

Medical Services Advisory Committee (MSAC) Public Summary Document

Application No. 1801–Autologous skin cell suspension for the treatment of acute burn wounds in paediatric and adult patients

Applicant: Health Technology Analysts Pty Ltd on behalf of AVITA Medical, Inc

Date of MSAC consideration: 31 July 2025

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, [visit the MSAC website](#)

1. Purpose of application

An application requesting Medicare Benefits Schedule (MBS) listing of autologous skin cell suspension (ASCS) prepared at the point of care (POC) for definitive closure of severe burn wounds $\geq 20\%$ total body surface area (TBSA) was received from Health Technology Analysts Pty Ltd on behalf of AVITA Medical, Inc by the Department of Health, Disability and Ageing.

2. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness, cost-effectiveness and total cost, MSAC supported the amendment of existing MBS items for immediate and delayed definitive burn wound closure to include the use of ASCS for the treatment of full-thickness (FT) and deep-partial thickness (DPT) acute burn wounds comprising greater than or equal to 20% TBSA in adult patients and greater than or equal to 10% TBSA in paediatric patients, as well as for whole of face burn wound closure. MSAC agreed that the fees for the existing items are adequate for the inclusion of ASCS as a treatment option. MSAC noted ASCS could be used as a stand-alone treatment or in conjunction with autologous skin grafting. MSAC did not support an additional MBS modifier item to provide additional funding for burns treatment requiring combined ASCS and autologous skin grafting, as the existing MBS item structure for burns treatment already accounts for variations in procedural time and difficulty. MSAC considered ASCS was non-inferior for safety compared to autologous skin grafting and had superior effectiveness for donor site sparing and reduction of autograft procedures. MSAC noted that although the costing analysis did not capture long-term patient outcomes, ASCS in combination with autologous skin grafting was likely to be cost saving for patients with burns over 30% TBSA. MSAC considered on average ASCS was likely to be at least cost-neutral compared to standard treatment for the overall population of burns over 20% TBSA. MSAC noted the financial impact to the MBS was likely to be minimal due to the low utilisation of current MBS items and because the modifier item was not supported. MSAC noted the ASCS device cost (\$redacted per device, with multiple devices required per patient) could not be funded through the MBS or the Prescribed List. MSAC noted that the treatment of severe burns occurs in specialised burn units in public hospitals. MSAC considered that private patients may incur out of pocket costs for the device.

Consumer summary

This is an application from Health Technology Analysts Pty Ltd on behalf of AVITA Medical, Inc requesting amendment of existing Medicare Benefits Schedule (MBS) items for immediate and delayed definitive severe burn wound closure to include autologous skin cell suspensions (ASCS), with no amendment to the current MBS fees. The application also proposed a new MBS item to provide additional funding for when ASCS is used in combination with split-thickness skin grafts (STSG), to cover the additional time required for preparation and application, compared to skin graft surgery alone.

Severe burns are those that cover more than 20% of the total body surface area. These burns can be classified as deep partial-thickness burns or full-thickness burns. Deep partial-thickness burns (DPT) result in damage to the outer layer of the skin (epidermis) and the deeper layers of the skin (dermis). Full-thickness burns result in damage to the epidermis, dermis and underlying tissue, and are also called third-degree burns. Severe burns, especially full-thickness burns and many deep partial thickness burns, require surgery to close the wound. This usually involves removing a layer of skin from one area of the body (the donor site) and placing it on the burn wound so that it can heal. This is called a skin graft. A Split Thickness Skin Graft (STSG) involves the epidermis and part of the dermis. Because this procedure involves removing skin from the donor site, it can cause extra pain and scarring and lengthy hospital stays. The procedure may also need to be repeated to ensure the burn wound fully heals.

This application uses a device (called ReCell®) that harvests some of the patient's own skin cells and turns them into a mixture (ASCS) that can be sprayed onto burn wounds. This reduces the need to use a large donor site, so this should improve healing times, reduce pain and shorten hospital stays compared with skin graft treatments. ASCS cannot be used by itself for full-thickness burns – it must be used with a skin graft or another treatment. However, using ASCS with a skin graft reduces the size of the donor site that is needed. ASCS can be used by itself for DPT burns, especially for burns in children.

MSAC noted that ASCS is likely as safe as a skin graft, as they both have similar adverse events, infection, scar formation and delayed wound healing. ASCS is likely to be as effective as a skin graft in relation to burn wound healing and pain, but results in shorter hospital stays, causes less donor site pain and potentially results in fewer procedures to cover tissue defects.

The ReCell® device is ineligible for listing on the Prescribed List of Medical Devices and Human Tissue Products, which means the device cost cannot be reimbursed. MSAC noted that other devices used for burn wound treatment (such as skin graft blades) are also ineligible for the Prescribed List and are currently paid for by hospitals, and the same will likely happen with ASCS device. MSAC noted that the inclusion of ASCS in the existing MBS items for severe burn wound closure treatment could result in an additional cost to the private health system, however the financial impact on the MBS was likely to be minimal due to the low utilisation of current MBS items.

Overall, MSAC was supportive of public funding of ASCS for adults with severe burns covering 20% or more of the total body surface area, and for children (aged less than 15 years) with severe burns covering 10% or more than the total body surface area. MSAC supported the smaller total body surface area threshold in children because children may have less skin available for grafting than adults and therefore may have greater clinical need for skin sparing techniques such as ASCS. MSAC did not support the modifier MBS item as the existing MBS item structure for burns treatment already accounts for variations in procedural time and difficulty.

Consumer summary

MSAC's advice to the Commonwealth Minister for Health, Disability and Ageing

MSAC supported amending existing MBS items for immediate and delayed severe burn wound closure to include ASCS for adults with burns $\geq 20\%$ total body surface area and children with burns $\geq 10\%$ total body surface area, with no amendment to the current MBS fees. MSAC considered ASCS to be just as safe and effective as skin graft treatment for some burns, but ASCS is likely to shorten hospital stay, causes less donor site pain and fewer subsequent procedures. The financial impact to the MBS is expected to be minimal. Although the device cost is not covered under the Prescribed List, it is likely that it will be paid for by hospitals (as is done for other devices used for burn wound closure). MSAC did not support the modifier MBS item for additional preparation and application processes when ASCS is combined with skin graft treatment.

3. Summary of consideration and rationale for MSAC's advice

MSAC noted this was an application from Health Technology Analysts Pty Ltd on behalf of AVITA Medical, Inc requesting amendment of existing MBS items for immediate (MBS items 46117 – 46124) and delayed (MBS items 46134–46135) definite burn wound closure to include ASCS, with no amendment to the current MBS fees. The application also proposed a modifier MBS item for combined ASCS and STSG treatments. This submission used the expedited pathway, bypassing PASC.

MSAC granted the applicant request for a hearing during the MSAC meeting. At the hearing, representatives of the applicant stated the clinical effectiveness of the ASCS in treating severe burn wounds and confirmed that ASCS would not be used on its own for treatment of full-thickness burns but could be used alone for the deep partial-thickness portion of a burn covering $\geq 20\%$ total body surface area (TBSA).

MSAC noted that public consultation feedback was received from 2 professional associations (the Australian and New Zealand Burn Association [ANZBA] and the Australian Society of Plastic Surgeons [ASPS]), 5 health professionals and 1 consumer. MSAC noted the feedback was supportive of the technology and its inclusion in the MBS items. MSAC noted the ASPS stated that the results for ASCS are highly variable and dependent on the operator but noted recent advancement in the technology may improve its reliability. The feedback also indicated that additional training would not be required, although it suggested limiting use to accredited burns units.

MSAC noted that all 14 specialist burns units in Australia contribute to the Burns Registry of Australia and New Zealand (BRANZ), along with 4 specialist burns units in New Zealand. These facilities treat adult patients who have burns covering $>10\%$, and children with burns covering $>5\%$ TBSA. According to BRANZ data, in 2022–23, 2,423 adult (2.1% mortality in hospital) and 735 paediatric (2.9% mortality in hospital) burns patients were admitted to hospital, with both these numbers being a decrease from previous years. For adults, the median TBSA burned was 2.5%, and 6.1% of patients had burns covering $>20\%$ TBSA. For children, the median TBSA burned was 2.0%, and 3.9% of patients had burns covering $>20\%$ TBSA. For First Nations patients, 238 were admitted to hospital with burns and 8.0% of patients had burns covering $>20\%$ TBSA.

MSAC noted the clinical management algorithm and considered it appropriate. In Australia, severe burns are typically delivered by 14 specialist burns units, all located in public hospitals.

These units are equipped to manage complex cases, including surgical excision, fluid resuscitation, and wound closure using techniques like STSG. Private hospitals may provide less complex procedure such as burn contractures or tissue defects following excision of necrotising fasciitis. To support the evolving clinical practice for severe burn wounds closure, including the use of ASCS alongside STSG, amendments to existing MBS items have been proposed.

MSAC noted the proposal from the department to consider inclusion of burns covering $\leq 20\%$ TBSA. Although not included in the application, the department considered that there was a risk that lengthy and complicated item descriptors would result in confusion and uncertainty for patients and providers. The proposal intended to simplify the item descriptors to reduce this risk. While current use of MBS items for these smaller burns is low, MSAC concerned that there was a risk for potential misuse if including smaller burns areas for adults. MSAC supported paediatric burns $\geq 10\%$ TBSA be eligible, noting that additional MBS item descriptor amendments would be required if including these patients.

MSAC acknowledged that amendment of the existing MBS items would be complex. MSAC advised the department that for implementation of any new or modified descriptors incorporating use of ASCS should be device-agnostic and will need to:

- apply to all adults with burns $\geq 20\%$ TBSA
- apply to all children aged ≤ 15 years with burns $\geq 10\%$ TBSA
- apply to whole of face burns
- apply to adults with burns $\geq 20\%$ TBSA where one or more of the surgeons performing the burn closure is treating a burn area that is less than 20% TBSA individually (multiple surgeons rule)
- include children with burns $\geq 10\%$ TBSA where one or more of the surgeons performing the burn closure is treating a burn area that is less than 10% TBSA individually (multiple surgeons rule)
- not change current rebates.

MSAC supported use of ASCS in combination with STSG, and also as a sole treatment if clinicians determine it to be appropriate. However, MSAC did not support the modifier item (noting that similar extra costs are already absorbed elsewhere) nor extending ASCS to all immediate and delayed burn wound closure item numbers for burns of all sizes (this was not part of the application and costs were not assessed).

MSAC noted the clinical claim was ASCS treatment, with or without STSGs, offers superior donor site sparing compared to STSGs alone in severe burn wounds (deep partial-thickness and full-thickness burns covering $\geq 20\%$ TBSA), and that it demonstrates non-inferior effectiveness in achieving definitive wound closure and non-inferior safety in treating patients with severe burns.

MSAC noted that the key evidence presented was from 2 small within-patient randomised controlled trials (RCTs) with a total of 42 patients. Hospital length of stay (LOS) data was derived from a United States retrospective study that may have limited applicability to the Australian health system. However, consultation feedback was supportive of the claims of reduced hospital LOS, and this was supplemented by findings included in the pre-MSAC response from an abstract presented at the 2025 British Burn Association Annual Meeting.¹ MSAC noted the pre-MSAC response stated around 18,000 ReCell® devices have been distributed since its inclusion on the ARTG in 2006 and had a very low complaint rate. MSAC considered ASCS had non-inferior longer-term (up to 14 months) clinical outcomes for healing, pain and visual appearance at the

¹ Carter JE and Phillips B (2025) '[The clinical impact of skin cell suspension autograft from a national registry perspective](#)', abstract presented at the British Burn Association Annual Conference, Brighton, 4–6 June 2025.

treatment site. ASCS also had non-inferior safety in terms of adverse events (AEs) and serious AEs, device-related AEs, graft loss, infection, scar formation and delayed wound healing. MSAC noted the external validity limitations of within-patient RCT designs and considered that ASCS was likely to reduce hospital LOS, require fewer autograft procedures, and use less donor skin, resulting in less pain and faster healing at the donor site.

MSAC noted the base-case costing in the applicant-developed assessment report (ADAR) demonstrated cost savings were greatest in burns covering $\geq 40\%$ TBSA, meaning that 20% of the cohort contributed 70% of the savings. However, the ADAR's base-case cost analysis did not include the cost of the device used to prepare the ASCS. MSAC agreed with ESC that this was not appropriate for the economic evaluation. Including device costs reduced total cost savings per patient by approximately 80% (from a saving of \$24,068.10 to \$5,350.93). MSAC noted that ASCS only became cost saving for burns covering $\geq 30\%$ TBSA: 30–39% TBSA resulted in a cost saving of \$1,685; and $\geq 40\%$ TBSA resulted in a cost saving of \$10,755. MSAC noted cost savings were largely driven by reduced hospital LOS and the number of definitive closure procedures required to treat severe burns. In an additional analysis of hospital costs that included the cost of the ASCS device and LOS offsets (Table 19). MSAC noted that ASCS for 20–29% TBSA resulted in an additional cost to hospitals of \$29,819, 30–39% TBSA resulted in a cost saving of \$33,491, and $\geq 40\%$ TBSA resulted in a cost saving of \$168,363.

MSAC noted the financial impact estimated net cost to hospitals was \$1.52 million in year 1 to \$2.42 million by year 6, although this did not include any offsets from reductions in LOS and number of definitive closures. The pre-MSAC response provided an additional cost analysis that included these offsets estimated ASCS would result in a net cost to the MBS and private hospitals of \$256,161 in year 1 to \$403,099 in year 6.

Overall, MSAC considered that the financial impact to the MBS was likely to be minimal, as the same number of burns would be treated, using the same MBS item numbers, with the only difference being the choice of technique to be used under the amended MBS items. In addition, MSAC did not support the proposed modifier item, which would have resulted in a small cost to the MBS. MSAC noted current use of MBS items for burns covering $\geq 20\%$ TBSA was low, and it was likely that very few patients with private health insurance will opt to be treated as a private patient. MSAC noted that large burns could require use of 3–5 ASCS devices, and the device was not eligible for inclusion on the Prescribed List of Medical Devices and Human Tissue Products (PL). This means the cost (\$redacted for the proposed ReCell® device) will be incurred by hospitals and/or privately by patients. However, MSAC noted that other devices required for treatment of severe burns (such as skin graft blades and meshers) are also ineligible for the PL and are currently paid for by hospitals (usually public hospitals with specialised burn units).

4. Background

MSAC had not previously considered ASCS prepared at the POC for definitive closure of severe burn wounds $\geq 20\%$ TBSA.

5. Prerequisites to implementation of any funding advice

The RECELL® Autologous Cell Harvesting Device (ACHD) is currently registered on the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA) under ARTG ID 338864 as a class III medical device (Table 1).

Table 1: RECELL® autologous cell harvesting device on the ARTG

Product name & sponsor	ARTG summary	Intended purpose
Emergo Asia Pacific Pty Ltd T/a Emergo Australia – RECELL 1920 Autologous Cell Harvesting Device – autologous skin cell grafting kit	ARTG ID: 338864 Start date: 3 July 2020 Category: Medical Device Class III GMDN: 58417 Autologous skin cell grafting kit	To disaggregate cells from a patient's split-thickness skin sample and collect these cells for reintroduction to the patient. These cells can be used for autologous application to the prepared wound bed as determined by a physician for the treatment of burns or other acute wounds.

Source: ADAR Table 1; Therapeutic Goods Administration (2020)²

Abbreviations: ARTG, Australian Register of Therapeutic Goods; GMDN, Global Medical Device Nomenclature

6. Proposal for public funding

This application requests amendments to the existing MBS items for the definitive closure of burns where the defect area is $\geq 20\%$ of TBSA. The applicant-developed assessment report (ADAR) indicated that the method used in ASCS differs from other methods, therefore requiring its own classification within the item descriptors. The ADAR recommended that the terminology used in the descriptors for both immediate and delayed burn wound closure techniques be updated to specifically mention ASCS treatment alongside existing methods, ensuring comprehensive coverage of all available treatment options (Table 2 and Table 3).

The fee proposed in the ADAR for the preparation and application of ASCS alone remains unchanged relative to the existing fees for immediate (46117 to 46124) and delayed (46134 and 46135) definitive closure items, as equivalent health professionals will perform the procedure and require a similar level of skill.

While clinician time for direct substitution of split-thickness skin graft (STSG) with ASCS is expected to be adequately covered by the current fees, use of STSG and ASCS in conjunction to treat full thickness (FT) burns will require additional clinician time, which the ADAR suggests could be up to 30 minutes. When STSG and ASCS are used in conjunction, this time will be in addition to the time needed to prepare and apply meshed STSG. Hence, a modifier item has been proposed to adjust the fee for a 15% increase to the co-claimed definite closure item (Table 4).

²Therapeutic Goods Administration 2020 'Emergo Asia Pacific Pty Ltd T/a Emergo Australia - ReCell 1920 Autologous Cell Harvesting Device - Autologous skin cell grafting kit (338864)', viewed 7 May 2025 <https://www.tga.gov.au/resources/artg/338864>

Table 2: Proposed item descriptor for item 46117 to include autologous skin cell suspension – immediate closure

Category 3 – Therapeutic Procedures T8 – Surgical Operations 13 – Plastic And Reconstructive Surgery
MBS item 46117 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; or (ii) Autologous skin cell suspension; or (iii) Autologous skin cell suspension in conjunction with autologous skin grafting; or (iv) allogenic skin grafting, or biosynthetic skin substitutes, to temporise the excised wound; excluding aftercare (H) (Anaes.) (Assist.)
Fee: \$1,373.65 Benefit: 75% = \$1,030.25

Abbreviations: TBSA = total body surface area

Note: Additions to the existing MBS item descriptor are shown in red

Table 3: Proposed item descriptor for item 46134 to include autologous skin cell suspension – delayed closure

Category 3 – Therapeutic Procedures T8 – Surgical Operations 13 – Plastic and Reconstructive Surgery
MBS item 46134 Definitive burn wound closure, or closure of skin defect secondary to necrotising fasciitis, if the defect area involves $20\% \leq \text{TBSA} < 30\%$ of total body surface, using autologous tissue (split skin graft or autologous skin cell suspension or other) following previous procedure using non-autologous temporary wound closure, excluding aftercare (H) (Anaes.) (Assist.)
Fee: \$2,260.45 Benefit: 75% = \$1,695.35

Abbreviations: ASCS = autologous skin cell suspension; STSG = split-thickness skin graft; TBSA = total body surface area

Note: Additions to the existing MBS item descriptor are shown in red

Table 4: Proposed modifier item

Category 3 – Therapeutic Procedures
Modifier Item for the preparation and application of autologous skin cell suspension burns – (Item XXXX)
Item XXXX is a modifier item that provides additional funding for burns requiring the use of split-thickness skin grafts in conjunction with autologous skin cell suspension for burns covering $>20\%$ total body surface area. The modifier item can be co-claimed with: Immediate definitive burn wound closure items 46117 to 46124 Delayed definitive burn wound closure items 46134 to 46135 Claiming the Modifier Item The modifier item (XXXX) should be claimed immediately after the burns closure item it is associated with. When claiming the modifier item with an eligible burn closure item: The modifier item and the associated burn closure item are treated as one service for the purpose of the Multiple Operation Rule. The derived fee resulting from claiming the modifier item will be an additional 15% of the fee for the co-claimed service. The derived fee is calculated before the Multiple Operation Rule is applied.

Abbreviations: ASCS = autologous skin cell suspension; STSG = split-thickness skin graft; TBSA = total body surface area

The ADAR proposed amendments to the MBS items specific to $\geq 20\%$ TBSA (items 4611–46124 and 46134–46135) as well as the creation of a new modifier item that can be co-claimed with any of these existing items. However, for a patient with $\geq 20\%$ TBSA burn treated by multiple surgeons, one or more of the surgeons performing definite closure (immediate or delayed) may treat a burn area that is $< 20\%$ TBSA individually. As such, the ADAR notes additional amendments of MBS items 46113–46116 and 46130–46133 may be required to include coverage for ASCS (the modifier item may also need to extend to these services). Based on the population requested in the application, any such amendments would need to specify that use of an ASCS item for a burn area $< 20\%$ is only permitted when the total burn area is $\geq 20\%$ TBSA.

7. Population

One population, intervention, comparator and outcome (PICO) set was provided for the use of ASCS $\pm$ STSG treatment for deep partial-thickness (DPT) and/or FT burn wounds $\geq 20\%$ TBSA (Table 5).

Table 5: PICO criteria for assessing ASCS $\pm$ STSG treatment for PT and DPT burn wounds $\geq 20\%$ TBSA

Component	Description
Population	Adult and paediatric patients with FT and/or DPT burn wounds $\geq 20\%$ TBSA
Prior tests	N/A
Intervention	ASCS $\pm$ STSG
Comparator	STSG
Outcomes	Safety: - AEs and SAEs - Device-related AEs - Graft loss - Infection - Scar formation - Delayed healing/wound assessment Effectiveness: - Treatment site healing - Donor site healing and donor skin requirements - Pain and visual appearance in recipient site and donor site Health care system outcomes: - LOS - Number of autograft procedures
Systematic review question: What is the safety, effectiveness and cost-effectiveness of ASCS $\pm$ STSG compared to STSG alone in severe burn wounds $\geq 20\%$ TBSA?	

Abbreviations: AE = adverse event; ASCS = autologous skin cell suspension; DPT = deep partial-thickness; LOS = length of hospital stay; PT = partial-thickness; SAE = serious adverse event; STSG = split-thickness skin graft; TBSA = total body surface area

According to recent data from the Burns Registry of Australia and New Zealand (BRANZ), 2,896 burn cases were reported across 2022–2023, of which 6.8% (n = 151) of adult patients and

3.9% (n = 29) of paediatric patients had a severe burn injury $\geq 20\%$ TBSA.³ The majority of patients are transferred to a specialist burn unit, with 74.5% undergoing a wound management procedure in theatre and 67.3% of those patients receiving a skin graft.

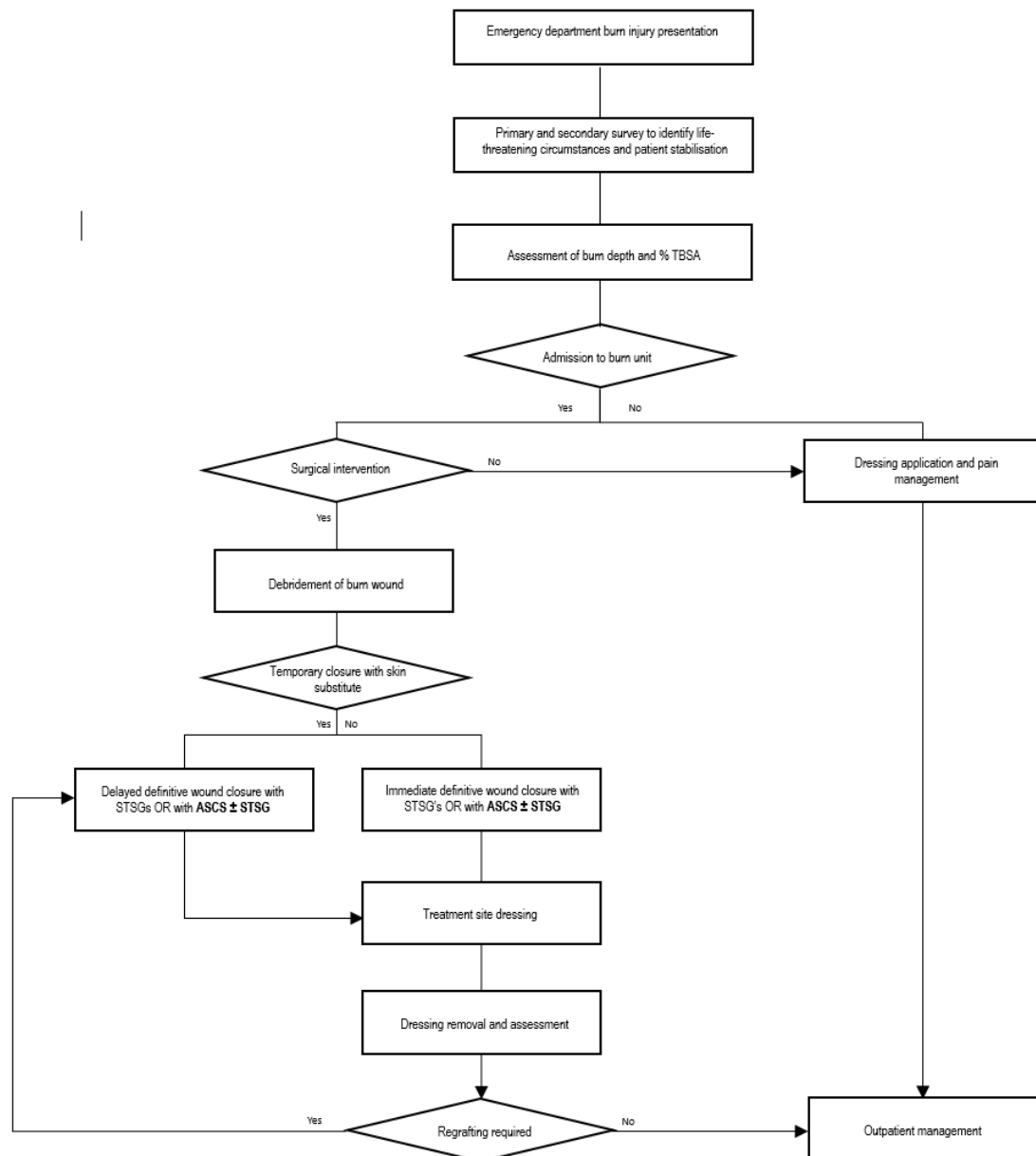
Depending on the clinical needs of the patient and burn severity, ASCS could be used as a replacement for, or in conjunction with, STSG. For DPT burns, ASCS is expected to replace or be used alongside STSG, whereas for FT burns, ASCS would be used in addition to STSG in most cases. A modifier MBS item (Table 4) is proposed for cases where ASCS is used in conjunction with STSG, accounting for the additional clinician time required.

Due to the heterogeneous nature of burn injuries, treatment and clinical management can vary significantly on a case-by-case basis, and clinical management guidelines often differ between burn units. A summary of the current and proposed clinical management guidelines is presented in Figure 1.

The content of the summarised clinical management algorithm was appropriate and consistent with current clinical burn management guidelines.

³ Burns Registry of Australia and New Zealand, 2024, Annual Report 2022–2023.

Figure 1: Summarised clinical management algorithm



Abbreviations: ASCS = autologous skin cell suspension; STSG = split-thickness skin graft; TBSA = total body surface area
 Note: The figure summarises the proposed and current clinical management guidelines; **bolded** text denotes the proposed intervention.

This application progressed through the expedited MSAC pathway on the recommendation of the Department, thereby bypassing PASC. As such, there was no PICO confirmation against which to compare the PICO presented by the applicant.

Throughout the ADAR, the population was defined as adult and paediatric patients with FT and/or DPT burn wounds $\geq 20\%$ TBSA. However, in the PICO criteria (Table 5), this was stated as 'adult and paediatric patients with FT and DPT burn wounds $\geq 20\%$ TBSA.' The commentary considered this definition may make the population unclear, as a patient may have either FT or DPT burns, or a combination of the two.

According to the ADAR, the target population was identified through consultation with key opinion leaders, who defined this population as that of highest clinical need for treatment with ASCS. Consultation feedback received during development of the commentary identified that the

greater the TBSA burn, the more likely skin grafting procedures would be required. Larger burns also have a greater impact on the availability of donor skin, so other treatment strategies may be needed such as wide meshing and cell supplementation or the use of a dermal substitute/cadaveric skin.

The commentary also notes conflicting information in the literature regarding what was classified as a severe burn in paediatric patients. Input from a clinician suggests >10% TBSA in paediatric patients can be classified as severe burn, as paediatric patients have a smaller surface area than adults, and require fluid resuscitation from this point onwards to prevent hypovolaemic shock.

8. Comparator

The comparator proposed in the ADAR was STSG without ASCS. STSG is currently the standard of care for treatment of severe burns, therefore the commentary considered the choice of comparator to be appropriate.

STSGs involve harvesting a thin slice of the patient's skin from a healthy donor site, including epidermal and dermal tissue. The donor skin is then placed over the burn wound and joined to the surrounding skin. For smaller burns, sheet grafts are used, which require a 1:1 ratio of donor skin to graft site. For larger burns, there may be insufficient donor area available, in which case, techniques such as meshed and meek STSGs can be used to expand the donor skin to cover a larger area without harvesting more donor skin. For example, in large %TBSA burns, meshed STSGs are used, which involves making slits in the donor skin allowing the skin to extend (2–3 or more times). The wider the mesh, the more likely are poorer cosmetic outcomes.

In some cases of delayed wound closure, STSGs are used after skin substitutes have allowed for tissue regeneration. Skin substitutes provide coverage of avascular structures that would otherwise not sustain a graft. Skin substitutes may also be used for temporary coverage to allow for staging before treatment for primary closure with STSGs. Therefore, STSGs are used in a delayed setting commonly for either regrafting after initial skin grafting fails or is insufficient, or in cases where temporary skin substitutes have been used for initial wound management and a follow-up procedure using STSGs may be used for definitive wound closure.

STSG is currently funded on the MBS for immediate definitive (MBS items 46117–46124) and delayed definitive (MBS items 46134, 46135) wound closure of burns with defect areas $\geq 20\%$ TBSA (Table 6).

Table 6: MBS items for immediate and delayed wound closure of burns with defect areas $\geq 20\%$ total body surface area

Description	MBS Item number	Total body surface area of defect	Listing date
Immediate definitive closure items			
Excised burn wound closure if the service:	46117	20% or more but less than 30%	1 July 2023
(a) is performed at the same time as the procedure for the primary burn wound excision; and	46118	30% or more but less than 40%	1 July 2023
(b) involves:	46119	40% or more but less than 50%	1 July 2023
(i) autologous skin grafting for definitive closure; or	46120	50% or more but less than 60%	1 July 2023
(ii) allogenic skin grafting, or biosynthetic skin substitutes, to temporise the excised wound;	46121	60% or more but less than 70%	1 July 2023
excluding aftercare (H)	46122	70% or more but less than 80%	1 July 2023
	46123	80% or more	1 July 2023
Excised burn wound closure of whole of face, if the service:	46124	whole of face	1 July 2023
(a) is performed at the same time as the procedure for the primary burn wound excision; and			
(b) involves:			
(i) autologous skin grafting for definitive closure; or			
(ii) allogenic skin grafting, or biosynthetic skin substitutes, to temporise the excised wound;			
excluding aftercare, other than a service associated with a service to which item 46100 applies (H)			
Delayed closure items			
Definitive burn wound closure, or closure of skin defect secondary to necrotising fasciitis, using autologous tissue (split skin graft or other) following previous procedure using non-autologous temporary wound closure, excluding aftercare (H)	46134	20% or more but less than 30%	1 July 2023
	46135	30% or more	1 July 2023

Abbreviations: H = indicates hospital-based aftercare

9. Summary of public consultation input

Consultation input was welcomed from:

1801 – Autologous Skin Cell Suspension for the treatment of acute burn wounds in paediatric and adult patients (Health Technology Analysts Pty Limited on behalf of AVITA Medical, Inc)	No. of Inputs Received
Organisations (2)	
I am providing input on behalf of a medical, health, or other (non-consumer) organisation. For example, input on behalf of a group of clinicians, research organisation, professional college, or from an organisation that produces a similar service or technology.	2
Health Professionals (5)	
I am a health professional or health academic working in the area.	5
Consumers (1)	
I have the health condition that this health service or technology is for and have experience with the proposed health service or technology.	1
Grand Total	8

The organisations that submitted input were:

- Australian & New Zealand Burn Association (ANZBA)
- Australian Society of Plastic Surgeons (ASPS).

Level of support for public funding

All respondents were supportive of the public funding of this application. ASPS noted its support on the basis that allocation of an MBS item number is the most appropriate way of supporting the adoption of this technology without endorsing a specific commercial product.

Comments on PICO

- A health professional stated that anyone with a burn of more than >20% total body surface area (TSBA) would benefit from autologous cells, and noted the proposed population as not too broad, suggesting it should be used for any burns over 10% TBSA, especially children. Two other health professionals noted the proposed eligible population as appropriate.
- Four health professionals noted the proposed approach as appropriate.
- A health professional stated there is no comparison for autologous cells, with allografts being a temporary measure, and leading to an inflammatory response. Another stated the comparators are traditional methods of skin grafting currently used. Two others noted the comparator(s) as appropriate.
- A health professional noted clinical outcomes as correct. Two others described them as 'straightforward' and 'honest', and 'clear' and 'appropriate', respectively.
- One health professional noted their lack of qualifications to determine costs and fees, but stated the proposed fee appeared appropriate. Another suggested the fee was reasonable and allows facilities to appropriately recover some costs for equipment, whereas other current funding schemes do not. Another health professional expressed support for the proposed fee.

Perceived Advantages

- An individual with experience with this technology (with 50% TBSA) described it as 'amazing' in reducing scarring and the need for a skin graft, describing the areas where the technology was used as 'almost undetectable'.

- A health professional noted autologous cells will heal the site quicker, produce less pain, and allow re-harvest quicker, all of which are potentially life-saving in burn victims.
- A health professional noted its use as easy, accessible, and quick.
- Another health professional noted the introduction of this technology in their state was associated with a decrease in hospital admission length.
- A health professional noted smaller donor site and better colour-matched scar, and echoed the sentiments of other health professionals.
- Another health professional noted the following benefits: reduced donor site size; reduced donor site pain; reduced frequency of dressing changes; reduced time of wound healing; reduction in rate of secondary reconstructive procedures after acute burn surgery; improved scar quality; and improved scar pain and itch.
- A health professional noted that a significant proportion of burn inpatients are First Nations patients, or those with disabilities. Another noted that this technology is unique in its capacity to provide acute and reconstructive wound treatments which match skin colour and functionality, therefore, is applicable for all ethnicities and skin types, including First Nations people.
- ANZBA noted the technology decreases wound healing time.

Perceived Disadvantages

- ASPS stated that the results for autologous skin cell suspension are highly variable and dependent on the operator but noted recent advancements in its technology may improve its reliability.

Support for Implementation and Issues

- A health professional noted there would be no issues with implementation, with training of surgeons considered 'easy'.
- Another health professional stated that as the technology is already in use, there would be no barriers to implementation as training, clinical, and administrative systems are already in place for its current and ongoing use.

10. Characteristics of the evidence base

The ADAR is based on 2 multicentre randomised controlled trials (RCTs) (CTP001-5 and CTP001-6) (Table 7). Both RCTs comprise a small number of patients and do not report all the outcomes specified in the PICO criteria. In addition, the included patients are only somewhat representative of the MBS proposed population: one RCT (CTP001-5) does not report on burn sizes relevant to the MBS proposed population ($\geq 20\%$ TBSA) and the other (CTP001-6) includes patients with burns covering 5–50% TBSA, although it is unclear what proportion of patients have burns that match those of the MBS proposed population ($\geq 20\%$ TBSA). Consequently, additional studies were provided as supportive evidence. These included retrospective subgroup analyses of a single-arm compassionate use study (CTP004) and 2 continued access protocols: an RCT (CTP001-7) that continued from the CTP001-6 RCT and a single-arm study (CTP001-8) that continued from the CTP001-7 RCT (Table 8). However, the CTP001-7 RCT had a patient sample somewhat representative of the MBS patient population and should have been included in the ADAR as primary clinical evidence alongside the CTP001-6 RCT (Table 7).

Table 7: Key features of direct level II evidence comparing ASCS with STSG

Reference	N	Design/duration/follow-up length	Risk of bias ^a	Patient population	Comparison	Outcome(s)	Use in modelled evaluation
CTP001-5	101	Within-patient controlled multicentre RCT 21 May 2010–26 August 2015 Follow-up: 52 weeks	Some concerns	Adults (18–65 years) with 1–20% TBSA acute DPT thermal burns requiring autografting for definitive closure <i>Mean age (SD):</i> 39.5 (13.1); range 18.2–63.5 <i>Male sex:</i> 84% <i>Mean TBSA (SD):</i> 10.0% (SD 4.5). range 3–20 <i>Mean Baux score (SD):</i> not reported	<i>Intervention:</i> ASCS <i>Comparator:</i> meshed STSG (2:1 ratio)	Primary: incidence of wound closure ($\geq 95\%$ re-epithelialisation) of treated sites at 4 weeks; incidence of complete donor site healing at 1 week (100% re-epithelialisation) Secondary: pain, visual appearance, scarring at treatment and donor sites	No
CTP001-6	30	Within-patient controlled multicentre RCT 26 January 2015–1 February 2017 Follow-up: 52 weeks	Some concerns	Patients aged ≥ 5 years with 5–50% TBSA, acute mixed-depth/full thickness burns <i>Mean age (SD):</i> 39.1 (15.8) <i>Male sex:</i> 83% <i>Mean TBSA (SD):</i> 21.0% (SD 13) <i>Mean Baux score (SD):</i> not reported	<i>Intervention:</i> ASCS + meshed STSG <i>Comparator:</i> meshed STSG	Primary: confirmed treatment area closure prior to or at week 8; comparison of expansion ratios Secondary: patient satisfaction with Patient and Observer Scar Assessment Scale	No
CTP001-7 ^b	12	Within-patient controlled multicentre RCT October 2016–September 2018 Follow-up: 52 weeks	Some concerns ^c	Patients aged ≥ 5 years with 5–50% TBSA, acute burns requiring skin grafting <i>Mean age (SD):</i> 43.6 (12.9) <i>Male sex:</i> 92% <i>Mean TBSA (SD):</i> not reported <i>Mean Baux score (SD):</i> not reported	<i>Intervention:</i> ASCS + meshed STSG <i>Comparator:</i> meshed STSG	Primary: confirmed treatment area closure prior to or at week 8; comparison of expansion ratios Secondary: mortality, adverse events	No

Abbreviations: ASCS = autologous skin cell suspension, DPT = deep partial-thickness, RCT = randomised controlled trial, SD = standard deviation; STSG = split-thickness skin graft; TBSA = total body surface area.

Notes:

a = Assessed with Cochrane Risk of Bias tool v2.0

b = Included as supportive evidence by the applicant. Since the reasoning for this was not provided in the report, the study was included as primary clinical evidence by the assessment group.

c = Assessed by the assessment group

Source: CTP001-5: Holmes et al. (2015)⁴, CTP001-6: Holmes et al. (2019)⁵; CTP001-7: ClinicalTrials.gov (2024)⁶

Results from the single-arm studies (CTP004 and CTP001-8) were compared with matched cohorts from the USA 2012 National Burn Repository (NBR) version 8.0 dataset and the control arm of RCT CTP001-6. These indirect retrospective comparisons (level III-3 evidence) evaluated clinical outcomes separately for adults (≥ 18 years) with burn injuries $>50\%$ TBSA (data from

⁴Holmes IV, JH, Molnar, JA, Carter, JE, Hwang, J, Cairns, BA, King, BT, Smith, DJ, Cruse, CW, Foster, KN, Peck, MD, Sood, R, Feldman, MJ, Jordan, MH, Mozingo, DW, Greenhalgh, DG, Palmieri, TL, Griswold, JA, Dissanaik, S & Hickerson, WL 2018, 'A Comparative Study of the ReCell® Device and Autologous Split-Thickness Meshed Skin Graft in the Treatment of Acute Burn Injuries', *J Burn Care Res*, vol. 39, no. 5, pp. 694-702.

⁵Holmes, JH 4th, Molnar, JA, Shupp, JW, Hickerson, WL, King, BT, Foster, KN, Cairns, BA & Carter, JE 2019, 'Demonstration of the safety and effectiveness of the RECELL® System combined with split-thickness meshed autografts for the reduction of donor skin to treat mixed-depth burn injuries', *Burns*, vol. 45, no. 4, pp. 772-82.

⁶ClinicalTrials.gov 2024. 'CONTINUED ACCESS PROTOCOL: Demonstration of the Safety and Effectiveness of ReCell® Combined with Meshed Skin Graft for Reduction of Donor Area in the Treatment of Acute Burn Injuries', viewed 16 March 2025 <https://clinicaltrials.gov/study/NCT02994654>.

CTP004) and for paediatric patients (<18 years) from the CTP004 and CTP001-8 studies (Table 8).

Table 8: Key features of supportive indirect level III evidence comparing ASCS with STSG

Reference ^a	ASCS treated cohort	NBR comparator cohort	CTP001-6 control group	Propensity score stratification ^c	Outcome(s)	Use in modelled evaluation
CTP004 retrospective analysis	Single-arm study n=49 Adults (≥18 years) with burn injuries >50% TBSA <i>Treatment:</i> ASCS + meshed STSG <i>Mean age (SD):</i> 37.9 (11.9) <i>Male sex:</i> 74% <i>Mean TBSA (SD):</i> 65.6% (SD 11.2) <i>Mean Baux score (SD) ^d:</i> 110.1 (19.8)	Registry data n=277 Adults (≥18 years) with burn injuries >50% TBSA <i>Treatment:</i> standard of care <i>Mean age (SD):</i> 39.6 (13.0) <i>Male sex:</i> 76% <i>Mean TBSA (SD):</i> 61.9% (SD 10.1) <i>Mean Baux score (SD) ^d:</i> 107.6 (17.4)	Control arm of RCT n=28 Adults (≥18 years) with burn injuries 5–50% TBSA <i>Treatment:</i> meshed STSG <i>Mean age (SD):</i> 41.1 (14.3) <i>Male sex:</i> 82% <i>Mean TBSA (SD):</i> 20.3% (SD 12.5) <i>Mean Baux score (SD) ^d:</i> 62.0 (19.5)	<i>NBR cohort:</i> no statistically significant differences in age, gender, %TBSA or Baux score after adjustment. <i>CTP001-6 cohort:</i> no statistically significant differences in age or gender; mean %TBSA and Baux score significantly higher for ASCS cohort after adjustment (p<0.0001 for both).	Healing by week 8, incidence of specific treatment-related AEs, number of autograft treatments to achieve definitive closure, hospital length of stay, mortality.	No
CTP004/CTP001-8 ^b retrospective analysis	Combined data from 2 single-arm studies n=39 (29 from CTP004; 10 from CTP001-8) <i>CTP004:</i> patients aged <18 years with life-threatening burn injuries <i>CTP001-8:</i> patients aged <18 years with burn injuries 5-50% TBSA <i>Treatment:</i> ASCS + meshed STSG <i>Mean age (SD):</i> 7.1 (4.9) <i>Male sex:</i> 46% <i>Mean TBSA (SD):</i> 40.1% (SD 19.2) <i>Mean Baux score (SD) ^d:</i> 50.3 (24.4)	Registry data n=245 Patients aged ≤16 years with burn injuries ≥8% TBSA <i>Treatment:</i> standard of care <i>Mean age (SD):</i> 8.7 (5.0) <i>Male sex:</i> 73% <i>Mean TBSA (SD):</i> 28.1% (SD 15.5) <i>Mean Baux score (SD) ^d:</i> 39.3 (17.0)	Control arm of an RCT n=30 Patients aged ≥5 years with burn injuries 5-50% TBSA (2 patients <18 years) <i>Treatment:</i> meshed STSG <i>Mean age (SD):</i> 39.1 (15.8) <i>Male sex:</i> 83% <i>Mean TBSA (SD):</i> 21.0% (SD 13) <i>Mean Baux score (SD):</i> not reported	<i>NBR cohort:</i> no statistically significant differences in age, gender, Baux score; mean %TBSA significantly higher for ASCS cohort (p=0.0439) after adjustment. <i>CTP001-6 control group:</i> not conducted as no formal comparisons performed between treatment groups.	Healing by week 8, incidence of specific treatment-related AEs, number of autograft treatments to achieve definitive closure, hospital length of stay, mortality.	No

Abbreviations - AE = adverse event, DPT = deep-partial thickness; NBR = National Burn Repository, RCT = randomised controlled trial, SD = standard deviation; TBSA = total body surface area.

Notes

a = As these studies were provided as supporting evidence, no quality appraisals were undertaken

b = CTP001-7 evaluated the same primary endpoints as CTP001-6 but was underpowered. The study design was subsequently transitioned to a single-arm format without a comparator, leading to protocol CTP001-8.

c = Propensity scores were derived from a logistic regression model adjusting for age, gender, %TBSA and Baux score. For the CTP001-4/CTP001-8 retrospective analysis, %TBSA and Baux score were not included in the model for the CTP001-6 cohort due to the lack of overlap in %TBSA between treatment groups.

d = Higher scores indicate a greater risk of complications and death

Source - CTP001-4 retrospective analysis: Attachment 2.4 RECELL® For Treating Adult Patients with Greater than 50% Total Body Surface Area Burns; CTP001-4/CTP001-8 retrospective analysis: Attachment 2.5 RECELL® For Treatment of Paediatric Patients with Acute Burn Injuries

Methodological considerations

Study selection and data extraction

The selection of databases searched was adequate, and the search strategies were broad enough to capture any relevant published literature. However, it was unclear whether conference proceedings and other grey literature sources (including the International Network of Agencies for Health Technology Assessment [INAHTA] HTA database) were searched. Searches were conducted in the applicant's trials repository, and the reference lists of retrieved studies were hand-searched.

Very few details were reported regarding the study selection and data extraction processes. The publication date of the included studies was limited to those included in and published after the 2019 NICE review update. While this means that studies published prior to 2014 were not included in the ADAR, this was appropriate, since the most recent iteration of RECELL® (ARTG ID: 338864) has been commercially available only since 2015.

Limiting study eligibility to comparative studies for the effectiveness and safety outcomes is appropriate, given the clinical claims of superior donor-site sparing and non-inferiority in terms of wound closure and safety, compared with conventional burn management. However, the study selection process was not accurately documented, and the listed study selection criteria were not uniformly applied. The number of studies included in the review should be 10 (5 clinical and 5 economic studies) rather than 23 (18 clinical and 5 economic studies) for the following reasons:

- 11 of the clinical studies comprised retrospective case reports and retrospective analyses of interim data from the CTP004, CTP001-7 and CTP001-8 trials (included as supportive evidence), which would have been better listed among the excluded studies as duplicate or superseded publications
- 7 publications contributed data for the 5 studies included as primary clinical evidence (when there are multiple publications for a single study it is advisable to note this distinction in the PRISMA diagram to avoid confusion).

Synthesis of evidence

Direct comparisons

Although the PICO focuses on the treatment of severe burns with $\geq 20\%$ TBSA, the ADAR included 'broader clinical evidence on ASCS for all burn injuries' because 'patients with burns exceeding 20% TBSA may receive ASCS alone or in combination with STSGs, even when individual areas treated with ASCS are smaller than 20%.' As a result, one of the two included pivotal RCTs (CTP001-5) does not report on burn sizes relevant to the MBS proposed population (i.e. $\geq 20\%$ TBSA). To maintain consistency with the PICO criteria, the CTP001-5 study should have been either excluded from review or provided as supportive clinical evidence only. The other RCT (CTP001-6) includes patients with burns covering 5–50% TBSA, although it was unclear what proportion of patients in this study have burns that match those of the MBS proposed population ($\geq 20\%$ TBSA).

The rationale of including studies in patients with smaller burns ($< 20\%$ TBSA) than the MBS proposed population disregards the fact that severe burns are accompanied by significant adverse systemic effects, such as hyperinflammation, immune dysfunction, metabolic

dysregulation and vasodilatory shock, some of which remain for several years after the injury.^{7,8} These effects would likely interfere with wound healing and other outcomes in these patients, potentially even in individual areas of more superficial burns. Therefore, results from studies where most patients have burns covering <20% TBSA cannot be reasonably generalised to the MBS proposed population with severe burns ($\geq 20\%$ TBSA).

The proportion of females in the CTP001-5, CTP001-6 and CTP001-7 studies was 16%, 17% and 8%, respectively, which is much lower than that in the MBS proposed population. For example, the proportion of females in the MBS proposed population who received the relevant services (MBS items 46117–46123, 46134, 46135) in the 2-year period January 2023 to December 2024 was 45% (31/69).⁹ This is an important difference, given that women in Australia are more likely to have worse outcomes and are nearly 2.5 times more likely to die following a burn injury than men, independent of other risk factors.¹⁰

Indirect comparisons

The USA 2012 NBR version 8.0 dataset, used as the control sample for the indirect comparative analyses, was chosen because it was the most up-to-date version available for analysis. However, this dataset contains data collected from 2002 to 2011. A recent report suggested that changes in burn management that have occurred since 2011 in the USA make the 2012 NBR dataset outdated. This may skew the data in favour of the intervention. For example, since the 2012 NBR data were collected, there has been an overall reduction in the number of autografting procedures per %TBSA burned, and the average surgical time for both graft and donor sites has decreased as the burn size increased. Additionally, burn care costs have increased significantly.¹¹

Propensity score stratification was used to adjust for confounding in the retrospective analyses. The model used logistic regression, with 'treatment group' as the outcome and baseline variables of age, gender, %TBSA and Baux score as the predictors. Patients from both treatment groups were categorised into 5 groups based on the calculated propensity scores, and stratification was deemed adequate if p-values were >0.05 for the 4 characteristics. The use of propensity score (PS) stratification using widely recognised predictors (age, gender, %TBSA, Baux score) for specific burn wound outcomes was appropriate, given the imbalanced and non-contemporaneous treatment groups.

11. Comparative safety

The main safety outcomes in the ADAR are based on 2 multicentre RCTs (CTP001-5, CTP001-6). However, as discussed in Section 7, patients in RCT CTP001-5 are not representative of the MBS proposed population. Therefore, the main safety outcomes discussed in the commentary are

⁷ Jeschke, MG, van Baar, ME, Choudhry, MA, Chung, KK, Gibran, NS & Logsetty, S 2020, 'Burn injury', *Nat Rev Dis Primers*, vol. 6, no. 1, p. 11.

⁸ Nielson, CB, Duethman, NC, Howard, JM, Moncure, M & Wood, JG 2017, 'Burns: Pathophysiology of Systemic Complications and Current Management', *J Burn Care Res*, vol. 38, no. 1, pp. e469-e81.

⁹ Services Australia 2025, *Medicare Item Reports*, viewed 13 March 2025, https://medicarestatistics.humanservices.gov.au/statistics/mbs_item.html.

¹⁰ Moore, EC, Pilcher, D, Bailey, M & Cleland, H 2014, 'Women are more than twice as likely to die from burns as men in Australia and New Zealand: an unexpected finding of the Burns Evaluation And Mortality (BEAM) Study', *J Crit Care*, vol. 29, no. 4, pp. 594-8.

¹¹ Carter, JE, Amani, H, Carter, D, Foster, KN, Griswold, JA, Hickerson, WL, Holmes, JH, Jones, S, Khandelwal, A, Kopari, N, Litt, JS, Savetamal, A, Shupp, JW, Sood, R, Ferrufino, CP, Vadagam, P, Kowal, S, Walsh, T & Sparks, J 2022, 'Evaluating Real-World National and Regional Trends in Definitive Closure in U.S. Burn Care: A Survey of U.S. Burn Centers', *J Burn Care Res*, vol. 43, no. 1, pp. 141-8.

from the CTP001-6 and CTP001-7 RCTs, which have patient samples that are partially representative of the MBS patient population (Table 9 and Table 10).

Of the 30 patients included in CTP001-6, 17 patients (57%) in each treatment group experienced adverse events, most of which were mild (27%) or moderate (37%) in severity (Table 9). There were no differences noted in the rate and severity of the prespecified safety events, which included delayed healing, infection, allergic response to trypsin (a component of the ASCS enzyme), wound durability or scars necessitating surgical intervention. There was one patient death reported, which was deemed to be due to the patient's underlying condition rather than treatment related.

Table 9: Key safety outcomes in CTP001-6 up to 52 weeks after treatment

Prespecified selected safety events	ASCS + STSG, n (%) n=30	STSG (control), n (%) n=30
Number of subjects experiencing AE ^a	17 (57%)	17 (57%)
Delayed healing	1 (3.3%)	3 (10%)
Infection	0 (0%)	2 (7%)
Allergic response to trypsin	0 (0%)	N/A
Wound durability ^b	0 (0%)	0 (0%)
Scars necessitating surgical intervention ^c	1 (3%)	1 (3%)

Abbreviations: AE = adverse event; ASCS = autologous skin cell suspension; N/A = not applicable; STSG = split-thickness skin graft.
Source: Holmes et al. (2019)⁵

^a Not all adverse events listed in table

^b In turns of recurrent wound breakdown following initial complete closure

^c Patient also underwent surgical intervention for scar at non-study sites

Of the 12 patients enrolled in CTP001-7, 2 (16.7%) experienced severe adverse events (SAEs) comprising a failed skin graft (1 from ASCS-treated injury and 1 from STSG-treated injury) and delayed wound healing (Table 10). Most of the other adverse events (AEs) were injury or procedural complications. No patient deaths were reported.

Table 10: Key safety outcomes in CTP001-7 up to 52 weeks after treatment

Prespecified selected safety events, n (%)	ASCS + STSG, n (%) n=12	STSG (control), n (%) n=12
Number of subjects experiencing AEs ^a	6 (50%)	2 (17%)
Delayed healing	2 (17%)	0 (0%)
Failed skin graft	2 (17%)	0 (0%)
Graft loss	1 (8%)	1 (8%)

Abbreviations: AE = adverse event; ASCS = autologous skin cell suspension; N/A = not applicable; STSG = split-thickness skin graft.
Source: ClinicalTrials.gov (2024)⁶

^a Not all adverse events listed in table

The ADAR provided safety data from the CTP001-5 RCT that included patients with deep partial-thickness burns covering 1-20% TBSA (n=101). These results have not been tabulated in this summary because they are not generalisable to the MBS proposed population. In brief, in RCT CTP001-5, more AEs occurred with ASCS alone compared with STSG treatment (35.6% vs 21.8%, $p = 0.0013$), although most events were mild in severity. No patient deaths were reported. There were no differences in the incidence of AEs between ASCS and STSG donor sites. There were 5 device-related AEs reported (2 mild skin graft failures and hypertrophic scarring), although the AEs related to the scarring were not related to the study device itself.

Interpretation and limitations of the safety data

The main safety data considered in the commentary were derived from 2 small RCTs (CTP001-6, CTP001-7) (low certainty evidence) (Table 11). Both trials included patients with burns covering 5–50% TBSA (mean of 21% in the larger trial; not reported for the smaller trial), so it was unclear how many patients had burns <20% TBSA. In addition, the proportion of females included was very low (8–17%), which is not representative of the potential MBS population.

Overall, the results indicate that ASCS in combination with meshed STSG is as safe as meshed STSG alone in this particular patient group up to one year after treatment. However, the small sample sizes and low frequency of key safety outcomes raise doubts about the precision of this finding. None of the studies reported significant adverse events specifically attributable to the use of the RECELL device.

The ADAR also cited as primary evidence an RCT (CTP001-5; n=101) comparing ASCS and meshed STSG in patients with burns covering up to 20% TBSA. The results from this study agreed with those of the other 2 RCTs for safety outcomes, but they cannot be used to form any definitive conclusions with respect to the MBS proposed population.

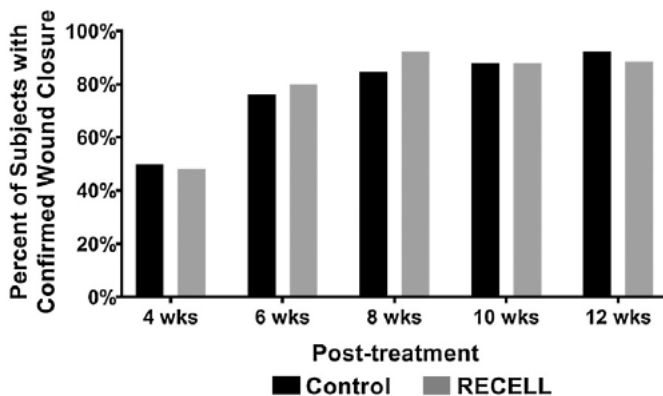
12. Comparative effectiveness

The main effectiveness outcomes in the ADAR are based on 2 multicentre RCTs (CTP001-5, CTP001-6). However, as discussed in Section 7, the patients in RCT CTP001-5 are not representative of the MBS proposed population. Therefore, the main effectiveness outcomes discussed in the commentary are from the CTP001-6 and CTP001-7 RCTs, which have patient samples partially representative of the MBS patient population (Table 7 and Table 8).

Definitive closure of treatment site

In CTP001-6, confirmed treatment area definitive closure by week 8 was defined as complete skin re-epithelialisation without drainage. Wound closure was evaluated from week 4 through week 12. The proportion of patients with confirmed wound closure was similar between the ASCS plus STSG and STSG treatments at all time points (n=26) (Figure 2). By week 8, definitive closure had been achieved in 92% of patients in the ASCS treatment arm and in 85% in the control group. Thus, the healing of ASCS-treated sites was non-inferior to that of the STSG sites. The difference in proportion between the two treatments was –7.7% (97.5% confidence interval [CI] 6.40%).

Figure 2: Proportion of patients with confirmed wound closure by treatment area at weeks 4–12 in CTP001-6 ⁵



The ADAR also provided data from the CTP001-5 RCT, which included patients with deep partial-thickness burns covering 1–20% TBSA. In brief, definitive closure was achieved at 4 weeks in 97.6% (81/83) of the ASCS-treated sites and 100% (83/83) of the STSG-treated sites.

Reduction of donor skin harvesting

In CTP001-6, the expansion ratios of the measured treated area to the donor site area were compared for each treatment, including both initial treatments and any re-treatments (n=30). The average donor site areas for ASCS plus meshed STSG and STSG alone were 264 cm² and 368 cm², respectively, which represented a 32% reduction in donor skin requirement (p<0.001). A geometric mean ratio (GMR) >1 was needed to establish ASCS superiority. The GMR for treatment areas compared to donor sites was 1.97 for ASCS plus STSG and 1.35 for STSG alone. The GMR of the expansion ratio (ASCS:STSG) was 1.46, confirming the superiority of ASCS in reducing donor skin usage (p<0.001).

CTP001-7 RCT also reported expansion ratios for ASCS plus meshed STSG and STSG alone (n=12). The GMR for treatment areas compared to donor sites was 2.11 for ASCS plus STSG and 1.65 for STSG alone, representing a GMR of the expansion ratio (ASCS:STSG) of 1.28.⁶

The ADAR also provided data from RCT CTP001-5 that included patients with deep partial-thickness burns covering 1–20% TBSA. The average area of the donor sites used for ASCS alone was approximately 40 times smaller than the average area used for the STSG treatment in DPT burns (4.7 cm² vs 194.1 cm², p<0.0001), which represented a donor site reduction of 97.5% (n=83). Consequently, at week 2, donor wound healing was better at the ASCS donor site (90.0% vs 67.3%, p<0.001).

Pain, visual appearance and scarring

In CTP001-6 (n=30), there was no statistically significant difference in patient satisfaction regarding treatment preference, scarring outcome or Patient and Observer Scar Assessment Scale (POSAS) patient and observer scores or overall opinions. Pain ratings assessed with the pain question of POSAS indicated no difference between ASCS plus meshed STSG and STSG alone in treatment area pain from week 1 to week 12 and at week 52. There was also no statistically significant difference in wound healing in either blinded and non-blinded assessments at any study visit in either the intent-to-treat or per protocol population.

The ADAR also provided data from RCT CTP001-5 that included patients with deep partial-thickness burns covering 1–20% TBSA. There was no difference in pain between ASCS and STSG sites (15 weeks) or in patient satisfaction with appearance or scarring (52 weeks). Pain at the

donor site was significantly lower at the ASCS donor site compared with the STSG donor site through to week 8 ($p \leq 0.005$).

Number of autograft treatments to achieve definitive closure

A retrospective indirect comparison between adults (≥ 18 yrs) from a cohort of 41 patients who received ASCS plus meshed STSG (CTP004) and 277 adults from the NBR who received standard care found that the former required a median of 2.0 (range 1.0–6.0) autografts to achieve definitive closure, compared with a median of 5.0 (range 1.0–32.0; propensity-adjusted $p < 0.0001$) in the latter group. All patients had severe burns ($> 50\%$ TBSA).

A similar comparison in paediatric patients (< 18 years) found that the ASCS group (CTP004/CTP001-8; $n=39$) required a median of 1.0 treatment, compared with 2.0 for the NBR standard care cohort ($n=245$; propensity-adjusted $p < 0.0001$). Mean %TBSA was significantly higher in the CTP004/CTP001-8 paediatric group (40.1% vs 28.1%, $p=0.0439$) compared with the NBR paediatric cohort.

Comparing data from the CTP004 and CTP001-8 studies with that of the 2012 NBR may favour the intervention, particularly with respect to number of autografting procedures, as there has been an overall reduction in the number of these procedures per %TBSA burned since 2011.¹¹ In contrast, the significantly higher mean %TBSA in the CTP004/CTP001-8 paediatric group, compared with the NBR paediatric cohort, likely favours the control group. It is unclear whether or to what extent these 2 potentially opposing confounders affected this outcome.

Hospital length of stay

The CTP004/CTP001-8 studies and the NBR were compared for length of hospital stay (LOS). In adults with severe burns ($> 50\%$ TBSA) the median LOS per %TBSA was 1.2 days in both the ASCS plus meshed STSG ($n=40$; propensity-adjusted $p=0.602$) and standard care groups ($n=277$). For the paediatric cohort, the median LOS per %TBSA was 1.7 days for the ASCS cohort ($n=39$) and 1.2 days for the NBR standard care cohort ($n=245$; propensity-adjusted $p=0.999$).

These data are limited by the problems noted in the previous section, as well as the various factors other than age, gender, %TBSA and Baux score that can affect LOS in severely burned patients, such as the treating physician and local institutional protocols. These could not be controlled for in this analysis.

Interpretation and limitations of the effectiveness data

The main effectiveness data considered in the commentary are derived from 2 small RCTs (CTP00-6, CTP00-7) (low certainty evidence) (Table 11). Both trials included patients with burns covering 5–50% TBSA (mean of 21% in the larger trial; unreported for the smaller trial), so it was unclear how many patients had burns $< 20\%$ TBSA. In addition, the proportion of females included was very low (8–17%), which was not representative of the potential MBS population.

Overall, the results indicate that ASCS in combination with meshed STSG in this particular patient group was equivalent to STSG alone in achieving wound closure 8 weeks after grafting, while requiring an average 32% less donor skin for grafting and causing no differences in patient satisfaction, scarring outcome or pain over the year following treatment.

Supportive clinical evidence from an indirect comparison of ASCS plus meshed STSGs and standard care in adults with burns $\geq 50\%$ TBSA indicated that the former treatment required fewer autograft procedures per patient. There was also no statistically significant difference

between the treatments in median LOS in days per %TBSA for adults ($\geq 50\%$ TBSA) or children. However, the data for these indirect comparisons had significant confounding that remained even after propensity score adjustment for key prognostic factors. These outcomes are also sensitive to contextual factors, such as treating physician and local institutional protocols, that could not be accounted for in the analysis.

The ADAR also cited as primary evidence an RCT (CTP001-5; n=101) comparing ASCS and meshed STSGs in patients with burns covering up to 20% TBSA. The results from this study agreed with those of the other 2 RCTs in terms of treatment equivalence in donor site sparing and time to wound closure outcomes, but they cannot be used to form any definitive conclusions with respect to the MBS proposed population.

Table 11: Summary of findings table for important outcomes for patients with burn wounds (5–50% TBSA)

Section in report	Outcome	Participants and studies	Relative effect (95% CI)	Anticipated absolute effects (95% CI)			Interpretation	GRADE Certainty of evidence
				ASCS + STSG	STSG	Difference		
2.4.1	Treatment site healing at week 8	n=35 (2 RCTs: CTP00-6 CTP00-7)	RR 1.05 (0.91 to 1.20)	94.3%	88.6%	44 more per 1,000 (from 80 fewer to 177 more)	ASCS + STSG may reduce or have no effect on treatment site healing (8 weeks)	⊕⊕⊕⊖ Low ^{a,b,c,d}
2.4.2	Donor site reduction	n=30 (1 RCT: CTP00-6)	-	Mean donor site size: 264 cm ² (SD 119)	Mean donor site size: 368 cm ² (SD 150)	MD 104.00 cm² lower (172.52 to 35.48 lower)	ASCS + STSG reduces donor site size	⊕⊕⊕⊖ Low ^{a,c,d}
2.3.1	Total AEs	n=42 (2 RCTs: CTP00-6, CTP00-7)	RR 1.43 (0.50 to 4.09)	54.8%	45.2%	195 more per 1,000 (from 226 fewer to 1,000 more)	ASCS + STSG may increase or have little to no effect on total AEs (52 weeks)	⊕⊕⊕⊖ Low ^{a,b,c,d}

Abbreviations: AE = adverse event; ASCS = autologous skin cell suspension; CI = confidence interval; MD = mean difference; RCT = randomised controlled trial; RR = risk ratio; SD = standard deviation; STSG = split-thickness skin graft

Notes:

^a Evaluator and patient blinded but few details on random allocation process

^b Consistent findings across studies

^c Direct comparison to standard care but population only somewhat relevant; unclear whether burn management in USA is generalisable to Australian practice

^d Small sample sizes and small number of studies; wide confidence intervals

Bolding indicates statistically significant difference between groups

The GRADE assessment provided in the ADAR included the CTP00-5 and CTP00-6 RCTs; however, the commentary focused on the CTP00-6 and CTP00-7 RCTs because they better aligned with the PICO criteria. Consequently, this GRADE assessment was conducted by the assessment group.

⊕⊕⊕⊕ **High quality:** We are very confident that the true effect lies close to that of the estimate of effect.

⊕⊕⊕⊖ **Moderate quality:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

⊕⊕⊖⊖ **Low quality:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

⊕⊖⊖⊖ **Very low quality:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

Clinical claim

The ADAR claimed non-inferior safety and effectiveness for definitive wound closure, and superior donor site sparing for ASCS treatment, compared with STSG alone.

The available direct evidence (as considered in the commentary) was of low certainty, comprising 2 small RCTs (CTP00-6, CTP00-7) of heterogeneous patient samples with limited applicability to the MBS proposed population. The analyses involving indirect comparisons between ASCS and STSG have more applicable populations but they are limited by significant confounding and report few relevant outcomes.

The very limited data available suggest that ASCS in combination with meshed STSG may be at least as effective as STSG alone in achieving definitive closure by week 8 in patients with burns covering 5–50% TBSA, while being no less safe. ASCS also significantly reduced the amount of healthy skin required for grafting. However, the patients (mostly adults) included in these studies were heterogeneous with respect to burn size and are not entirely representative of the MBS proposed population, since it is unclear how many of them had burns covering <20% TBSA. In addition, the proportion of female participants was much lower than is expected in the MBS proposed population.

13. Economic evaluation

A simple costing analysis comparing total costs of ASCS ± STSG versus STSG alone for treating patients with severe burns (≥20% TBSA) was presented in the ADAR. Alongside this the systematic search for existing economic evidence undertaken in the ADAR retrieved 6 relevant studies, all of which reported incremental costs, often alongside other incremental outcomes in a cost-consequence analysis (CCA) framework. Key clinical and resource use inputs used in the ADAR analysis (LOS; number of definitive closure procedures) were sourced from the studies retrieved via this review, rather than from clinical evidence review.

Overview of costing analysis

The costing analysis presented in the ADAR compared the total cost of ASCS ± STSG to STSG alone for the treatment of patients with severe burns (≥20% TBSA) from the perspective of the Australian healthcare system. This approach (i.e. costing analysis) was not fully aligned with the intended context. Given that the clinical claim was superiority in donor site sparing and non-inferiority in terms of effectiveness (definitive wound closure) and safety, a cost-effectiveness or cost-utility analysis would usually be recommended. Nevertheless, the ADAR reasonably concluded that such an analysis was unlikely to be informative due to the lack of robust data. As such, the evaluation for this application essentially amounts to an assessment of incremental costs. While this approach may provide insight into the potential resource use and cost implications of improved donor site sparing, it does not account for the broader impacts on patient wellbeing or long-term recovery, and results should be interpreted with this in mind.

These incremental costs could be considered alongside incremental differences in various other outcomes in a disaggregated manner (i.e. CCA). A CCA was not specifically done in the ADAR, the applicant cited differences between the Australian and American healthcare settings and a lack of data available to inform a CCA as the reason this was not done. Despite this, clinical input data sourced from US-based studies were used to inform the costing analysis presented in the ADAR (Table 12).

Table 12 : Summary of the economic evaluation

Component	Description
Perspective	Australian healthcare system perspective <i>While the ADAR indicated that a health system perspective was adopted, the base case analysis was limited in its perspective to considering only a limited number of costs to the MBS and private health insurance system.</i>
Population	Patients with severe burns covering $\geq 20\%$ TBSA who have sustained DPT and/or FT burns wounds that would require skin grafting.
Intervention	ASCS $\pm$ STSG
Comparator	STSG alone
Type of analysis	Costing analysis
Outcome	Total cost per patient
Time horizon	Index episode of hospital care
Generation of the base case	Analysed based on inputs informed by literature; costs are mainly driven by LOS and definitive closure procedure inputs.
Treatment structure	General treatment pathway for patients with severe burns $\geq 20\%$ TBSA, with results presented for each TBSA interval: 20–29%, 30–39% and 40+%. This treatment pathway aligns with the current MBS items and published literature used to inform LOS ¹² and the number of definitive closure procedures. ¹³
Discount rate	Not applicable
Software	Microsoft Excel

Abbreviations: DPT = deep partial-thickness; FT = full-thickness; LOS = length of hospital stay; STSG = split-thickness skin grafts; TBSA = total body surface area

Source: ADAR Table 30 (p63).

While the ADAR indicated a health system perspective was adopted, the base case analysis considered only a limited number of costs, which risks providing an incomplete picture of total costs per patient. Specifically, the base case analysis included MBS item costs related to wound closure, wound dressing and specialist visits, along with private hospital bed costs, but excluded ASCS device cost and other costs associated with the hospital episode of care.

Inputs of costing analysis

The base case costing analysis was developed to compare the total cost to the MBS and private health system of ASCS $\pm$ STSG versus STSG alone for the treatment of severe burns (rather than from a broader 'health care system' perspective). This analysis was driven largely by inputs for LOS and number of definitive closure procedures, sourced from Carter et al. (2022)¹² and Kowal et al. (2019)¹³, respectively. The epidemiological, clinical and cost inputs are explained in the following sections.

¹² Carter, JE, Carson, JS, Hickerson, WL, Rae, L, Saquib, SF, Wibbenmeyer, LA, Becker, RV, Walsh, TP & Sparks, JA 2022, 'Length of Stay and Costs with Autologous Skin Cell Suspension Versus Split-Thickness Skin Grafts: Burn Care Data from US Centers', *Adv Ther*, vol. 39, no. 11, pp. 5191-202.

¹³ Kowal, S, Kruger, E, Bilir, P, Holmes, JH, Hickerson, W, Foster, K, Nystrom, S, Sparks, J, Iyer, N, Bush, K & Quick, A 2019, 'Cost-Effectiveness of the Use of Autologous Cell Harvesting Device Compared to Standard of Care for Treatment of Severe Burns in the United States', *Adv Ther*, vol. 36, no. 7, pp. 1715-29.

Epidemiological and clinical inputs

The burn incidence by %TBSA was informed by Toppi et.al. (2019),¹⁴ based on data from BRANZ. These data include adult patients (aged ≥ 18 years) admitted to hospital with severe burns $\geq 20\%$ TBSA between August 2009 and June 2013.

The ADAR indicated that each device has the capacity to treat up to 10% TBSA for an average-sized adult (as described in Carter et.al. 2022)¹². For simplicity, the ADAR assumed device use based on an average-sized adult.

The ADAR acknowledges that while the proposed patient population includes both adult and paediatric patients, utilisation within paediatric patients is expected to be low. Several key inputs (burn incidence by %TBSA, LOS, number of definitive procedures, device capacity) are specific to adult cohorts, suggesting the costing analysis is, in essence, representative of per-patient costs within an adult population. While the ADAR suggested uptake among paediatric patients is expected to be low, generalisability of the costing analysis results to the paediatric population may be limited. A study by Harrison and Steel (2006)¹⁵ indicated that hospitalisation and LOS are higher for paediatric patients compared to adults.

As informed by Kowal et.al. (2019)¹³—but with further adjustments to more accurately reflect the treatment pathway for burns in Australian clinical practice—the number of definitive closure procedures for burns treated with ASCS $\pm$ STSG was based on %TBSA. It was assumed that 1 definitive closure procedure would be required for burns ranging from ≥ 20 –39% TBSA, and 2 would be required for burns $>40\%$ TBSA. For patients with STSG alone, the number of definitive closure procedures was informed by data from the American Burn Association NBR 2002–2011 (sourced indirectly from Kowal et al. 2019). Average values across both FT and DPT burns were used to estimate the number of definitive closure procedures for each %TBSA category (20–29%, 30–39%, $>40\%$). The data indicated average values of 2.92–4.09 definitive closure procedures per person, depending on %TBSA. An additional scenario with conservative estimates for the number of definitive procedures was applied for STSG in the sensitivity analysis undertaken in the ADAR (assuming 2 definitive closure procedures for burns $>20\%$ TBSA).

The base case selection may favour ASCS $\pm$ STSG, considering there has been an overall reduction in the number of autograft procedures per %TBSA burned since 2011.¹¹ Australian clinical input noted that the number of definitive closure procedures required for patients treated with STSG depends on the availability favourable donor sites, which depends on burn location. It was suggested that a burn up to 30% TBSA could be closed in 1 STSG sitting, >30 –50% TBSA would require 2 procedures, 50–60% TBSA may require 3, and $\geq 70\%$ TBSA may require 4 or more procedures (noting these are arbitrary bounds). A further sensitivity analysis was undertaken in the commentary using input data from Foster et al. (2021),¹⁶ which reflects more updated data than that selected for the base case. These data indicated average values of 2.00–3.40 definitive closure procedures per person, depending on %TBSA.

The average LOS was sourced from a US-based study,¹² which analysed electronic medical records from 500 facilities from January 2019 to August 2020. This is considered reasonable, as the study assessed costs and LOS among patients treated with ASCS $\pm$ STSG compared to STSG

¹⁴ Toppi, J, Cleland, H & Gabbe, B 2019, 'Severe burns in Australian and New Zealand adults: Epidemiology and burn centre care', *Burns*, vol. 45, no. 6, pp. 1456-61.

¹⁵ Harrison, J & Steel, D 2006, 'Burns and scalds', *NISU Briefing*, vol. 7, pp. 15pp.

¹⁶ Foster, K, Amani, A, Carter, D, Carter, J, Griswold, J, Hickerson, B, Holmes, J, Jones, S, Khandelwal, A, Kopari, N, Litt, J, Savetamal, A, Shupp, J, Sood, R, Vadagam, P, Kowal, S, Walsh, T, Sparks, J & Ferrufino, C 2021, 'Evaluating Health Economic Outcomes of Autologous Skin Cell Suspension (ASCS) For Definitive Closure in US Burn Care Using Contemporary Real-World Burn Center Data', *J Current Med Res Opinion*, vol. 4, no. 11, pp. 1042-54.

alone. In the study, patients were matched 1:1 for age, sex and %TBSA to generate comparable patient cohorts. Nevertheless, it is possible that other confounding factors may still be present. The overall confidence in these relative LOS estimates based on this retrospective review is low.

LOS varies according to %TBSA burned. Clinical advice received by the commentary group suggested that, based on experience, patients receiving STSG with 20–30% TBSA burns are likely to be discharged within 1 month, those with 30–40% TBSA burns are likely to be discharged in 1–2 months, patients with >40% TBSA generally require >2 months and patients with 70–80% TBSA burns may need prolonged hospitalisation, with discharge after 3–4 months. At a high level, these timelines align with the findings of Carter et al. (2022), indicating reasonable applicability to the Australian context. Local clinical advice did not highlight any key factors in the Australian clinical setting that might influence LOS differently from that of the Carter et al. (2022) study. However, it was noted that if trial cohort numbers are low, confounding factors such as poor social circumstances, age, comorbidities, mental health issues and complications could have a profound effect on LOS.

A summary of the epidemiological and clinical inputs used in the costing analysis are summarised in Table 13.

Table 13: Summary of epidemiological and clinical inputs used in costing analysis

Parameter	Value	Source
Incidence		
Incidence of burns per %TBSA interval	20–30% TBSA: 0.5 31–49% TBSA: 0.26 >50% TBSA: 0.24	Toppi et al. (2019) ¹⁴
Utilisation inputs		
Number of ASCS (RECELL®) devices needed	1 device per 10% TBSA	Carter et al. (2022) ¹²
Proportion of patients requiring temporary closure procedures (thus delayed definitive closure procedures)	20–29% TBSA: 0.2 (ASCS), 0.3 (STSG) 30–29% TBSA: 0.5 (ASCS), 0.75 (STSG) 40%+ TBSA: 1.0 (ASCS), 1.0 (STSG)	Expert clinical opinion
Proportion of patients requiring immediate definitive closure procedures	20–29% TBSA: 0.8 (ASCS), 0.7 (STSG) 30–29% TBSA: 0.5 (ASCS), 0.25 (STSG) 40%+ TBSA: 0.0 (ASCS), 0.0 (STSG)	Expert clinical opinion
Number of dressing procedures required	20–29% TBSA: 1.2 (ASCS), 3.2 (STSG) 30–29% TBSA: 1.5 (ASCS), 4.2 (STSG) 40%+ TBSA: 3.0 (ASCS), 5.1 (STSG)	Calculated based on clinical algorithm and usage proportions
Number of specialist consultations required	20–29% TBSA: 1.2 (ASCS), 3.2 (STSG) 30–29% TBSA: 1.5 (ASCS), 4.2 (STSG) 40%+ TBSA: 3.0 (ASCS), 5.1 (STSG)	Calculated based on clinical algorithm and usage proportions
Average LOS (days)	20–29% TBSA: 31.7 (ASCS), 27.6 (STSG) 30–29% TBSA: 27.4 (ASCS), 42.2 (STSG) 40%+ TBSA: 51.0 (ASCS), 104.5 (STSG)	Carter et al. (2022) ¹²
Number of definitive closure procedures required	20–29% TBSA: 1 (ASCS), 2.9 (STSG) 30–29% TBSA: 1 (ASCS), 3.5 (STSG) 40%+ TBSA: 2 (ASCS), 4.1 (STSG)	Kowal et al. (2019), with adjustment made to 40%+ TBSA group to assume 2 procedures required (instead of 1 procedure as reported in Kowal et al. 2019) ¹³

Abbreviations: ASCS = autologous skin cell suspension; LOS = length of hospital stay; STSG = split-thickness skin graft; TBSA = total body surface area

Source: ADAR Table 33 (pp 68-69)

Cost inputs

The cost inputs considered in the analysis included MBS item costs related to wound closure, dressing and specialist visits, hospital costs and device costs. The consideration of MBS items, including costs related to wound closure, dressing and specialist visits was reasonable. However, overall, the base case analysis considered only a limited number of cost items, including the aforementioned MBS items and private hospital bed costs of \$1,075 per day (informed by a New South Wales [NSW] Health article).¹⁷ Other costs incurred by private patients, such as theatre fees, intensive care costs, drugs, dressings and other consumables, and other MBS fees (e.g. for anaesthesia) were not included.

The ADAR presented an 'additional analysis' for which the total cost per day in hospital was informed by public hospital Australian Refined Diagnosis-Related Groups (AR-DRGs) (\$3,670.84; calculated as a simple average across items Y01Z and Y02A-C) instead of the 'bottom-up'-like approach taken in the base case. The approach taken in this supplementary analysis appears likely more relevant to the patient population (given most specialised burn treatment services are provided in public hospitals across Australia³). Also, it avoids limitations in the identification of relevant cost items, as noted in relation to the base case.

The ASCS (RECELL®) device cost (\$redacted informed by AVITA Medical) was applied in the scenario analysis; however, its exclusion from the base case analysis was inappropriate. The device price was essential in the base case analysis, as the treatment depends on the device.

The ADAR failed to incorporate AEs associated with the ASCS ± STSG and STSG alone arms, despite evidence from pivotal trials (CTP001-5, CTP001-6) reporting device-related AEs such as skin graft failure and hypertrophic scarring. As indicated in the clinical section of the commentary (Table 11), the anticipated absolute AE rate for ASCS ± STSG (54.8%) was 10% higher compared to STSG alone (45.2%). However, this finding was not significant and of low certainty (Table 11). Overall, the commentary concluded that ASCS ± STSG appears to be as safe as STSG alone, with no reported SAEs specifically attributable to use of the RECELL® device and no differences in the rate and severity of the prespecified safety events reported in the CTP001-6 study. As such, the impact of this exclusion on the incremental estimates may be limited.

A retrospective review by Elkady et al. (2024)¹⁸ (included in the ADAR's systematic review of economic literature) demonstrated a significant reduction in postoperative complications when comparing ASCS ± STSG to STSG alone in a US cohort of patients with burns ≥10% TBSA (median %TBSA 18.0 vs 16.3, respectively). The study also demonstrated reductions in LOS and number of surgical procedures associated with ASCS ± STSG but is limited by its retrospective nature. The authors attributed the reduced complications to a reduction in the number of surgical procedures and LOS, effectively minimising the risk of complications.

Results of the costing analysis

The weighted total estimated cost per patient from the 'MBS and private healthcare system perspective' considered in the ADAR for ASCS ± STSG and STSG was \$41,898.04 and \$65,966.15, respectively, with a saving of \$24,068.10 per patient for the combined treatment. This cost saving was largely driven by savings in the treatment of cases with high %TBSA burned.

¹⁷ NSW Health, 2024, *Health insurers rorting public hospital beds [Online]*. NSW Government, viewed 7 May 2025, <https://www.nsw.gov.au/media-releases/health-insurers-rorting-public-hospital-beds>.

¹⁸ Elkady, D, Larson, BM, Sharma, S, McNinch, NL, Beaucock, B, Richard, BL & Khandelwal, A 2024, 'Effectiveness of Autologous Skin Cell Suspension in Large Total Body Surface Area Burns: Analysis of Clinical Outcomes and Patient Charges', *J Burn Care Res*, vol. 45, no. 6, pp. 1489-98.

Those with a TBSA of $\geq 40\%$, despite comprising only 20% of the total cohort, contributed 70% of the total cost savings (Table 14). For each TBSA subgroup (i.e. 20–29%, 30–39% and $\geq 40\%$), per-patient cost savings under the base case assumptions were estimated at $-\$792.66$, $-\$26,516.61$ and $-\$69,364.99$, respectively (Table 14).

Table 14: Base case results of cost to MBS and private health system, disaggregated by %TBSA

TBSA interval	Incidence	Cost ASCS $\pm$ STSG	Cost STSG	Incremental cost per patient	% of total
20–29%	0.50	\$18,107.13	\$18,502.66	$-\$395.53$	1.64%
30–39%	0.26	\$8,646.41	\$15,503.23	$-\$6,856.82$	28.49%
40%+	0.24	\$15,144.50	\$31,960.26	$-\$16,815.76$	69.87%
Weighted total cost	—	\$41,898.04	\$65,966.15	$-\\$24,068.10$	100.00%

Abbreviations: ASCS = autologous skin cell suspension; STSG = split-thickness skin graft

Source: ADAR Table 42 (p77)

Note: Unweighted incremental costs were $-\$792.66$ for the 20–29% TBSA category, $-\$26,516.61$ for the 30–39% TBSA category and $-\$69,364.99$ for the 40%+ TBSA category.

Weighted total costs (i.e. weighted across TBSA intervals) disaggregated by each costing component are summarised in Table 15.

Table 15: Disaggregated incremental costs, weighted across %TBSA groups

Component	ASCS $\pm$ STSG	STSG	Incremental cost	% of total
Immediate temporary burn wound closure $\geq 20\%$ but $\leq 30\%$ TBSA	\$1,039.73	\$1,219.89	$-\$180.16$	0.75%
Immediate definitive burn wound closure $\geq 20\%$ but $\leq 30\%$ TBSA	\$771.57	\$591.42	$\$180.16$	-0.75%
Delayed definitive burn wound closure	\$1,545.46	\$8,989.59	$-\$7,444.13$	30.93%
Dressing	\$459.79	\$1,006.93	$-\$547.13$	2.27%
Specialist consultation	\$169.59	\$389.21	$-\$219.61$	0.91%
Private hospital cost (based on mean LOS)	\$37,911.88	\$53,769.11	$-\$15,857.23$	65.88%
Total cost	\$41,898.04	\$65,966.15	$-\$24,068.10$	NA

Abbreviations: ASCS = autologous skin cell suspension; LOS = length of hospital stay; NA = not applicable; STSG = split-thickness skin graft; TBSA = total body surface area

Source: Attachment 3.1 Costing analysis, calculated during the commentary

The key drivers of the costing analysis are summarised in Table 16.

Table 16: Key drivers of the costing analysis

Description	Method/Value	Impact Base case: cost saving \$24,068.10 per patient
LOS	Average LOS informed by Carter et.al. (2022) ¹² applied in the base case analysis for both the intervention and comparator. This LOS was reported based on electronic medical record data collected from January 2019 to August 2020 at 500 health facilities. Alternative scenarios of $\pm 10\%$ LOS for ASCS $\pm$ STSG were applied in sensitivity analysis undertaken in the ADAR. LOS inputs informed by Kowal et al. (2019) ¹³ /Foster et al. (2021) ¹⁶ separately for FT and DPT burns were applied in additional sensitivity analysis undertaken in the commentary.	High impact potentially favours ASCS $\pm$ STSG procedure. High uncertainty given comparative LOS data based on retrospective review. A 10% increase in LOS resulted in a 15.8% reduction in cost savings (incremental cost: - \$20,276.92 per patient) while a 10% decrease in LOS led to a 15.8% increase in cost savings (incremental cost: \$27,859.29 per patient). Use of the alternate LOS inputs for FT and DPT burns resulted in 33.08% and 23.19% lower cost savings, respectively, compared to the base case.
Number of definitive closure procedures	As informed by Kowal et.al. (2019) ¹³ , 1 definitive closure procedure for burns ≥ 20 –39% TBSA and 2 for burns $>40\%$ TBSA were applied for ASCS $\pm$ STSG in the base case analysis. For STSG alone, as reported by the American Burn Association NBR 2002–2011, average values for FT and DPT burns were used to estimate the number of definitive closure procedures per person for each %TBSA category (ranging from 2.92–4.09 procedures, depending on %TBSA). An additional scenario with conservative estimates for the number of definitive procedures was applied for STSG in sensitivity analysis undertaken in the ADAR (assuming 2 definitive closure procedures for all burns $\geq 20\%$ TBSA). Number of definitive wound closure procedures, informed by Foster et al. (2021) ¹⁶ , was applied in additional sensitivity analysis undertaken during the commentary.	High impact, potential to favour ASCS $\pm$ STSG considering there has been an overall reduction in the number of autograft procedures per %TBSA burned since 2011 ¹¹ . Use of conservative estimates resulted in 22% less cost savings (incremental cost: - \$18,745.27 per patient) compared to the base case. Use of input values from Foster et al. (2021) (based on more recent evidence than those from Kowal et al. 2019) reduced the estimated cost savings by 11.76% compared to the base case.
Severity of burn	Incidence of burns per %TBSA interval was sourced from BRANZ data. ¹⁴ Proportions for the 20–29% TBSA 30–39% TBSA and 40%+ TBSA intervals were 0.5, 0.3 and 0.2, respectively. The costing analysis reported higher cost savings in the 40%+ TBSA interval compared to the 20–29% and 30–39% intervals.	Potentially high impact; direction of effect unclear; limited uncertainty in the inputs. %TBSA burned and incremental costs are directly associated (i.e. with each increasing %TBSA burned category, estimated incremental cost savings increase), implying weightings given to each %TBSA category could be significant drivers. These data are taken from BRANZ data with high applicability to the decision context.
Device cost	ASCS (RECELL®) device cost of \$redacted per device was informed by AVITA Medical. This cost was excluded in the base case analysis. This exclusion creates uncertainty in total per-patient costs. An additional scenario with the proposed device cost was applied in additional sensitivity analysis undertaken during the commentary.	High, favours ASCS $\pm$ STSG. Inclusion of device cost to the base case analysis reduced the estimated cost savings by 77.77% compared to the base case (incremental cost: - \$5,350.93).

Description	Method/Value	Impact Base case: cost saving \$24,068.10 per patient
Population	Several key inputs were specific to adult-only cohorts, including incidence of burn by %TBSA burned, number of devices needed relative to %TBSA burned, LOS and number of definitive closure procedures required. Overall, the current analysis is likely to create uncertainty in the total cost per patient of ASCS $\pm$ STSG due to the absence of paediatric patients. Harrison and Steel (2006) ¹⁵ indicated that hospitalisations and LOS were higher for paediatric patients compared to adults.	Low impact, based on ADAR assertion that use of the ASCS procedure is less likely among paediatric patients due to limited availability of donor sites. Among the overall eligible population (as estimated in Section 4 of ADAR), paediatric patients comprise only 11.7%.

Abbreviations: ASCS = autologous skin cell suspension; BRANZ = Burn Registry of Australia and New Zealand; DPT = deep partial thickness; FT = full thickness; LOS = length of hospital stay; STSG = split-thickness skin graft; TBSA = total body surface area
Source: Compiled during the commentary

An Australian Institute of Health and Welfare (AIHW) report by Harrison and Steel (2006)¹⁵, highlighted that both LOS and hospitalisation rate were higher among children and paediatric patients, leading to higher associated costs compared to adults. As such, the costing analysis based largely on adult patient-specific inputs may not be generalisable to paediatric patients.

LOS inputs for the base case analysis were informed by Carter et.al. (2022)¹², a US-based study. Some sensitivity analyses were performed in the ADAR using $\pm 10\%$ TBSA in the ASCS $\pm$ STSG arm, and additional scenarios using alternative literature-based evidence¹³ were added during the commentary. These analyses showed that variations in LOS inputs had significant effects on the estimated cost savings. Furthermore, disaggregation of the total weighted cost estimates showed that differences in hospital accommodation costs (driven by reductions in LOS) accounted for 65.9% of the estimated cost savings in the base case (Table 16).

The next biggest cost driver was differences in the number of delayed definitive closure procedures (30.9% of total incremental costs; Table 16). These inputs were also sourced from historic US-based data or assumptions.¹³ This indicates uncertainty in the cost savings of the ASCS $\pm$ STSG procedure, due to the absence of Australia-based LOS and number of autograft procedure data.

The results of key univariate sensitivity analyses are summarised in Table 17.

Table 17: Sensitivity analyses

Analysis	ASCS ± STSG	STSG	Incremental cost	% change from base case
Base case	\$41,898.04	\$65,966.15	-\$24,068.10	—
Conservative estimate for number of definitive closure procedures for STSG	\$41,898.04	\$60,643.32	-\$18,745.27	-22.12%
Exclude cost of private hospital bed	\$3,986.16	\$12,197.04	-\$8,210.88	-65.94%
LOS +10% in ASCS ± STSG arm	\$45,689.23	\$65,966.15	-\$20,276.92	-15.88%
LOS -10% in ASCS ± STSG arm	\$38,106.85	\$65,966.15	-\$27,859.29	15.88%
<i>LOS informed by Kowal et. al. (2019) and Foster et al. (2021) (FT/mixed depth)</i>	<i>\$41,460.01</i>	<i>\$57,565.95</i>	<i>-\$16,105.94</i>	<i>-33.08%</i>
<i>LOS informed by Kowal et. al. (2019) and Foster et al. (2021) (DPT)</i>	<i>\$22,536.75</i>	<i>\$41,022.67</i>	<i>-\$18,485.92</i>	<i>-23.19%</i>
<i>Number of definitive procedures for STSG informed by Foster et al. (2021)</i>	<i>\$41,898.04</i>	<i>\$63,135.67</i>	<i>-\$21,237.63</i>	<i>-11.76%</i>

Abbreviations: ASCS = autologous skin cell suspension; DPT = deep partial thickness; FT = full thickness; LOS = length of hospital stay; STSG = split-thickness skin graft

Source: ADAR Table 46 (p 88); Attachment 3.1 Costing analysis; additional sensitivity analyses conducted during the commentary are presented in *italics*.

When costs for the RECELL® device were included in the base case analyses, the resulting cost savings reduced to \$5,350.93 (i.e. incremental cost: -\$5,350.93); 77.77% lower cost savings compared to the base case (Table 18).

Table 18: Respecified base case that includes device cost, disaggregated by %TBSA

TBSA interval	Incidence	ASCS ± STSG	STSG	Incremental cost	% of total	% change from base-case (-\$24,068.10)
20–29% TBSA	0.50	\$25,591.98	\$18,502.66	\$7,089.32	-132% ^a	NA ^b
30–39% TBSA	0.26	\$13,818.13	\$15,503.23	-\$1,685.10	31%	NA ^b
40%+ TBSA	0.24	\$21,205.11	\$31,960.26	-\$10,755.15	201%	NA ^b
Weighted total cost	NA	\$60,615.21	\$65,966.15	-\$5,350.93	100%	-77.77%

Abbreviations: ASCS = autologous skin cell suspension; NA = not applicable; STSG = split-thickness skin graft

Source: ADAR Table 46 (p 88); Attachment 3.1 Costing analysis; additional sensitivity analyses conducted during the commentary are presented in *italics*.

^a inverted outcomes, which indicated the procedure was not cost-saving.

^b this percentage change to the base case outcome is not applicable, given that these are components of the weighted total cost.

Unweighted incremental costs were \$14,207.34 for 20–29% TBSA category, -\$6,516.61 for the 30–39% TBSA category and -\$44,364.99 for the 40%+ TBSA category.

The additional analysis presented in the ADAR, which the applicant describes as reflecting the potential costs to hospitals of the intervention versus STSG alone, considered both hospitalisation costs (based on public hospital AR-DRGs), average LOS and the cost of the RECELL® device. In the 20–29% TBSA subgroup, the intervention was not cost-saving (Table 19).

Table 19: Additional scenario analysis for cost to hospitals (based on public hospital AR-DRGs) and inclusive of device cost

TBSA interval	20-29% TBSA		30-39% TBSA		40%+ TBSA	
Description	ASCS± STSG	STSG	ASCS± STSG	STSG	ASCS± STSG	STSG
Cost per day in hospital	\$3,614.27	\$3,614.27	\$3,614.27	\$3,614.27	\$3,614.27	\$3,614.27
ASCS (RECELL®) device cost	\$ redacted	\$0.00	\$ redacted	\$0.00	\$ redacted	\$0.00
LOS (days)	31.7	27.60	27.40	42.20	51.00	104.5
Total cost to hospital	\$ redacted	\$99,753.87	\$ redacted	\$152,522.22	\$ redacted	\$377,691.29
Incremental cost to hospital	\$ redacted		-\$ redacted		-\$ redacted	

Abbreviations: ASCS, autologous skin cell suspension; LOS, length of stay; STSG, split-thickness skin graft; TBSA, total body surface area

Source: adapted from ADAR in-line Commentary

14. Financial/budgetary impacts

The financial impact analysis in the ADAR adopted an epidemiological approach to inform the utilisation estimates and financial impacts of the proposed listing of ASCS on the MBS. The proposed population was patients with severe burns $\geq 20\%$ TBSA who have sustained DPT and/or FT burn wounds that require skin grafting. Estimates for the number of eligible patients were informed by BRANZ data for patients with burns $\geq 20\%$ TBSA. In addition to these data, applicant-estimated uptake of ASCS using published data on private health insurance coverage across Australia (i.e. 55%; assumed to remain stable from years 1–6), expert opinion on the proportion of use of delayed definitive closure items, and a literature-derived estimate of the proportion of ASCS + STSG use were also included. The applicant-estimated uptake of ASCS was 50% in year 1, increasing to 80% in years 4–6.

Estimated use and financial impact to the MBS

The expected use of ASCS ± STSG or STSG alone under existing MBS items for temporary or immediate wound closure (items 46117–46123) and delayed definitive wound closure (items 46134, 46135) was estimated in the ADAR. The estimated annual number of private health insurance patients experiencing severe burns ($\geq 20\%$ TBSA burned) reflected the eligible population. Uptake of ASCS ± STSG was then estimated as a percentage of this eligible population, based on the applicant's uptake estimates. All patients incurred the cost of an immediate or temporary wound closure. Based on the expert opinion presented in the ADAR, 25% of patients with burns $\geq 20\%$ but $< 30\%$ TBSA and 75% of patients with burns $\geq 30\%$ TBSA, were assumed to also require a delayed wound closure item.

Expected utilisation of the proposed modifier item (to be claimed when ASCS is used in combination with STSG) was also estimated in the ADAR as a proportion of estimated ASCS ± STSG use. This modifier item was valued at an additional fee of 15% of the value of the definitive wound closure item claimed.

The estimated total cost to the MBS of the amended MBS items at 75% benefit was \$220,009. This figure was predicted to be consistent across years 1–6 of the analysis, given that the number of patients with severe burns ($\geq 20\%$ TBSA) is expected to remain relatively stable. The estimated annual cost of \$220,009 reflects the estimated costs for use of MBS items 46117–

46135, irrespective of intervention type (i.e. not only for use of the intervention [ASCS or ASCS in combination with STSG], but also for use of the comparator [STSG alone]). Overall, the net cost to the MBS for these existing MBS items was estimated to be \$0, with no expected increase in the size of the eligible or treated populations.

The estimated additional cost to the MBS of the proposed modifier item, as calculated in the ADAR (75% benefit), was \$10,871 in year 1, increasing to \$17,260 in year 6, with this increase driven by the assumed increased uptake of the intervention over time. The net financial impact of ASCS will be incurred due to the addition of the modifier item when ASCS and STSG are used in combination. As such, the cost to the MBS of the proposed modifier item at 75% benefit is equivalent to the net financial impact presented in the ADAR.

The financial implications to the MBS resulting from the proposed listing of ASCS are summarised in Table 20.

Table 20: Net financial implications of ASCS to the MBS

Parameter	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated use and cost of ASCS						
Number of patients eligible for ASCS ^a	87	87	87	87	87	87
Total cost to MBS at 75% benefit ^b	\$220,009	\$220,009	\$220,009	\$220,009	\$220,009	\$220,009
Number of patients utilising ASCS ^c	44	52	61	70	70	70
Cost of ASCS ^d	\$110,004	\$132,005	\$154,006	\$176,007	\$176,007	\$176,007
Number of patients utilising STSG ^e	43	35	26	17	17	17
Cost of STSG ^f	\$110,004	\$88,003	\$66,003	\$44,002	\$44,002	\$44,002
Total cost of proposed amendment ^g	\$220,009	\$220,009	\$220,009	\$220,009	\$220,009	\$220,009
Estimated use and cost of modifier item for ASCS						
Number of eligible patients ^a	87	87	87	87	87	87
Number of patients utilising ASCS ^c	44	52	61	70	70	70
Number of patients utilising modifier ASCS items ^h	28	34	40	45	45	45
<i>Commentary alternate estimate of patients utilising the modifier item</i>	38	46	54	61	61	61
Total cost of modifier item ⁱ	\$10,871	\$12,822	\$15,349	\$17,260	\$17,260	\$17,260
<i>Commentary alternate estimate for total cost of modifier item</i>	\$13,259	\$15,687	\$18,692	\$21,081	\$21,081	\$21,081
Net cost to MBS ^j	\$10,871	\$12,822	\$15,349	\$17,260	\$17,260	\$17,260
<i>Commentary alternative net cost to MBS^j</i>	\$13,259	\$15,687	\$18,692	\$21,081	\$21,081	\$21,081

Abbreviations: ASCS = autologous skin cell suspension; MBS = Medicare Benefits Schedule; STSG = split-thickness skin graft

Source: ADAR Tables 60-61 (pp 102-1-3); Attachment 4.1 BIM

^a estimate based on average number of patients with burns $\geq 20\%$ TBSA and proportion of patients in Australia that have private health insurance (55%).

^b estimate based on utilisation (access to private health insurance) multiplied by MBS item fees at 75% benefit.

^c estimate based on uptake percentage proposed by the applicant multiplied by total eligible patients for ASCS.

^d estimate based on number of patients utilising ASCS times MBS items fees at 75% benefit.

^e estimate based on utilisation of ASCS times incidence of STSG as proposed by Toppi et. al. 2019.

^f estimate based on number of patients using STSG times MBS items cost at 75% benefit.

^g total cost of ASCS plus total cost of STSG.

^h utilisation of ASCS times proportion of use of modifier item 65% as reported by Lim et.al. 2014.

ⁱ estimate based on number of uses of modifier items times additional 15% fee of existing MBS items at 75% benefit (i.e. difference between additional 15% fee of existing MBS item at 75% benefits and existing MBS item costs)

^j assumed net financial impact of ASCS due to addition of modifier item.

Note: additional sensitivity analyses conducted during the commentary are presented in *italics*.

The ADAR applied a 65% estimated utilisation of ASCS to predict utilisation of the proposed modifier item. Upon review of the source publication (Lim et al. 2014),¹⁹ it would appear more appropriate to apply a figure of 88%. Within the source publication, 69 patients (9.2%) had a major burn of >15% TBSA requiring a single wound closure surgery, of which 18 (26.1%) were treated with STSG, 6 (8.7%) were treated with ASCS alone, and 45 (65.2%) were treated with ASCS and STSG in combination. Thus, it can be said that of all patients with a major burn receiving ASCS (n = 51), 6 (11.8%) received ASCS alone, while 45 (88.2%) received ASCS in combination with STSG. Therefore, it would seem more appropriate to apply the 88.2% to the predicted utilisation of ASCS to estimate expected use of the modifier item. An alternative scenario, applying the 88.2% figure, was explored in the commentary (results are included in Table 20).

The 2022–2023 BRANZ report indicated that the majority of specialised burn treatment services are provided in 17 public hospitals across the country. Indeed, AIHW data shows that in 2022–2023, of all acute separations for Major Diagnostic Category (MDC) '22 – Burns' items, 8,214 (97.8%) and 188 (2.2%) were in public and private hospitals, respectively.²⁰ In the budget impact analysis, 55% of private health insurance patients each year were included, and their cost was estimated accordingly. It is correct that all patients with a severe burn and private health insurance would comprise the eligible population for ASCS funded via the MBS. While those with private health insurance may elect to be treated as a private patient, available claims data for existing MBS items of relevance to this application (items 46117–46135), suggest minimal uptake of existing items (despite a large number of claims isolated to item 46123 exclusively in Victoria). Specifically, in the 2024 calendar year, there were 3 claims across MBS items 46117–46122, 60 claims for MBS item 46123 and 1 claim across items 46134–46135.²¹ As such, it seems possible that uptake of the relevant MBS items for the definitive closure of severe burns may be overstated. Alternatively, it could suggest there are current barriers to uptake of the existing MBS items.

The ADAR assumed that uptake of the ASCS (RECELL®) device would be 50% in the first year of listing, increasing to 80% by year 4. It is noted that 11.7% of the eligible population in the ADAR estimates are paediatric, and that the applicant has suggested use would be low among this group of patients. Therefore, the high (80%) uptake rate by year 4 may be conservative.

In the costing analysis, ASCS was associated with a reduced number of definitive closure procedures in comparison to STSG alone, which, if included in the financial estimates, would be associated with cost offsets. If realised, this reduction in procedures could be reflected in a reduction in the overall number of claims for MBS definitive closure items in the financial analysis (i.e. cost offsets from the perspective of the MBS), making the estimate presented potentially conservative.

The net financial impact to the MBS was evaluated across multiple scenarios by the ADAR and the commentary, with the range of financial outcomes varying between –10% and 51% relative to the base case. Overall, the variables that were most impactful to the estimated net financial impact were the proportion of the population with private health insurance (assuming 100% coverage increased the annual estimates by 50–51%) and the proportion of burns within each

¹⁹ Lim, J, Liew, S, Chan, H, Jackson, T, Burrows, S, Edgar, DW & Wood, FM 2014, 'Is the length of time in acute burn surgery associated with poorer outcomes?', *Burns*, vol. 40, no. 2, pp. 235-40.

²⁰ Australian Institute of Health and Welfare (AIHW) 2024. *Admitted patients care 2022-23 – Table 5.3 Acute separations by Major Diagnostic Category version 10.0 and medical/surgical/other partition, public and private hospitals, 2022–23*, viewed 25 March 2025 <https://www.aihw.gov.au/hospitals/topics/admitted-patient-care>.

²¹ Servies Australia 2025, *Medicare Item Reports*, viewed 25 March 2025 https://medicarestatistics.humanservices.gov.au/statistics/mbs_item.html.

TBSA interval (use of alternative values informed by Foster et al. (2021)¹⁶ for FT or DPT burns increased the annual net budget impact by 10% and 7%, respectively).

Net impact to other healthcare budgets

The ADAR estimated the impact of ASCS on hospital budgets, based on the ASCS device cost and device capacity (unit cost \$redacted each unit has the capacity to treat up to 10% TBSA, as informed by Carter et al. (2022)¹²). Overall, the estimated cost to hospital budgets for the ASCS device was estimated at \$1.5 million in year 1, increasing to \$2.5 million in year 6. This estimate considered costs for the ASCS device only.

The financial implications to hospitals from the proposed listing of ASCS, as estimated in the ADAR, are summarised in Table 21.

Table 21: Net financial implications of ASCS to hospital budgets

Description	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Total number of devices required ≥20% TBSA ^a	redacted	redacted	redacted	redacted	redacted	redacted
RECELL® device unit cost ^b	\$redacted	\$ redacted	\$ redacted	\$ redacted	\$ redacted	\$ redacted
Total cost to hospitals ^c	\$1,519,542	\$1,765,201	\$2,114,609	\$2,424,643	\$2,424,643	\$2,424,643

Abbreviations: ASCS = autologous skin cell suspension; TBSA = total body surface area

Source: ADAR Tables 61 (p 108); Attachment 4.1 BIM

^a total number of devices was estimated based on estimated number of patients expected to utilise ASCS in each %TBSA category multiplied by number of devices required in each category.

^b RECELL® device unit cost informed by AVITA medical.

^c estimate based on number of devices required multiplied by RECELL device unit costs (i.e. $c = a \times b$)

This additional analysis, considering only the device cost, is insufficient to represent total costs to other budgets (including private health insurance and patient out-of-pocket expenses).

Nevertheless, LOS and the number of definitive closure procedures were key drivers of cost savings in the costing analysis. If included in the financial estimates these would be considered as cost offsets. As such, the approach presented may be conservative.

15. Other relevant information

Nil.

16. Key issues from ESC to MSAC

Main issues for MSAC consideration

Clinical issues:

- ESC noted the intervention appears to reduce donor sites and reduce autograft procedures, but there was no consistent benefit shown for treatment site healing, pain or visual appearance.
- Evidence limitations include limited, low-quality clinical data on LOS and wound closure numbers. LOS data are derived from a US retrospective study with potential residual confounding; closure assumptions may favour ASCS due to historical data trends. ESC considered that the approach used was reasonable due to the small sample sizes.
- ESC considered that safety appears to be non-inferior in terms of AEs and SAEs, device-related AEs, graft loss, infection, scar formation and delayed wound healing.

Economic issues:

- The ADAR assumes that the cost of the ReCell® device (\$redacted) will be absorbed by hospitals, but ESC was concerned that patients may need to pay out-of-pocket costs for the device if treated as a private patient was as the device is not eligible for inclusion on the Prescribed List of Medical Devices and Human Tissue Products (PL).
- In the ADAR's base case claimed cost savings were greatest in burns $\geq 40\%$ TBSA (20% of the cohort contributed 70% of the savings). However, ESC noted that when the device cost was included in the base-case analysis the overall cost savings reduced by $\sim 80\%$ (from $-\$24,068.10$ to $-\$5,350.93$). ESC also noted that when the cost of the device was included ASCS was not cost-saving for burns with a 20–29% TBSA but remained cost-saving for burns with a TBSA of $\geq 30\%$.
- ESC noted that the main drivers of the claimed savings with ASCS were LOS, number of delayed definitive closure procedures, and device costs. ESC advised that additional sensitivity analyses around these parameters were required for MSAC consideration.
- ESC noted that while the costing analysis provides insight into estimated resource use for burn patients, it does not capture long-term patient outcomes.

Financial issues:

- ESC advised that the claimed cost offsets associated with reductions in LOS and delayed closure procedures were not reflected in the financial analysis, making estimates conservative. Notwithstanding the issue of who will bear the cost of the device, savings to hospitals may be higher than presented in the base case.
- ESC noted that 11.7% of eligible patients are paediatric, with expected low ASCS use in this group. ESC advised that the 80% uptake estimate by year 4 may be conservative.
- ESC noted the eligible population was uncertain; however, the current uptake of existing MBS items was likely the best indicator for estimating uptake of ASCS. ESC considered the low usage of current MBS items indicated that the financial impact may be overestimated. Additionally, since burns units are typically affiliated with public hospitals, patients with private health insurance may opt to be treated as public patients in these circumstances.

ESC discussion

ESC noted this application, from Health Technology Analysts Pty Ltd on behalf of AVITA Medical Inc, was for the amendment of existing Medicare Benefits Schedule (MBS) items to include autologous skin cell suspension (ASCS) for the treatment of paediatric and adult patients with

full-thickness (FT) and deep-partial thickness (DPT) acute burn wounds comprising $\geq 20\%$ total body surface area (TBSA). The application also proposed an additional modifier item for combined ASCS and split-thickness skin graft (STSG) treatments. The relevant existing MBS items are 46117–46124 for immediate treatment and 46134 and 46135 for delayed treatment. No MBS fee changes are requested for the existing MBS items.

ESC noted that ASCS is a cell-based therapy that uses the patient's own skin cells, turns them into mixture, and applied to the burn wound. The treatment requires a single-use ReCell® system with a proposed unit cost of \$redacted. The Therapeutic Goods Administration listed the therapy in 2020. The ReCell® device was rejected for inclusion on the Prescribed List of Medical Devices and Human Tissue Products (the PL) because it is not implanted. ESC noted that severe burns are typically managed in public hospitals. However, some patients may elect to be treated as private patients within public hospitals, in which case relevant MBS items for burns treatment may be claimed, depending on the patient's clinical circumstances.

ESC discussed who would bear the cost of the ReCell® device, given that MBS items can only provide a rebate for professional services. ESC noted that the ADAR assumed that hospitals will absorb the cost of the device. ESC noted that many of the consumables used in the management of burns are not included on the PL and for private patients such consumables would be covered by arrangements between individual hospitals and private health insurers. ESC considered that the cost of the ReCell® device may be covered by the funding mechanisms in place for these other consumables. However, ESC was concerned that as the device was not eligible for the PL there was a possibility that patients may need to contribute some or all of the cost of the device and there was uncertainty regarding the out-of-pocket costs because the amount paid by the patient could differ based on arrangements between specific hospitals and insurers.

ESC noted the clinical management algorithm indicated ASCS would be added to STSGs after debridement of the burn wound and temporary closure with a skin substitute (if needed), and in delayed definitive wound closure ASCS would be used either on its own or in combination with STSG. ESC noted that the clinical claim was that ASCS treatment, with or without STSGs, offers superior donor site sparing compared to STSGs alone in severe burn wounds, non-inferior effectiveness in achieving definitive wound closure, and non-inferior safety in treating patients with severe burns.

ESC noted that the majority of the public consultation feedback was from health professionals and stakeholders who currently use the treatment and was supportive. The consultation input suggested the technology was mostly used in Western Australia, where it is standard care. ESC considered that advice from burns surgeons and other related stakeholders outside of Western Australia would be useful to determine the intervention's current or future use in clinical practice.

The consultation feedback indicated that ASCS results in faster healing, reduced LOS, reduced pain and level of scarring, and better functional outcomes. Feedback was that quality of life and psychosocial impacts are positive due to less scarring and shorter LOS. One burn survivor supported the treatment, advising that the scarring is less visible from when they received the treatment.

ESC noted that the main evidence base was from a small ($N = 30$) multicentre, prospective, within-patient randomised controlled trial (RCT; CTP001-6). Patients comprised those aged ≥ 5 years with 5–50% TBSA, acute mixed-depth/FT burns. The co-primary endpoints were confirmed treatment area closure (healing) before or at week 8 and comparison of the actual expansion ratio (computed as the ratio of measured treated area to measured area of the donor site). Because patients acted as their own controls, ESC noted that differences in length of stay (LOS) could not be calculated from this study. ESC acknowledged that large RCTs were rarely conducted for non-elective plastic surgery treatments. ESC noted that females comprised 17% of

the study participants, but in Australia, 45% of recipients for relevant MBS items for burn treatment (MBS items 46117–46123, 46134, 46135 over a 2-year period from January 2023 to December 2024) were female. However, ESC acknowledged this may not be a concern as the higher proportion of females seen in MBS item utilisation data (45%) may reflect differences in service access, care pathways, or MBS coding practices rather than a higher incidence of severe burns in women. It was also acknowledged that severe burns are more commonly observed in men, and no biological rationale for a gender-specific difference in response to ASCS treatment was identified.

ESC considered that, although the PICO population was limited to treatment of severe burns with $\geq 20\%$ TBSA, the broader clinical evidence for ASCS for all burn injuries was relevant due to the complexity of patient selection in real-world settings. The applicant's search strategies were not limited to the specific population of the PICO and used broader terms than usual. ESC considered these changes appropriate, given the likely small evidence base. This resulted in the inclusion of CTP001-7, another small RCT.

ESC noted that primary clinical evidence from 2 small RCTs (CTP001-6 and CTP001-7; $n = 42$) directly comparing ASCS plus meshed STSG and ASCS alone in patients with 5–50% TBSA burns found no differences between ASCS plus meshed STSG and standard care in rates of adverse events, delayed healing, graft failure, infection, allergic response to trypsin (component of the ASCS enzyme), and wound durability or scars necessitating surgical intervention up to 1 year after treatment. In addition, 94% of patients in the ASCS treatment arm and 89% in the control arm achieved definitive wound closure 8 weeks after grafting. An average of 32% less donor skin was required ($p < 0.001$) for ASCS plus meshed STSG, with no differences in patient satisfaction, scarring outcomes, or pain over the year after treatment. ESC noted supportive evidence that included indirect comparison of ASCS plus meshed STSG and standard care in adults with burns $> 50\%$ TBSA using data from a single-arm study ($n = 49$) and Burns Registry of Australia and New Zealand (BRANZ) data ($n = 277$), which resulted in fewer autograft procedures per patient (median 2.0 vs 5.0; $P < 0.0001$). Supporting evidence also included an indirect comparison of ASCS plus meshed STSG and standard care in paediatric patients with life-threatening burn injuries or injuries $\geq 8\%$ TBSA using data from 2 combined single-arm studies ($n = 39$) and BRANZ data ($n = 245$).

ESC noted that one meta-analysis of ASCS vs standard treatments appeared to demonstrate superiority for ASCS (Obeid 2025²²), whereas another meta-analysis appeared to demonstrate non-inferiority (Lou et al. 2024²³) for the overall weighted effect size (with mixed effectiveness for the outcomes of size of donor site for treatment [superior], size of study treatment area [non-inferior], operation time [non-inferior] and pain scores [superior]). A paediatric case study (Oshima 2025²⁴) also suggested positive results for ASCS, and ESC considered it appropriate that the treatment be used in children. However, ESC considered the 20% TBSA threshold to be too high for children due to the limited availability of donor sites compared with adults. ESC suggested using a lower threshold of $\geq 10\%$ TBSA for children aged less than 15 years, which would require additional amendments to the proposed MBS item descriptors.

²² Obeid, FM, Effect of autologous skin cell suspensions versus standard treatment on re-epithelialization in burn injuries: a meta-analysis of RCTs. *Medicina* 2025 61(529). <https://doi.org/10.3390/medicina61030529>

²³ Lou, J et al., The efficacy and safety of autologous epidermal cell suspensions for re-epithelialization of skin lesions: A systematic review and meta-analysis of randomized trials. *Skin Res Technol* 2024 30(6):e13820. doi: 10.1111/srt.13820

²⁴ Oshima J, Inoue Y, Sasaki K, et al. Autologous Skin Cell Suspension Monotherapy Without Split-Thickness Skin Grafting for Deep Dermal Burns in Pediatric Patients: A Case Series. *Cureus* 2025 17(4): e83210. DOI 10.7759/cureus.83210

ESC noted the ADARs rationale that an additional modifier item for combined ASCS and STSG treatments was required due to the combination treatment requiring up to 30 minutes of additional procedural time. ESC noted that the MBS Review Taskforce for Plastics and Reconstructive Surgery underpinned the development of the current burns items. The MBS review recommendations used TBSA as the basis for rebate, rather than procedural time, and recognised there would be high variability in procedural time and complexity between patients and each individual burn site treated. ESC noted departmental advice that an additional modifier item would add further complexity to the claiming of burns items, would require complex system upgrades to enable the administration of the modifier item in addition to the existing modifier item, and was unlikely to result in significant clinical benefits to patients. ESC advised that a modifier item to additionally fund burns treatment that require combined STSG and ASCS was unnecessary, as the existing burns treatment item structure already accounts for differences in procedural time and difficulty.

ESC noted that the economic evaluation was a costing analysis comparing the total cost of ASCS ± STSG with STSG alone for patients with severe burns ≥20% TBSA who have sustained DPT and/or FT burn wounds that would require skin grafting. ESC considered this to be partially appropriate but noted that the analysis did not account for regrafting costs and that it would have been more suitable to use public hospital Australian Refined Diagnosis-Related Groups (AR-DRG) costs to represent total inpatient costs (rather than the average private hospital beds used). In addition, ESC considered that the device cost should have been included in the base-case analysis, as per the MSAC guidelines which recommend a healthcare system perspective for the economic evaluation, inclusive of health and health-related resource use (costs and cost offsets), and health-related outcomes. ESC noted that the model inputs were mostly from US and UK studies, including US-based LOS data rather than Australian data; however, ESC considered this reasonable due to the limited availability of alternative data.

ESC noted that the estimated total weighted cost to the MBS and health system, as specified in the ADAR, was – \$24,068.10 per patient, suggesting that ASCS treatment is cost-saving. However, this weighted cost represented multiple TBSA intervals, and cost savings increased as the TBSA increases. ESC noted additional scenario analyses that included the device cost and used AR-DRG costs reduced the cost savings to hospitals to \$8,389.86 per patient. However, when considering 20–29% TBSA patients only, the intervention was not cost-saving and increased costs to hospitals to \$29,818.51 per patient. ESC agreed with the pre-ESC response that differences in LOS and the number of closure procedures required for patients with ASCS ± STSG versus STSG alone is expected to be greater for higher TBSA burns, which explains why the cost savings were most pronounced in burns ≥40% TBSA, representing 20% of patients but contributing 70% of total savings.

Overall, ESC considered the claim of cost savings to be highly uncertain as varying the primary cost drivers resulted in changes to the base-case cost savings, ranging from a 2% to a 78% difference, with both increases and decreases in cost savings observed. The key cost drivers included:

- LOS, which was uncertain given that the comparative LOS data are based on a retrospective review. ESC agreed with the pre-ESC response, noted that these were the best available evidence, but noted that the low quality of data should be acknowledged.
- Number of definitive closure procedures, which potentially favours ASCS ± STSG, considering there has been an overall reduction in the number of autograft procedures per %TBSA burned since 2011. Again, the pre-ESC response noted that these were the best available evidence.
- Device cost, which was inappropriately excluded in the base case and favours the intervention. Including this in the base case reduced the cost savings by 78%.

- Burn severity and the direction of its effect on cost-savings was unclear however, the uncertainty was limited as the input data was drawn from the BRANZ, a high-quality, context-relevant source. The intervention only becomes cost-saving for burns of $\geq 30\%$ TBSA when device costs are included.
- Population, as the inputs were adults only. However, the paediatric population would likely comprise only about 11.7% of the total patient population.

ESC noted that altering these cost drivers results in a large change to the base case net cost – as high as –65.9% if private hospital bed costs are excluded, or +32.9% if private hospital bed costs are increased by 50%. In addition, although ESC considered the cost savings approach reasonable, it noted that this approach does not capture long-term patient outcomes.

ESC considered the epidemiological approach and the inputs to the financial impact to be appropriate. The impact on the MBS was calculated to be \$10,871 in year 1, increasing to \$17,260 by year 6. ESC noted that without the proposed modifier item, there was no estimated net impact on the MBS costs.

ESC noted that the net cost to hospitals was - \$1.52 million in year 1 to \$2.42 million by year 6, due to the assumption that hospitals would absorb the cost of the ReCell® device. However, ESC noted that potential cost offsets such as reduction in LOS and reduction in definitive closure procedures required with the use of ASCS were not included, which may overestimate the overall costs.

Overall, ESC agreed with the commentary that the financial impact was incomplete and that additional sensitivity analyses aimed at refining the understanding of when the intervention might become cost-saving or more clinically justified would be useful for MSAC decision making, including:

- a threshold analysis for cost savings in 20–29% TBSA burns (for example, under what LOS reductions or device price reductions would it become cost-saving)
- the inclusion of regrafting costs in the base case analysis, to reflect the clinical algorithm
- the inclusion of cost offsets from reduced LOS and closure procedures in the financial analysis, to provide a more accurate analysis and give decision-makers visibility of the likely impact
- varying the cost of the ASCS (ReCell®) device as well as the %TBSA for the average-sized adult, as one device was estimated to treat within a sensitivity analysis in the financial modelling.

17. Applicant comments on MSAC's Public Summary Document

The applicant welcomes MSAC's support for amending selected existing MBS items for immediate and delayed definitive burn wound closure, acknowledging the demonstrated superiority of ASCS in donor site sparing and reducing the need for autograft procedures compared with traditional autologous skin grafting.

In Western Australia, the use of ASCS is considered standard of care in burn treatment. Following this comprehensive assessment, the applicant hopes that ASCS will be more broadly considered and adopted as a treatment option across the rest of Australia when clinically appropriate.

18. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website: [visit the MSAC website](#)