

MSAC Application 1657.1

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

Application for MBS eligible service or health technology

MSAC Application Number:

1657.1

Application title:

Rhenium-188 radioisotope therapy for non-melanoma skin cancer

Submitting organisation:

ONCOBETA THERAPEUTICS PTY LTD

Submitting organisation ABN:

39624903180

Application description

Succinct description of the medical condition/s:

Non-melanoma skin cancer (NMSC), also known as keratinocyte cancer (KC), includes basal cell carcinoma (BCC) and squamous cell carcinoma (SCC) and various other less common lesions. NMSC is the most common form of cancer in Australia, with almost one million cases being diagnosed and treated each year. Although rarely fatal, treatment of NMSC represents a major cost burden to the health system, accounting for around 8% of total spending on cancer treatment and more than \$700 million of expenditure through the MBS. Although a range of definitive treatment options are currently available in Australia (and funded through the MBS) these are subject to various limits of effectiveness, safety, tolerability, and acceptability. New, non-invasive, non-scarring treatment options that can be delivered quickly in an outpatient setting would represent a significant improvement in the standard of care.

Succinct description of the service or health technology:

Rhenium Skin Cancer Therapy (RSCT) is a novel form of radioisotope therapy for NMSC, which uses the Beta emitter radioisotope Rhenium-188. During treatment, the affected area of the skin is covered with the sterile protective foil. The Re-188 is then applied in a matrix on the foil using a special applicator device. The irradiation time required to achieve the desired target dose at the defined penetration depth is calculated based on the radioactivity of the substance being applied and the surface area to be treated. After the calculated irradiation time, the matrix is removed by pulling the foil from the skin. The procedure is highly effective, while also non-invasive, painless, and non-scarring. It can be provided without anaesthesia, over a short period of time in an outpatient setting. As such, the service offers multiple practical, economic, and patient relevant benefits over existing management options.

Application contact details

Are you the applicant, or are you a consultant or lobbyist acting on behalf of the applicant?

Consultant

Are you applying on behalf of an organisation, or as an individual?

Organisation

Is the applicant organisation the organisation you are representing in the HPP today?

Yes

Application details

Does the implementation of your service or health technology rely on a new listing on the Pharmaceutical Benefits Scheme (PBS) and/or the Prescribed List?

No

Is the application for a new service or health technology, or an amendment to an existing listed service or health technology?

New

Please select any relevant MBS items.

MBS item number	Selected reason type

What is the type of service or health technology?

Therapeutic

PICO Sets

Application PICO sets

PICO set number	PICO set name
1	Rhenium-188 radioisotope therapy for non-melanoma skin cancer

Rhenium-188 radioisotope therapy for non-melanoma skin cancer

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 cm². Multiple lesions can be treated at once if the contiguous surface area of any single lesion does not exceed 8.0 cm².

Search and select the most applicable Medical condition terminology (SNOMED CT):

Intervention

Name of the proposed health technology:

Rhenium-SCT (Skin Cancer Therapy)

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 health care system). This includes identifying health care resources that are needed to be delivered at the same time as the comparator service:

External beam radiation therapy

Outcomes

Outcome description – please 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

Proposed Item AAAAA

MBS item number:

15958

Please search and select the proposed category:

THERAPEUTIC PROCEDURES

Please search and select the proposed group:

RADIATION ONCOLOGY

Please search and select the proposed item descriptor or draft a proposed item descriptor to define the population and health technology usage characteristics that would define eligibility for funding:

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); Applicable once per course of treatment.

Proposed MBS fee:

\$1,733.77

Indicate the overall cost per patient of providing the proposed health technology:

\$redacted

Please specify any anticipated out of pocket costs:

\$redacted

Provide 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.

How is the technology/service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):

Funding through MBS reimbursement and self-funding by patients.

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)?

Non-inferior

Please state what the overall claim is, and provide a rationale:

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.

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).

Estimated utilisation

Estimate the prevalence and/or incidence of the proposed population:

Not an epidemiological approach, market share approach was used for Section 4 as comparators are MBS listed.

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake(%):

Redacted

Year 2 estimated uptake(%):

Redacted

Year 3 estimated uptake(%):

Redacted

Year 3 estimated uptake(%):

Redacted

Estimate the number of patients who will utilise the proposed technology for the first full year:

Redacted

Optionally, provide details:

For more accurate estimates see Section 4 of the ADAR.

Will the technology be needed more than once per patient?

No, once only

Consultation

List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the health technology/service:

- Australian And New Zealand Society of Nuclear Medicine
- Royal Australian and New Zealand College of Radiologists

List all appropriate professional bodies / organisations representing the group(s) of health professionals that may be impacted by the health technology/service:

- Australian College of Dermatologists (ACD)
- Australian Society of Plastic Surgeons (ASPS)
- Skin Cancer College Australasia (SCCA)

List the patient and consumer advocacy organisations or individuals relevant to the proposed health technology:

- Melanoma & Skin Cancer Advisory Network (MSCAN)

List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed service or health technology:

Regulatory information

Would the proposed health technology involve the use of a medical device, in-vitro diagnostic test, radioactive tracer or any other type of therapeutic good?

Yes

Has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

Yes

Is the therapeutic good classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

No

Please enter all relevant ARTG IDs:

ARTG ID	ARTG name
351390	Oncobeta Therapeutics Pty Ltd - Radionuclide system, therapeutic, brachytherapy, manual

Is the intended purpose in this application the same as the intended purpose of the ARTG listing(s)?

Yes