

MSAC application 1801

**Autologous Skin Cell Suspension for
the treatment of acute burn wounds
in paediatric and adult patients**

Application for MBS eligible service or health technology

HPP Application number:

HPP200245

Application title:

Autologous Skin Cell Suspension for the treatment of acute burn wounds in paediatric and adult patients

Submitting organisation:

HEALTH TECHNOLOGY ANALYSTS PTY LIMITED

Submitting organisation ABN:

13099239442

Application description

Succinct description of the medical condition/s:

A burn is an injury resulting in a wound characterised by an inflammatory reaction leading initially to local oedema from increased vascular permeability, vasodilation and extravascular osmotic (Arturson 1980). It is caused by direct effect of the burn agent on microvasculature (The Royal Children's Hospital Melbourne 2023). Estimating burn depth and percentage total body surface area (% TBSA) allows clinicians to plan treatment for patients to mitigate risk of scarring and infection (The Royal Children's Hospital Melbourne 2023). Severe burns defined greater than 20% TBSA requiring treatment are categorised as either (Warby and Maani 2023):

1. Deep partial-thickness, which extends further into dermis (reticular dermis)
2. Full-thickness burns, where the epidermis and dermis are destroyed, producing irretrievable skin loss.

However, most severe burn wounds greater than 20% TBSA do not have a uniform depth throughout the affected area and are often classified as mixed depth.

Succinct description of the service or health technology:

The proposed medical service includes the preparation and application of an autologous skin cell suspension (ASCS) for definitive closure of burn wounds $\geq 20\%$

TBSA. Treatment with ASCS achieves definitive closure in DPT burns with confluent dermis, or as an adjunct to widely meshed split-thickness skin grafts (STSG) for full-thickness (FT) burns.

The preparation of ASCS involves a single use autologous cell harvesting device (ACHD) at point-of-care designed to spare autograft tissue. The ACHD employs a two-step approach to prepare the ASCS: first, it enzymatically treats the skin sample, and then it mechanically breaks down the tissue using the device's disaggregation mechanism. The resulting ASCS contains a mixed population of cells, including keratinocytes, fibroblasts, and melanocytes. This process results in a suspension of autologous skin cells that can be sprayed onto the wound site following debridement, promoting healing and reducing the need for extensive donor skin grafts.

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

Applicant organisation name:

AVITA Medical, Inc

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?

Amendment

What is the nature of the amendment? *(if an amendment)*

An amendment to the way the service is clinically delivered under the existing item(s)

Justification for amendment: *(if an amendment)*

The amendment is for the inclusion of autologous skin cell suspension (ASCS) treatment to existing burn wound definitive closure techniques.

In the immediate closure setting, current terminology for immediate definitive closure items in acute burn treatment only mentions skin grafts and skin substitutes. Neither of these treatments encompasses the use of a ASCS preparation and treatment.

In the delayed treatment setting, the existing terminology only specifies split skin grafts or "other" treatments. To provide clarity and reduce ambiguity regarding available treatment options in this phase, it is important to explicitly include ASCS as a recognised method for definitive burn wound closure.

To ensure comprehensive coverage of all viable treatment options, it is recommended that the terminology for both immediate and delayed burn wound closure techniques be updated to specifically mention ASCS treatment alongside existing methods. As burn care continues to evolve, it is crucial to recognise and integrate these advancements into existing treatment protocols. The inclusion of ASCS as a clinically effective treatment option alongside traditional methods like skin autografts and skin substitutes and reflects the ongoing progress in burn wound management.

Additionally, ASCS preparation has minimal impact on overall procedure time, particularly for extensive and complex burn cases (>20% total body surface area). The ASCS preparation takes approximately 20-30 minutes, which is usually inconsequential compared to the total duration of large burn procedures. For burns exceeding 20% total body surface area, the debridement and grafting process often extends for several hours, making the ASCS preparation time a small fraction of the overall procedure duration. Debridement of wound and preparation of ASCS can be done simultaneously by the healthcare provider trained in preparation of ASCS.

Therefore, an amendment to the burns $\geq 20\%$ total body surface area definitive closure items in the immediate (46117 to 46124) and delayed setting (46134 and 46135) is sufficient for the service as clinician time is not expected to be impacted and the fee will remain the same.

Relevant MBS items

Please select any relevant MBS items.

MBS item number	Selected reason type
46117	Expansion or amendment to existing item
46118	Expansion or amendment to existing item
46119	Expansion or amendment to existing item
46120	Expansion or amendment to existing item
46121	Expansion or amendment to existing item
46122	Expansion or amendment to existing item
46123	Expansion or amendment to existing item
46134	Expansion or amendment to existing item
46135	Expansion or amendment to existing item

What is the type of service or health technology?

Therapeutic

PICO sets

Application PICO sets:

Definitive closure in full-thickness/mixed depth and deep partial thickness burn wounds $\geq 20\%$ total body surface area in adults and paediatric patients

Population

Describe the population in which the proposed health technology is intended to be used:

The proposed health technology will be used for patients with severe burns covering greater than 20% TBSA, who have sustained DPT or FT/mixed depth burn wounds (i.e., burns wounds for which autologous split-thickness skin grafting is indicated). The proposed health technology is the preparation and use of ASCS, at the point-of-care (PoC), for definitive closure of burn wounds. Burn injuries are defined by some or all the different layers of cells in the skin are destroyed, typically by a hot liquid, a hot solid, or a flame. Burns that are FT or DPT often require surgical intervention by early closure to mitigate risk of infection and minimise scarring (Braza and Fahrenkopf 2023). Those with burns greater than 20% TBSA are limited by skin grafting as donor sites approximating the size of the burn wound is required to be harvested from healthy unaffected areas of skin. Preparation of ASCS requires a 1cm²

skin sample to treat up to 80cm² of skin (Avita Medical 2023). Hence, the proposed health technology is intended to reduce donor site requirements of conventional skin grafting in patients with severe burns greater than 20% TBSA that require autografting for definitive burn wound closure.

Select the most applicable Medical condition terminology (SNOMED CT):

Deep full thickness burn injury

Intervention

Name of the proposed health technology:

Autologous skin cell suspension prepared by enzymatic and mechanical disaggregation of a small skin sample (1 cm²) alone or in conjunction with STSG.

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:

The comparator for the proposed health technology are split thickness skin grafts (STSGs) for definitive closure.

Patients with deep partial thickness (DPT) and full thickness (FT) burn wounds $\geq 20\%$ total body surface area (TBSA) are currently managed most commonly using STSG for definitive wound closure techniques. STSGs are a thin shaving of skin harvested from the epidermal and dermal tissue and are performed in an operating theatre with the patient anaesthetised (NSW Statewide Burn Injury Service 2020). STSGs can also be meshed for skin expansion (~2-3 times) to reduce donor skin requirements or micro grafted (meek technique) where smaller portions of skin are harvested and expanded. However, both techniques are also limited by the availability of healthy donor skin and can result in non-uniform cosmetic results (Biswas 2010, Kadam 2016).

Prior to autografting, skin substitute products are often used in FT burns in cases of a less vascularised wound bed that cannot be immediately grafted (Halim 2010). These include NovoSorb biodegradable temporising matrix (BTM), Biobrane and MatriDerm. They provide an increase in the dermal component, reduce or remove

inhibitory factors of wound healing and can reduce inflammatory response and subsequent scarring. Hence skin substitutes provide either a temporary physiological closure usually for FT wounds after excision while awaiting autografting (Halim 2010). After 3 to 4 weeks, and/or when sufficient re-capillarisation is present, STSGs are then subsequently placed (Tapping 2024). Therefore, skin autografting is done in the delayed treatment setting.

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

The introduction of the proposed health technology to patient management will provide additional cell-based therapies for the treatment of major burns (Kearney 2018). That is, improving the management of donor sites by reducing size requirements, reducing pain and facilitate healing in both the donor and treatment site (Gravante 2007). Efficacy outcomes for donor site and recipient site were measured in both pivotal clinical trials (CTP001-5 and CTP001-6) which investigated the safety and effectiveness of RECELL® ACHD when used alone and in conjunction with widely meshed STSGs (Holmes IV 2018, Holmes 2019).

Efficacy outcomes

- Treatment site healing (CTP001-5, CTP001-6)
- Donor site healing (CTP001-5) and donor skin expansion (CTP001-5, CTP001-6)

Safety outcomes

- Adverse events (AEs) and serious adverse events (SAEs)
- Device-related AEs
- Graft loss
- Infection
- Scar formation
- Delayed healing/wound assessment
- Allergic response to trypsin

Patient relative outcomes

- Pain and visual appearance in recipient site and donor site

Other hospital related outcomes and considerations that are retrospectively reviewed in Compassionate Use cohort (CTP004) and Continued Access (CTP001-7/CTP001-8)

- Hospital length of stay
- Number of autograft procedures

Proposed MBS items

Please provide at least one proposed item with their descriptor and associated costs, for each population / intervention: (repeat the fields highlighted below for each proposed item provided)

Proposed item:

AAAAA

MBS item number (where used as a template for the proposed item):

46117

Category number:

THERAPEUTIC PROCEDURES

Category description:

SURGICAL OPERATIONS

Proposed item descriptor:

Excised burn wound closure, if the defect area is $20\% \leq \text{TBSA} < 30\%$ of total body surface and if the service:

(a) is performed at the same time as the procedure for the primary burn wound excision; and

(b) involves:

(i) Autologous skin grafting with or without autologous skin cell suspension for definitive closure; or

(ii) Autologous skin cell suspension for definitive closure; or

(iii) allogenic skin grafting, or biosynthetic skin substitutes, to temporize the excised wound;

excluding aftercare (H)

(Anaes.) (Assist.)

Proposed MBS fee:

\$1,373.65

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

\$1,373.65

Please specify any anticipated out of pocket expenses:

\$0.00

Provide any further details and explain:

Use of ASCS is expected to have minimal impact to the total procedure time. Hence no change to current MBS fee is proposed.

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

State-based funding in public hospitals.

Self-funded by patients in private practice

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

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

- ASCS ± STSGs is superior in reducing donor site requirements compared to STSGs alone
- ASCS ± STSGs is non-inferior for recipient site healing and scar outcomes compared to STSGs alone
- ASCS donor sites is superior in reducing pain and scarring compared with STSG donor sites

Overall, treatment of burn wounds $\geq 20\%$ TBSA is superior in reducing donor site requirements using ASCS ± STSGs vs STSGs alone.

Specifically, treatment of burn wounds is superior in reducing donor site requirements using ASCS + STSGs vs STSGs alone in FT burn sites. Additionally, treatment of burn wounds is superior in reducing donor site requirements using ASCS vs STSGs alone in DPT burn sites

Recipient site healing and scar outcomes was non-inferior in FT burns using ASCS + STSGs and in DPT burn sites using ASCS alone versus STSGs.

Therefore, treatment with ASCS is beneficial in facilitating definitive closure of burn wounds by reducing donor site morbidity without compromising important clinical outcomes associated with wound healing and long-term scar appearance.

The overall claim is supported by two prospective multi-centre, randomised clinical studies which were conducted in the US under an investigational device exemption (IDE) in a total of 131 subjects.

Estimated utilisation

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

The Burns Registry of Australia and New Zealand (BRANZ) captures data on almost all patients with severe burns, specifically those with a percentage of TBSA burned exceeding 20% (Burns Registry of Australia and New Zealand 2022). It also captures data on all first admissions to an Australian or New Zealand specialist burn service within 28 days of injury where a burn is the primary cause. In addition to the BRANZ registry data reported by the Major Burn Units other sources of national data provide context as to the level of burn injury in Australia. Additionally, the Australian institute of health and welfare (AIHW) reported 5,500 burn injury hospitalisations in 2021-2022 reporting period, or rate of 22 per 100,000 population (Australian Institute of Health and Welfare 2023).

The most recent BRANZ data for 2023 reported 2,896 burn cases (735 paediatric and 2,161 adult patients) for the 2022/23 period that met the BRANZ inclusion criteria (Burns Registry of Australia and New Zealand 2024). Consistent with previous Annual Reports, approximately half of both the paediatric and adult patients were transferred to a specialist burn service via another hospital and 74.5% of patients transferred to a specialist burn unit underwent a burn wound management procedure in theatre (Burns Registry of Australia and New Zealand 2024). Where data were complete, 67.3% of patients received a skin graft. Additionally, 6.8 percent of adults and 3.9% of paediatric patients had a major burn greater than or equal to 20% TBSA in the 2022/23 period (Burns Registry of Australia and New Zealand 2024). Additionally, BRANZ data from 2015 - 2021 reports similar percentage breakdowns for those who sustained major burn injury (TBSA greater than or equal to 20%).

It is estimated that 14.4 million Australians or 55 percent of the population have

private health insurance while the BRANZ annual report from 2020/2021 reports that 10.4% of admissions to Australian burns services were funded through private health insurance schemes. Private patients in public hospitals are entitled to MBS rebates for attendances and services provided by medical practitioners. Patients can receive private (MBS and private health insurance-rebated) services in a public hospital where the hospital arrangements support this type of service (Department of Health and Aged Care 2023).

Hence, it is approximated that the upper limit of the estimated utilisation will be based on the number of people who sustain a burn injury greater than or equal to 20% TBSA that requires a burn wound procedure in theatre, i.e., skin grafting and percentage of those multiplied by those who have private insurance and access to Medicare rebated services. This is approximated to ensure funded access to specialised services for patients that are treated in public hospital settings.

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

Year 1 estimated uptake (%):

28

Year 2 estimated uptake (%):

33

Year 3 estimated uptake (%):

39

Year 4 estimated uptake (%):

44

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

51

Optionally, provide details:

Utilisation will depend on clinician uptake and patients with private insurance in specialised public burn units.

Will the technology be needed more than once per patient?

Yes, multiple times

Over what duration will the health technology or service be provided for a patient? (preferably a number of years):

Dependent on number of surgeries required

Optionally, provide details:

The proposed health technology is only provided at time of surgery for autografting procedures.

What frequency will the health technology or service be required by the patient over the duration? (range, preferably on an annual basis):

at least once

Optionally, provide details:

Initially, the service will be provided once in the acute treatment phase after burn injury. However, during the initial service, and especially for larger burns greater than 20 percent TBSA, more than one device may be required to provide coverage of the treatment area. Each device has the capacity to treat 1,920 square cm. Number of devices or services over the duration of a year would also be subject to patient variability, response to treatment and resources used in conjunction with the proposed health technology.

Depending on patient response to initial autografting and ASCS procedure, ASCS treatment may be required in subsequent definitive closure procedures in the delayed setting.

Consultation

List all entities that are relevant to the proposed service / health technology. The list can include professional bodies / organisations who provide, request, may be impacted by the service/health technology; sponsor(s) and / or manufacturer(s) who produce similar products; patient and consumer advocacy organisations or individuals relevant to the proposed service/health technology.

Entity who provides the health technology/service

The Australian and New Zealand Burn Association (ANZBA)

Entity who may be impacted by the health technology/service

The Australian Society of Plastic Surgeons (ASPS)

Patient and consumer advocacy organisations relevant to the proposed service/health technology

The Royal Australasian College of Surgeons (RACS)

The Australian and New Zealand Burn Association (ANZBA)

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)? (if 'Yes' above)

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?

Class III

Please enter all relevant ARTG IDs:

ARTG ID	ARTG name
338864	Emergo Asia Pacific Pty Ltd T/a Emergo Australia - ReCell 1920 Autologous Cell Harvesting Device - Autologous skin cell grafting kit