MSAC Application

1657.1 - Rhenium-188 radioisotope therapy for non-melanoma skin cancer

PICO Set

Population

Describe the population in which the proposed health technology is intended to be used:
The target population for RSCT to be listed on the MBS are patients with histologically confirmed BCC or SCC in areas for which they are contraindicated for surgical excision, including where there are clinician concerns for the patient outcomes from surgery.

The maximum depth of the confirmed lesion should be no deeper than 3mm, with a surface area no greater than 8.0 cm^2. Multiple lesions can be treated at once if the contiguous surface area of any single lesion does not exceed 8.0 cm^2.

Specify any characteristics of patients with, or suspected of having, the medical condition, who are proposed to be eligible for the proposed health technology, describing how a patient would be investigated, managed and referred within the Australian healthcare system in the lead up to being considered eligible for the technology:
Patients with a KC that is identified and biopsied by a GP that fits the above histological criteria, but which may not be suitable for management in the GP clinic due to anatomical complexities, comorbidities, or recurrences would be referred to a specialist such as a dermatologist or plastic surgeon for management. In these situations, lesions still unsuitable for conventional management that do not require systemic or adjuvant therapy, would be referred to a radiation oncologist or nuclear medicine physician for treatment with RSCT. Radiation oncologists may also appraise suitability for treatment with a conventional radiation modality. To ensure patients access in some regional or remote areas, skin-specialist GPs may directly refer for RSCT given their integral role in the clinical pathway, particularly in the reduced presence of dermatologists and plastic surgeons.

Provide a rationale for the specifics of the eligible population:
The target lesions have been determined based on a large prospective study that included Australian patients, in addition to the known dose profile of RSCT that requires lesions to be of a certain depth (3mm or less) for treatment in a single session. Additionally, patients would be considered conventional excision/surgery or ablative techniques first and those that are unsuitable who would otherwise be appropriate for conventional radiation therapy.

Are there any prerequisite tests?
Yes

Are the prerequisite tests MBS funded?
Yes

Provide details to fund the prerequisite tests:
Provide a response if you answered 'No' to the question above

Intervention

Name of the proposed health technology:
Rhenium-SCT® (Skin Cancer Therapy)

Describe the key components and clinical steps involved in delivering the proposed health technology:
After selecting a patient based on lesion size and treatment depth determined by biopsy, the treating clinician, typically a radiation oncologist or nuclear medicine clinician, orders a carpoule of Rhenium-188 paste for the delivery of Rhenium-SCT. The paste is timed for delivery on the treatment day, considering the radioisotope's decay kinetics.

On the day of treatment, the clinician marks the treatment area, including a margin, and calculates the total surface area, inputting this information into a dosimetry algorithm. The Rhenium-188 paste is then prepared in the OncoBeta base station by a nuclear medicine technologist, who measures its initial radioactivity and enters this data into the dosimetry calculations.

The clinician applies an adhesive film over the treatment area before administering the Rhenium-188 paste onto the film, ensuring no direct contact with the patient’s skin. The nuclear medicine technologist remeasures the radioactive activity of the applied paste, which, combined with the surface area measurement and prescribed treatment depth, determines the total treatment duration—typically between 90 to 180 minutes.

At the end of the planned treatment time, the technologist removes the adhesive film and paste, completing the procedure. Follow-up care is similar to standard external beam radiotherapy, with the clinician providing guidance on skincare, such as using moisturisers to manage any skin desquamation.

Identify how the proposed technology achieves the intended patient outcomes:
Rhenium-SCT provides non-inferior efficacy and safety outcomes compared to conventional radiation therapy for the indicated skin cancers. It also improves quality of life, has a short overall episode of care, and is preferred by patients who have a history of skin cancer.

Does the proposed health technology include a registered trademark component with characteristics that distinguishes it from other similar health components?
Yes

Explain whether it is essential to have this trademark component or whether there would be other components that would be suitable:
It is essential to have the trademarked component because this is the only device capable (and ARTG-registered) of treating skin cancer with the rhenium-188 radioisotope.

Are there any proposed limitations on the provision of the proposed health technology delivered to the patient (For example: accessibility, dosage, quantity, duration or frequency):
Yes

Provide details and explain:
Provide a response if you answered 'No' to the question above

If applicable, advise which health professionals will be needed to provide the proposed health technology:
Radiation oncologists and Nuclear Medicine Physicians.

If applicable, advise whether delivery of the proposed health technology can be delegated to another health professional:
If applicable, provide a description of any related health professionals here

If applicable, advise if there are any limitations on which health professionals might provide a referral for the proposed health technology:
As above. Referral must be made by a specialist dermatologist or plastic surgeon if practical, otherwise a skin-GP in regional or rural settings to ensure timely patient access.

Is there specific training or qualifications required to provide or deliver the proposed service, and/or any accreditation requirements to support delivery of the health technology?
Yes.

Provide details and explain:
In addition to relevant clinical training and radiation safety training, OncoBeta provides accreditation of clinicians and technicians to support appropriate Rhenium-SCT administration and clinical operation.

Indicate the proposed setting(s) in which the proposed health technology will be delivered:
☐ Consulting rooms
☒ Day surgery centre
☐ Emergency Department
☒ Inpatient private hospital
☒ Inpatient public hospital
☐ Laboratory
☒ Outpatient clinic
☐ Patient's home
☐ Point of care testing
☐ Residential aged care facility
☐ Other (please specify)

Available anywhere that has facilities capable of being licensed to acquire, use and store open-source radioisotope treatment of patients.

Is the proposed health technology intended to be entirely rendered inside Australia?
Yes

Provide additional details on the proposed health technology to be rendered outside of Australia:
Provide a response if you answered 'No' to the question above

Comparator

Nominate the appropriate comparator(s) for the proposed medical service (i.e., how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian healthcare system). This includes identifying healthcare resources that are needed to be delivered at the same time as the comparator service:
External beam radiation therapy

List any existing MBS item numbers that are relevant for the nominated comparators:

EBRT Type	2024 MBS Item Numbers	Description	Proportion of patients treated
Electrons	15904, 15930	CT scan - Clinical Markup	**redacted**%
Electrons	15906, 15930	CT scan - CTV/PTV & OARs Marked w/ DVH produced	**redacted** %
3D Conformal Photons	15904, 15932	CT scan - Clinical Markup	**redacted** %
3D Conformal Photons	15906, 15934	CT scan - CTV/PTV & OARs Marked w/ DVH produced	**redacted** %
IMRT / VMAT	15910, 15938	CT scan - CTV/PTV & Multiple OARs Marked w/ DVH produced	**redacted** %
SXRT	15950, 15952, 15954	Single Fraction	**redacted** %
SXRT	15950, 15952, 15956	Single Fraction w/ Internal Eye Shield	**redacted** %
SXRT	15950, 15952, 15954	Multiple Fractions	**redacted** %
SXRT	15950, 15952, 15956	Multiple Fractions w/ Internal Eye Shield	**redacted** %
DXRT / Orthovoltage	15950, 15952, 15954	Single Fraction	**redacted** %
DXRT / Orthovoltage	15950, 15952, 15954	2 Fractions / week	**redacted** %
DXRT / Orthovoltage	15950, 15952, 15954	3 Fractions / week	**redacted** %

Provide a rationale for why this is a comparator:
Expert clinical opinion, and radiotherapy clinic data, which was sought on the methods currently used on the proposed target lesion/population.

Pattern of substitution – Will the proposed health technology wholly replace the proposed comparator, partially replace the proposed comparator, displace the proposed comparator or be used in combination with the proposed comparator?
☐ None (used with the comparator)
☐ Displaced (comparator will likely be used following the proposed technology in some patients)
☒ Partial (in some cases, the proposed technology will replace the use of the comparator, but not all)
☐ Full (subjects who receive the proposed intervention will not receive the comparator)

Outline and explain the extent to which the current comparator is expected to be substituted:
According to the surveyed doctors the proportion of patients expected to switch from EBRT to RSCT are:

- Electrons = **redacted** %
- IMRT/VMAT = **redacted** %
- SXRT = **redacted** %

However, the sponsor expects that substitution will be achieved by the 6th year of listing, so therefore the replacement of EBRT will increase gradually over time.

Outcomes

List the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be measured in assessing the clinical claim for the proposed medical service/technology (versus the comparator):

☒ Health benefits
☒ Health harms
☒ Resources
☐ Value of knowing

Outcome description – include information about whether a change in patient management, or prognosis, occurs as a result of the test information:
The clinical claim is that RSCT offers non-inferior safety and effectiveness compared to EBRT, at a lower cost to the Commonwealth.

Proposed MBS items

How is the technology/service funded at present? (e.g., research funding; State-based funding; self-funded by patients; no funding or payments):
Self-funded by patients

Provide at least one proposed item with their descriptor and associated costs, for each Population/Intervention:

MBS item number (where used as a template for the proposed item)	MBS item XXXX1
Category number	Category 3
Category description	Therapeutic procedures
Proposed item descriptor	RSCT radioisotope therapy planning Rhenium-SCT® dosimetry for treatment planning if all the following apply: (i) localisation is based on clinical mark-up, and image-based simulation is not required; (ii) delineation of structures is not possible or necessary, with tumour borders defined using a clinician-specified margin to establish the treatment volume; (iii) surface area measurements are obtained and utilised for planning purposes to determine lesion-specific treatment times; (iv) the planning process is required to deliver a prescribed dose to a specified depth;

	(v) doses are calculated in reference to a depth, using tables, charts, or data from a treatment planning system. Applicable once per course of treatment.
Proposed MBS fee	Fee: $203.70 Benefit: 75% = $152.80 85% = $173.15
Indicate the overall cost per patient of providing the proposed health technology	Insert overall cost per patient amount here
Please specify any anticipated out of pocket expenses	Specify anticipated out of pocket costs here
Provide any further details and explain	Provide further details here

MBS item number (where used as a template for the proposed item)	MBS item XXXX2
Category number	Category 3
Category description	Therapeutic procedures
Proposed item descriptor	RSCT radioisotope therapy Epidermal radioisotope therapy, using rhenium-188 paste per 0.5 cm2 on one or more cutaneous basal cell carcinoma (BCC) or cutaneous squamous cell carcinoma (SCC) if: a) malignancy has been confirmed and other diagnoses excluded by histological examination; and b) the maximum depth of the lesion/s is less than or equal to 3 mm; and c) the lesion contraindicated for surgical excision, or where there are clinician concerns for the patient outcomes from surgery; and d) the service is provided by a suitably trained radiation oncologist or nuclear medicine physician in an approved facility; and e) the service is referred by a dermatologist, plastic surgeon, or a skin-specialist GP if a dermatologist or plastic surgeon is not readily available. Applicable for total surface area of lesion/s treated.
Proposed MBS fee	Fee: $393.90 Benefit 75% = $295.43 85% = $334.82
Indicate the overall cost per patient of providing the proposed health technology	Insert overall cost per patient amount here
Please specify any anticipated out of pocket expenses	Specify anticipated out of pocket costs here
Provide any further details and explain	Provide further details here

MBS item number (where used as a template for the proposed item)	MBS item XXXX3
Category number	Category 3
Category description	Therapeutic procedures
Proposed item descriptor	RSCT radioisotope therapy service Service in provision of epidermal radioisotope therapy, using rhenium-188, of a cutaneous basal cell carcinoma (BCC) or cutaneous squamous cell carcinoma (SCC) Must be applied with Item XXXX2. Applicable once per course of treatment.
Proposed MBS fee	Fee: $1733.77 Benefit 75% = $1300.33 85% =$1473.70
Indicate the overall cost per patient of providing the proposed health technology	$**redacted**
Please specify any anticipated out of pocket expenses	$**redacted**
Provide any further details and explain	Based upon current rates charged to full-fee paying patients at private clinics. This would likely be spread proportionally across the proposed MBS codes

Algorithms

PREPARATION FOR USING THE HEALTH TECHNOLOGY

Define and summarise the clinical management algorithm, including any required tests or healthcare resources, before patients would be eligible for the proposed health technology:
In current practice, patients with suspected KC typically present initially to a GP or a skin-specialist GP, who in simple cases, surgically excises the lesion with or without concurrent histology, or ablates the lesion using cryotherapy or ED&C. The clinician may instead prescribe one of several available topical antineoplastic therapies. More challenging cases, such as: lesions deemed to be of higher risk following histological assessment, those in a complex anatomic location, or patients with relevant comorbidities, would usually be referred to a dermatologist or plastic surgeon, who in many cases would collaborate with a representative of the other speciality within a multidisciplinary care model. Radiation Oncologists are consulted or referred to by dermatologists and plastic surgeons if the patient is unsuitable or unwilling to undergo a surgical intervention, or if the lesion requires adjuvant radiation theory. In contrast, many skin-specialist GPs are highly experienced in surgical procedures and refer directly to radiation oncology if the patient if required.

Contraindications to surgery might include hypersensitivity to anaesthesia, major cardiac or pulmonary disease, bleeding disorders, pregnancy, concurrent cancer/chemotherapy, general frailty, or where there are unacceptable functional and/or cosmetic risks for surgery. Radiation therapy would usually be considered in such circumstances, with a wide range of EBRT and brachytherapy approaches available, as discussed previously. Some patients with clinically significant lesions who are contraindicated to both surgery and radiation therapy, or for whom a large disease burden or frequency would navigate away from such approaches, might be managed conservatively with cryotherapy, ED&C, topical creams/gels or PDT. Recurrent and/or secondary lesions would default back to an earlier decision point in the algorithm, whereby risk and/or treatment burden strongly influence subsequent decisions.

Is there any expectation that the clinical management algorithm before the health technology is used will change due to the introduction of the proposed health technology?

Yes

Describe and explain any differences in the clinical management algorithm prior to the use of the proposed health technology vs. the comparator health technology:
The only change to clinical practice in the proposed management algorithm is the addition of RSCT as an alternative to other radiation therapy modalities for definitive treatment of histologically confirmed BCC or SCC, with a depth ≤3 mm and area 1-8.0 cm2 in any area deemed unsuitable for surgery. At an individual patient level, RSCT would directly substitute other modalities of radiation therapy, with the two approaches almost never used consecutively for the same lesion. At a population level, it is envisaged that RSCT would sit permanently alongside other radiation therapy techniques in the management algorithm as an essential treatment alternative appropriate for a subset of patients. Some examples include: lesions in complex anatomic locations that would benefit from treatment with a conformal resin, concerns around dosing to sensitive organs, patients unable attend multiple sessions of conventional radiation

therapy course due to comorbidities or isolation, and patients unable to be treated using Linacs where patient set up can be challenging.

USE OF THE HEALTH TECHNOLOGY

Explain what other healthcare resources are used in conjunction with delivering the proposed health technology:

Rhenium-SCT administration requires the base station unit, mobile dosimeter, and a specific applicator, all provided by OncoBeta. The clinician defines the treatment area, takes measurements, and performs basic dosimetry calculations. A nuclear medicine technologist prepares the Re188 paste, calibrates and measures radioactivity, readies the applicator, and acts as the radiation safety officer. The clinician then applies the paste, while the technologist monitors the patient throughout the 1-3 hour session before disposing of the paste.

Explain what other healthcare resources are used in conjunction with the comparator health technology:

The comparator devices for radiation therapy are linear accelerators (Linacs) or dedicated superficial x-ray applicators. For external beam radiation therapy using photons, electrons, or superficial x-rays from linear accelerators, patients must undergo treatment simulation, planning/dosimetry, and multiple treatment sessions. Simulation and planning require clinician time to define the treatment area, radiation therapists for positioning, imaging, and dose planning, and validation by a medical physicist and the treating clinician. The treatment process spans 10-30 sessions, with radiation therapists administering the planned dose in each session.

Describe and explain any differences in the healthcare resources used in conjunction with the proposed health technology vs. the comparator health technology:

Key resource differences between Rhenium-SCT and comparator methods lie in capital and operational expenses, particularly in equipment and staffing needs. Rhenium-SCT uses OncoBeta-supplied equipment, avoiding the high capital costs of linear accelerators and the ongoing maintenance and calibration. While the simulation and planning process requires more clinician input, it is less time-consuming and less resource-intensive for department staff. Treatment is delivered in a single 1-3 hour session with one nuclear medicine technologist, compared to multiple sessions over weeks involving several radiation therapists.

CLINICAL MANAGEMENT AFTER THE USE OF HEALTH TECHNOLOGY

Define and summarise the clinical management algorithm, including any required tests or healthcare resources, *after* the use of the proposed health technology:

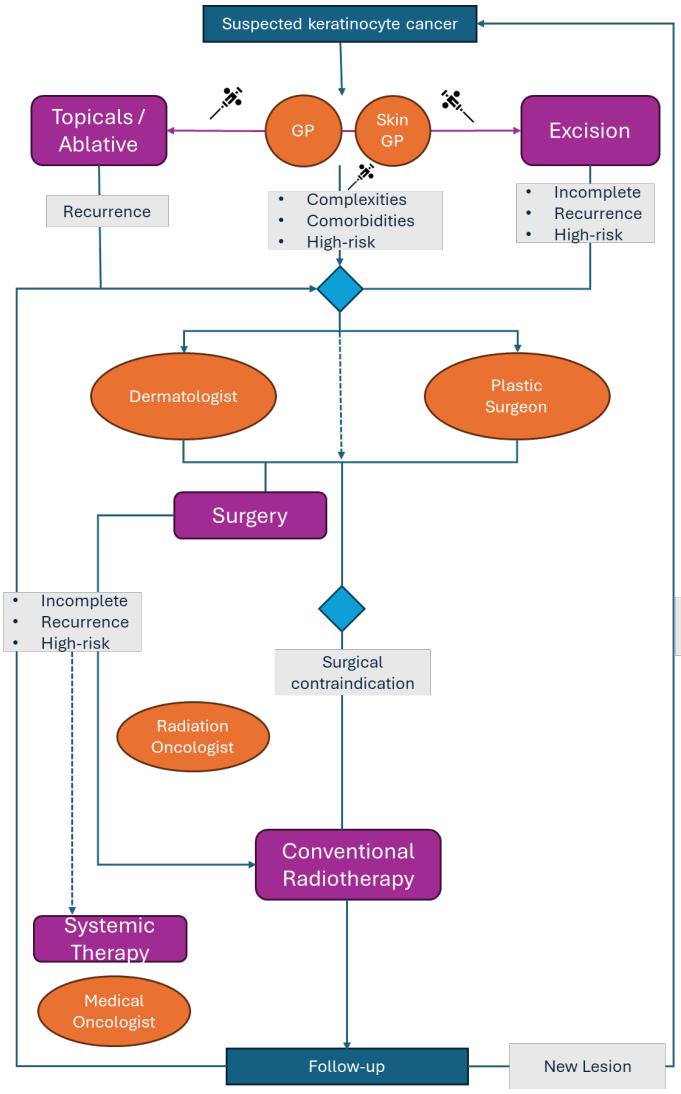
Patients are followed up by the treating clinician up to 3 times (in person or tele-health) dependent on the needs of the patient. The patient would return to their skin specialist for routine surveillance so any recurrence would be managed by standard procedures, including subsequent clinical diagnosis and/or biopsy, followed by a return to the clinical management algorithm.

Define and summarise the clinical management algorithm, including any required tests or healthcare resources, *after* the use of the comparator health technology:
Due to the protracted nature of comparator treatment, the patient is assessed frequently throughout the course, although the patient would return for 2-3 follow-up visits to the treating clinician. As above, the patient is returned to the care of their skin specialist for ongoing surveillance.

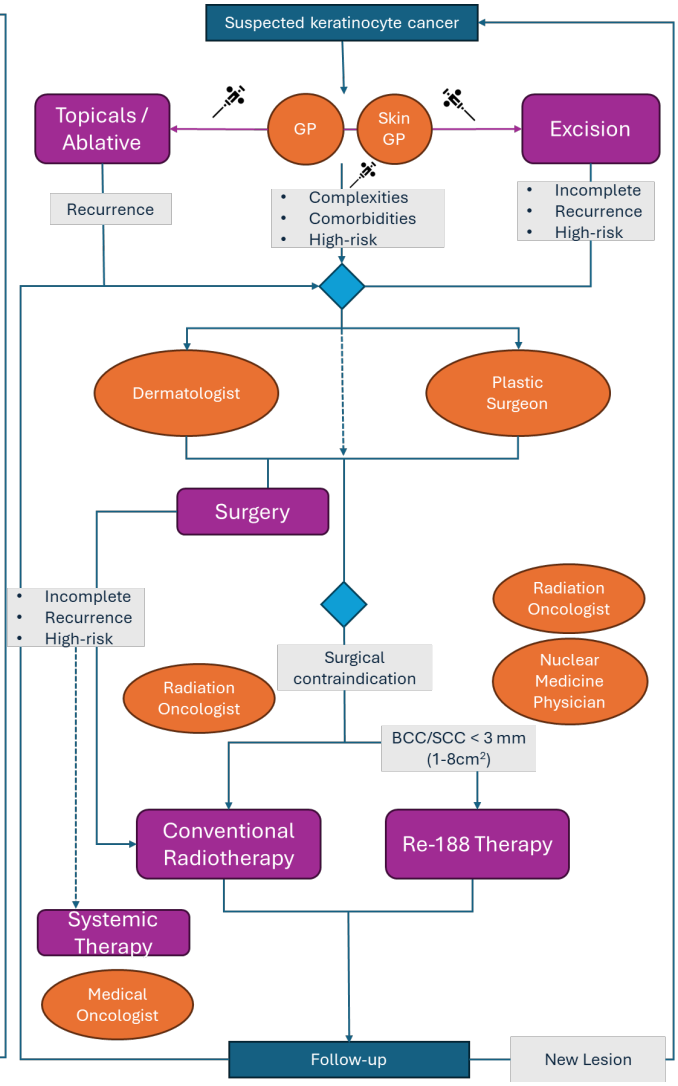
Describe and explain any differences in the healthcare resources used *after* the proposed health technology vs. the comparator health technology:
As above

Insert diagrams demonstrating the clinical management algorithm with and without the proposed health technology:

Before:



After:



Claims

In terms of health outcomes (comparative benefits and harms), is the proposed technology claimed to be superior, non-inferior or inferior to the comparator(s)?

☐ Superior
☒ Non-inferior
☐ Inferior

Please state what the overall claim is, and provide a rationale:
RSCT is non-inferior in terms of safety and efficacy in the target population compared to relevant EBRT modalities.

Why would the requestor seek to use the proposed investigative technology rather than the comparator(s)?
Patients who are unsuitable or unable to attend a fractionated course of radiation therapy, and/or where the treating clinician determines that the lesion can be more appropriately treated with RSCT (eg. Complex surfaces for which RSCT can be administered in a way that avoids excessive exposure of healthy tissue without complex treatment planning).

Identify how the proposed technology achieves the intended patient outcomes:
Rhenium-SCT provides non-inferior efficacy and safety outcomes compared to conventional radiation therapy for the indicated skin cancers. It also improves quality of life, has a short overall episode of care, and is preferred by patients who have a history of skin cancer.

For some people, compared with the comparator(s), does the test information result in:

A change in clinical management? Yes

A change in health outcome? No

Other benefits? Yes

Please provide a rationale, and information on other benefits if relevant:
RSCT avoids the patient burden of a protracted course of treatment with conventional radiation modalities. These often involve an extensive dose fractionation protocol, often daily across several weeks, that can be difficult for the patient due to comorbidities, demographic characteristics, geographical location, or employment/family commitments. In particular, the burden of disease in rural populations and unbalanced nationwide healthcare access can make broad access to conventional fractionated radiotherapy impractical. Mobility and/or cognitive issues may also preclude suitability for this schedule of conventional radiation therapy.

In terms of the immediate costs of the proposed technology (and immediate cost consequences, such as procedural costs, testing costs etc.), is the proposed technology claimed to be more costly, the same cost or less costly than the comparator?

☐ More costly
☐ Same cost
☒ Less costly

Provide a brief rationale for the claim:
Surveys of the current treating patterns of radiation oncologists for the proposed indications and their estimated switching rates to RSCT demonstrated the average cost of treating these lesions with conventional modalities, as well as the proposed cost savings to the Commonwealth for lesions that are treated with RSCT instead.

Summary of Evidence

Provide one or more recent (published) high quality clinical studies that support use of the proposed health service/technology. At 'Application Form lodgement',

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
1.	Prospective, multicentre, single arm, open-label, phase IV study.	EPIC-Skin Study ClinicalTrials.gov Identifier: NCT05135052 *6-month interim analysis published as:* Baxi, S., Vohra, S., Hong, A., Mulholland, N., Heuschkel, M., Dahlhoff, G., Cardaci, G., Mirzaei, S. and Sathekge, M., 2024. Effectiveness and Patient Experiences of Rhenium Skin Cancer Therapy for Nonmelanoma Skin Cancer: Interim Results from the EPIC-Skin Study. Journal of Nuclear Medicine, 65(9), pp.1450-1455.	EPIC-Skin study will assess clinic- and patient reported outcomes of Rhenium SCT as a treatment for BCC and SCC. All patients (n=189) will remain in the study for 24 mo from the time of their treatment with Rhenium SCT. Trial is currently ongoing, with 6 month interim results published, and 12 month interim results available as the pivotal results of the ADAR.	*6-month interim analysis:* pubmed.ncbi.nlm.nih.gov/39025650/	Sep 3, 2024