by current NCCN guidelines, AAD guidelines, Mohs guidelines and ASTRO guidelines?
 - b. Is there an advantage to have a tissue diagnosis for complete margins being excised versus just visual follow-up for detecting recurrence?
4. Should the use of IGSRT follow other ASTRO guidelines for the safe delivery of image guided radiation therapy?
 - a. If ultrasound is being used prior to and not in conjunction with SRT, then is it really imaged guided radiation therapy?
5. In the absence of randomized clinical trials or comparative studies are you confident that the addition of ultrasound guidance added to SRT improved clinical outcomes? If yes, what literature supports your position?
6. Is there potential risk for:
 - a. recurrence?
 - b. increase risk if needs surgical incision in future due to changes from irradiation?
 - c. Risk of new malignancies associated with irradiation in the future?
 - d. Challenges in detecting recurrence after irradiation?

If yes, how many years of follow-up do research studies need to be certain this is not causing inadvertent harm and should there be lower age limit to this technology given the lack of long-term data?

7. For patients who are non-surgical candidates who are considered for alternative RT, the appropriateness of RT should be performed by a radiation oncologist according to NCCN and ASTRO guidelines. Do you feel that this is required for superficial radiation therapy, as well? Why or why not?
 - a. Should a dermatologist or other qualified health care professional perform the radiation dosing, site planning, image guidance and other services associated with radiation therapy that are typically delegated to a radiation oncologist.
 - b. Who interprets the images used for HRUS? Is it the radiation oncologist, dermatologist, radiation therapist, ultrasound technician etc.?
 - c. What training requirements should be met and through what mechanism prior to delivering this treatment?
 - d. Can the fractionated treatments be delivered by other than a radiation technologist such as trained medical assistant or other ancillary personnel delegated by the supervising physician consistent with CMS guidelines for "incident-to" care?
8. Are there standardized published protocols to define ultrasound findings and measurements for superficial skin lesions?
 - a. If there are standards, do they take into account patients with irregular skin, irregular tumors, crusting, bleeding, ulceration, etc. as this can impact the depth of the lesion?
 - b. Several of the studies specify limitation of the high-resolution ultrasound (HRUS) to 6mm in depth? Do you agree with those findings? Why or why not?
9. Should there be limitations on the number of treatments or treatment sessions, use of image guidance, radiation planning procedures, and who can perform these procedures as far as education and training?
10. It has been purported that the cosmesis is superior with either SRT or EBT. How does the literature support that assertion to be the case? Is this based upon subjective or objective evidence? Is there any comparison to traditional excisions or Mohs procedures in cosmesis supported by the literature? What about the telangiectasias and skin changes that occur to the irradiated skin short term and long term?
11. What if complications develop during or between treatment sessions. Will a break in treatment alter treatment planning and potentially affect the outcome of the treatment?
12. Is there literature comparing cosmetic results of traditional excisions or Mohs procedures to SRT or EBT and does it support one being superior to the other?
13. What ancillary services/procedures/planning are required with the following:
 - a. Traditional surgical excision
 - b. Mohs excision
 - c. EBT
 - d. SRT