Australian Government

Department of Health

Application 1475:

Ablative Fractional Laser Therapy for Burn Scars

PICO Confirmation

(to guide a new application to MSAC)

(Version 1.0)

This PICO Confirmation Template is to be completed to guide a new request for public funding for new or amended medical service(s) (including, but not limited to the Medicare Benefits Schedule (MBS)). It is relevant to proposals for both therapeutic and investigative medical services.

Please complete all questions that are applicable to the proposed service, providing relevant information only.

Should you require any further assistance, departmental staff are available through the Health Technology Assessment (HTA Team) on the contact number and email below to discuss the application form, or any other component of the Medical Services Advisory Committee process.

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Summary of PICO criteria

To define the question(s) to be addressed in an Assessment Report to the Medical Services Advisory Committee (MSAC)

Component	Description	
Population	People with hypertrophic and keloid burn scars that are associated with significant functional or psychological impairment.	
Intervention	Ablative fractional carbon dioxide laser therapy in addition to reconstructive surgical procedures, provided by qualified plastic and reconstructive surgeons.	
Comparators	Reconstructive surgical procedures alone (in the absence of ablative fractional carbon dioxide laser therapy)	
Outcomes	*Patient relevant*	
	Safety-related outcomes	Treatment-associated local side effects Adverse events
	Therapeutic effectiveness	Scar functionality: range of motion, pliability Symptomatic control: neuropathic pain, itchiness Scar appearance: colour, thickness, cosmesis
	Health-related quality of life	Burn Specific Health Scale (BSHS-B) quality of life instruments – a burn specific multi-attribute instrument that measures simple abilities, hand function, affect, body image, interpersonal relationship, sexuality, heat sensitivity, treatment regimens, and work
	Healthcare system	
	Reconstructive surgical procedures	Number and / or complexity of procedures
	Duration of hospitalisation	Average length of stay
	Resources used to manage side effects and adverse events	Incidence and standard of care for adverse events
	Cost effectiveness	Cost per quality adjusted life year
	Financial implications	Number of patients treated Capital cost of equipment Reduction in surgical intervention and/or hospitalisation

PICO rationale for therapeutic and investigative medical services only

Population

People with hypertrophic and keloid burn scars that are associated with significant functional or psychological impairment.

Rationale

In Australia, an estimated 200,000 people suffer burn injury requiring medical treatment every year (Fiona Wood Foundation 2017). In 2013-14, an estimated 5,430 people with burn injury received medical treatments in hospitals[1] (AIHW 2016). These represent around 1% of all hospitalisations for injury. Of these cases, the rates of hospitalised burn injury in boys and girls of 0-4 years were the highest, at 75 cases and 51 cases per 100,000 population respectively (AIHW 2016). The two main causes of burn injury are exposure to smoke, fire and flames; and contact with heat and hot substances (AIHW 2016). A majority of hospitalised burn cases had injury to partial thickness of the skin (70%) or full thickness (23%), rather than only to the top layer of skin, causing erythema (7%) (AIHW 2016).

Survivors of severe burn injury commonly live with considerable scarring that has life-long negative impacts on all aspects of their lives. These include not only aesthetic appearance and physical functioning, but also psychological and social functioning that affects their relationships with other people and the broader society (Issler-Fisher et al 2016). A review by Falder et al (2009) lists a broad range of outcomes from burn scars. These include scar contractures that limit joint movement and deform anatomical structures (e.g. hand and grip strength); broad sensory perception triggered by touch or movement (e.g. pain, temperature, vibration and itch or chemical stimuli); post-traumatic stress disorder and depression, to name a few.

People living with burn scars are a heterogeneous population because of wide variations in age, mechanism of injury, number of scars, depth and sites of burn, and level of physical and social co-morbidities (Falder et al 2009). In drafting this document, a number of options for specifying the most appropriate population for receiving the proposed intervention - ablative fractional carbon dioxide (CO_2) laser therapy – have been explored. This is to ensure that the wording is sufficiently broad for capturing the heterogeneous nature of burn scars and impacts, and be reasonably specific to avoid inappropriate use of the intervention in unintended population. Table 1 describes the options that have been considered.

Table 1: Options for defining patient population

Source	Suggested or actual wording to define scar type or population
Applicant's Application Form	Patients suffering from consequences of burn scars and scars following other medical conditions, where large areas of skin are affected, leading to detrimental physical aesthetic and social sequelae, such as pruritus, pain, stigma, and contracture.
First draft	People with severe scarring resulting from burn injury.
Existing MBS items pertinent to scar management	Scars: MBS items 45506, 45512, 45515, 45518 Extensive burn scars: MBS item 45519 Severely disfiguring scarring: MBS items 45025, 45026

[1] Estimated based on hospital separations with a principal diagnosis recorded as T20-T31, where the mode of admission was not a transfer from another acute hospital and urgency status was recorded as 'emergency'.

Source	Suggested or actual wording to define scar type or population
Clinical recommendations by Gold et al 2014	Formal definitions was provided for the following scar types: Mature scar, Immature scar, Linear hypertrophic (e.g. Surgical / Traumatic), Widespread hypertrophic (e.g. burn), Minor Keloid and Major Keloid
PASC advice	Burn scars associated with significant functional or psychological impairment
Applicant's guidance (prior to endorsing PASC advice)	• Significant burn scars (difficult to define in an MBS item descriptor) • Hypertrophic and/or contracted burn scars • Burn scars associated with significant functional or psychological impairment
Selected clinical studies	Various description of scar types or patient population: • Issler-Fisher 2016: burn scars comprising structural changes (atrophic, hypertrophic, keloid scars) • El-Zawahry 2015: hypertrophic and keloidal scars • Waibel 2013: hypertrophic scars resulting from burns, surgery or traumatic injuries • Ozog 2013: mature burn scars • Qu 2012: mature, full-thickness, hypertrophic burn scars • Hultman 2013: hypertrophic burn scars • Shumaker 2012: Patients with functional deficits related to refractory scar contractures • Shumaker 2012b: Patients with multiple traumatic scars related to blast injuries … for potential mitigation of contractures, poor pliability, and textural irregularity
Common scar rating instruments for assessing scars in clinical research	• Vancouver Scar scale (VSS) • Patient and Observer scar assessment scale (POSAS) • University of North Carolina Scar Scale • Manchester Scale • Visual Analogue Scale (VAS) with scar rating • Stony Brook Scar Evaluation Scale • Phaseshift Rapid In Vivo Measurement of the Skin (PRIMOS) • Modified POSAS

As presented in Table 1, there is various wording for characterising a scar in clinical trials, clinical practice and the existing list of relevant MBS items. There are also scar-rating instruments that are used in clinical research. However, in clinical practice, these tools do not serve as an indicator for necessity of a reconstructive procedure, such as surgical reconstruction or laser resurfacing. Burn and reconstructive surgeons judge the need for a reconstructive intervention clinically, according to various patient and scar factors (including location of the scar, patient symptoms, restricted range of motion, psychological and social impact, chronic wound breakdown, quality of life and so on). Several of these factors are not incorporated into the existing scoring system.

In considering the above, the proposed population is: 'People with hypertrophic and keloid burn scars that are associated with significant functional or psychological impairment'. This description incorporates both the structural characteristics of scarring (i.e. hypertrophic and keloidal) and impacts of scarring. The word 'significant' would be left to professional judgment by burn and reconstructive surgeons, in line with standard clinical practice. The description includes all sources of burn injury (fire, chemicals, scalding water, grease and electricity). It also has no age restriction, because burn injury can affect people of all ages, and there is evidence that the intervention may be suitable for use in patients as young as 5 years old.

To mitigate "the risk of leakage beyond the intended population" discussed by the PICO Advisory Sub-Committee (PASC), the applicant has recommended the intervention be restricted to use by qualified plastic and reconstructive surgeons operating in burn centres (see next section and the

rationale for clinical circumstances of use on page 8). The most severe cases of burn scarring are referred to burn and reconstructive surgeons operating in burn centres. For this reason, restricting the clinical circumstances of use to burn centres would minimise the risk of the proposed intervention being used in patients with minor burn scars or inappropriate scars (e.g. atrophic scars). It would also prevent treatment of scars that are not of significant functional or psychological impairment. The applicant explained that it is unlikely that medical centres/clinics that are not burn centres would have (or invest in) the relevant equipment and trained personnel, so the technology and training requirements may be a risk mitigating factor without the need to define specific centres in the MBS descriptor. PASC considered it would be difficult (i.e. most unlikely) that the Department of Human Services (DHS - Medicare) could restrict MBS items (treatments) to specific centres/buildings. If needed, MBS items can be restricted to broad practitioner types, and an MBS item can be identified as a treatment provided in or out of hospital. However, establishing and administering more specific medical site restrictions is likely to be problematic administratively.

Intervention

Ablative fractional carbon dioxide laser therapy in addition to reconstructive surgical procedures, provided by qualified plastic and reconstructive surgeons.

Rationale for the technology

Burn scar management usually commences with more conservative measures. These include compression garments, massage, heat, ultrasound, aggressive physical and occupational therapy, and corticosteroid injections (Shumaker et al 2012). For refractory or more severe burn scars, surgical interventions may be required. These include shaving/dermabrasion of a scar, incision and release, skin grafting, flaps, and long-term splinting (Shumaker et al 2012).

Surgical management remains the mainstay of scar management, especially for contracted scars. Surgical interventions often aim at relieving tension and ultimately improving range of motion. While highly effective, surgical interventions may be associated with significant added morbidities. These include additional scarring at surgical sites, and relatively high recurrence rates, treatment delay, and efficacy constrained to the surgical site (Anderson et al 2014).

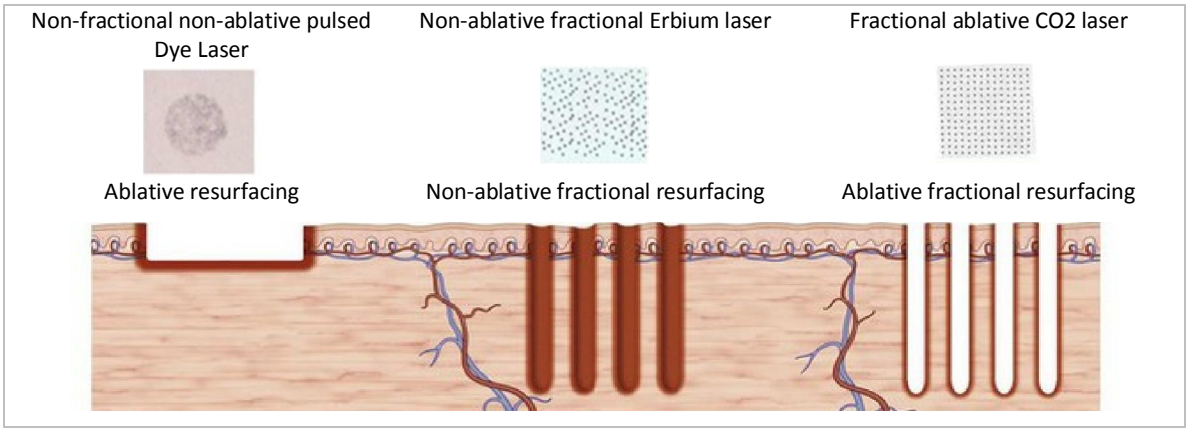
The development of laser scar treatment over the past 30 years has provided a treatment option that is less invasive than surgical interventions, but more effective than the non-invasive conservative approaches noted above (Anderson et al 2014).

Laser scar treatment works on the basis of remodelling skin by creating microscopic photo-thermal injury ('thermolysis') to specific target scarred skin areas. Skin remodelling from thermolysis following laser treatment shares the same features as wound repair and skin morphogenesis. However, the precise reason why microscopic thermal injury can improve a scar through skin resurfacing, while macroscopic thermal injury causes one, remains unknown (Anderson et al 2014).

There are different types of lasers available for skin resurfacing. They are characterised by whether they are fractionated or non-fractionated, and whether they are ablative or non-ablative. Non-fractionated lasers act on the entire treated surface, whereas fractionated lasers produce microscopic columns of thermal injury over the treatment area in a pixelated fashion (

Figure 1). Ablative lasers vaporize tissue layers in the columns whereas non-ablative lasers leave the skin intact (Albert 2017). Because of the removal of scar tissue, ablative fractional lasers may be more effective for thicker scars and for more severely contracted scars.

Figure 1: Comparison between ablative, non-ablative, fractional and non-fractional resurfacing



Source: Anderson et al (2014, supplementary material); Chan et al (2015)

Currently, three types of laser wavelengths are available. Carbon dioxide (CO_2) lasers (10 600-nm wavelength) are the most common. Erbium:yttrium-aluminum-garnet (Er:YAG) (2940-nm wavelength) and thulium (1927-nm wavelength) devices are also available (Anderson et al 2014).

The proposed intervention is ablative fractional CO_2 laser. This application is NOT brand-specific. Each CO_2 laser pulse removes 50-100 µm of tissue compared to 25-30 µm by Er:YAG (Tanna et al 2015). Clinical consensus is that ablative fractional CO_2 lasers typically produce the greatest improvement for hypertrophic and contracted scars (Anderson et al 2014). These scars are common among burns patients. Furthermore, the current consensus is that "an appropriate degree of surrounding thermal coagulation around the ablated column appears to facilitate the subsequent remodelling response. Because of somewhat weaker optical absorption by tissue water, CO_2 lasers possess a relatively greater potential for surrounding tissue coagulation than do Er:YAG lasers. Carbon dioxide lasers also decrease the potential for treatment-related bleeding" (Anderson et al 2014, p.188). To the applicant's knowledge, all burn centres providing treatment with ablative fractional device use the ablative fractional CO_2 laser device rather than an Er:YAG device. Plastic surgeons and dermatologists working in private practices might offer treatment using ablative fractional Er:YAG lasers. However, they are for different scar types (traumatic) and for patients with less severe scarring. For these reasons, the intervention is specified as ablative fractional CO_2 laser.

Ablative laser treatment is used in conjunction with reconstructive surgical procedures as part of a holistic treatment approach to scar management. In some cases, ablative laser treatment may reduce the extent of a surgical procedure (e.g. local flaps Z-plasty with laser therapy could be provided instead of regional or free flaps or tissue expanders) or replace the need for surgical intervention altogether (e.g. release of lip or eyelid ectropion due to burns).

It is worth noting that ablative laser treatment is considered a 'surgical procedure', because it is invasive, albeit to a lesser extent than surgical interventions. It is usually performed in an operating theatre, with approximately 60-70% of patients requiring general anaesthesia. The remaining patients receive local or regional anaesthesia (with or without sedation), performed by an anaesthetist. This is the same requirement as any other surgical reconstructive procedure. Paediatric patients are always treated under general anaesthesia.

In relation to treatment frequency, a minimum treatment interval of one to three months between fractional laser treatments is recommended, with treatments continued until a therapeutic plateau

or treatment goals are achieved (Anderson et al 2014). Although individual treatment courses vary, most patients receive a series of three to six treatments (Anderson et al 2014).

Rationale for clinical circumstances of use

The applicant indicated that only qualified plastic and reconstructive surgeons, trained in laser medicine and having obtained a laser safety certificate, should treat burn patients with ablative fractional CO_2 laser. This is because ablative fractional CO_2 laser in burn scar management is highly complex and technical. This opinion is consistent with views of a panel of dermatology and plastic surgery physicians, published in *Laser Treatment of Traumatic Scars with an Emphasis on Ablative Fractional Laser Resurfacing Consensus Report* (2014). The expert panel recommends that, while laser therapy for scars is generally well-tolerated with a low rate of complications, treating surgeons must exercise good judgement in applying the intervention for individual patients. As noted above, the risk that the intervention could be used beyond the intended population is also minimised by restricting it to qualified burn and reconstructive surgeons.

PASC advised that is seemed reasonable that use of the intervention be restricted to qualified burn and reconstructive surgeons. PASC noted that identifying qualified plastic and reconstructive surgeons in order to restrict use of this intervention would be difficult. DHS (Medicare) does not have a specific identifier code at the subspecialty level of burn and reconstructive surgeon. PASC considered that accreditation-recording processes (so DHS can identify providers of a specialised MBS service) have been established before. However, it generally requires a medical college to perform the role of establishing, maintaining and providing the list to DHS (Medicare). While awaiting formal arrangements for accreditation (and establishing processes that enables DHS to record practitioner information and progress rebate system adjustments), the patient population may not be able to be specifically restricted (other than on an in or out-of-hospital basis or to broader practitioner types).

PASC noted that the preferred approach of the applicant is to limit the service to plastic and reconstructive surgeons (trained in laser medicine), with laser safety certificates, and qualified in providing care to patients with severe burn scarring.

PASC noted that rural and regional areas may not have access to burn specialists. While noting that dermatologists are also mal-distributed towards urban centres, PASC noted the applicant's guidance that interested dermatologists could be trained (by burn specialists) to deliver the proposed treatment in rural areas. The applicant stated that currently, rural burn patients with acute injury (who meet certain criteria[2]) are referred to burn centres for acute treatment. Similarly, the majority of burn scars requiring treatment are referred to burn centres to receive reconstructive procedures. This has been the rationale for establishing burn centres, so patients with significant burns and scarring can receive specialist care (in recognition of the fact that burn scars are different to scars from other traumatic causes - because of the systemic inflammation that accompanies burns).

PASC noted that, due to financial constraints and smaller population pool, regional centres are much less likely to invest in an ablative fractional laser device of high quality (that would only be used to treat a small number of patients on the MBS). The applicant acknowledged that training dermatologists to provide the proposed intervention may be an option, but in practical terms, it is

[2] http://anzba.org.au/care/referral-criteria/

unlikely to make a difference to existing access to burn scar management services (because dermatologists also tend to be located in larger cities).

Comparator

Reconstructive surgical procedures for burn scars alone.

Rationale

As discussed under 'Population' on page 3, the characteristics of burn scars are highly heterogeneous, depending on the scar location, size, thickness, presentation (e.g. contracture, ulceration, erythematous) and type (e.g. keloid or hypertrophic). Accordingly, the standard of care comprises a range of non-surgical and surgical treatments, including scar excision, skin flaps and skin grafts, physical therapy and compression therapy.

The applicant indicated that **ablative fractional CO_2 laser therapy is currently being routinely used at burn centres** for the management of burn scar in conjunction with other non-surgical and surgical interventions. The services have been claimed under MBS item numbers 45515 and 45518. However, the applicant notes that these two MBS item numbers do not adequately capture the extent of the procedure and treated areas. Items 45515 and 45518 are not appropriate comparators as the items were never intended to cover ablative fractional laser resurfacing and the procedure has never been MSAC-assessed for safety, clinical effectiveness and cost effectiveness.

The MSAC's *Technical Guidelines* for therapeutic medical services (MSAC 2016) defines the 'main comparator' as the medical service that is most likely to be replaced by health care providers in practice. Since ablative fractional CO_2 laser therapy is already provided for the intended population, this document identifies the medical service most likely be used in the absence of ablative fractional CO_2 laser therapy as the main comparator. Based on this rationale, surgical reconstructive procedures for burn scars are identified as the main comparator. The applicant confirmed that ablative fractional CO_2 laser therapy is indicated and performed for the same patient population. These patients would have undergone more extensive surgical reconstructive procedures before the introduction of ablative fractional CO_2 laser therapy. Similar to the current treatment algorithm, the choice of surgical reconstructive procedures prior to introduction of ablative fractionated laser varied widely. The applicant has identified a list of the most frequently used MBS items for scar reconstructions (Table 2).

Table 2: Current MBS items for surgical reconstructive procedures for burn scars

Surgical procedures	MBS item numbers
Scar excision/release with or without split thickness skin graft	45515; 45518; 45439; 45442; 45448; 45451
Expanders (insertion & removal)	45566; 45568
Local flaps	45200; 45203; 45206

There are two existing MBS items for ablative non-fractional laser therapy for scar treatment (Table 3). The applicant explained that these non-fractional lasers are provided by dermatologists and plastic surgeons (in their private practices) for treating traumatic and surgical scars. They could use non-fractional lasers for smaller and less severe burn scars but non-fractional lasers have been superseded by fractional lasers because of lower effectiveness. The applicant stated that burn centres do not routinely use non-fractional lasers, because these lasers are not effective for severe scar cases. The applicant emphasised that, unlike other traumatic scars, burn injury causes an

inflammatory reaction in the whole body which precipitate hypertrophic scarring. Given the different patient populations, non-fractional lasers provided in private practice for non-burn scar would not be replaced if the proposed services were to be listed (i.e. not a suitable comparator).

Table 3: Current MBS items for laser treatment of scarring

Category 3 – Therapeutic Procedures **OPERATIONS | PLASTIC & RECONSTRUCTIVE**
45025: CARBON DIOXIDE LASER OR ERBIUM LASER (not including fractional laser therapy) resurfacing of the face/neck for severely disfiguring scarring resulting from trauma, burns or acne) – limited to 1 aesthetic MBS Fee: $177.35 **45026:** CARBON DIOXIDE LASER OR ERBIUM LASER (not including fractional laser therapy) resurfacing of the face or neck for severely disfiguring scarring resulting from trauma, burns or acne) – more than 1 aesthetic area. MBS Fee: $398.55

It is worth noting that non-ablative fractional lasers are also not routinely used in burn centres. Like ablative non-fractional laser, non-ablative fractional lasers do not have the potency or efficacy to treat burn scars requiring reconstruction. When used, non-ablative fractional lasers are usually for completing the surgical reconstructive treatment, such as treating vascularity and pigmentation within a scar, before or following therapy with either ablative fractional lasers or surgical procedures. They can also be used for atrophic scars, which is not the scar type considered in this application. For these reasons, they are not a suitable comparator or alternative to fractional ablative therapy.

In paediatric burn centres, patients may also receive treatment with a non-fractional non-ablative laser - Pulse Dye Laser (PDL) device. The PDL is used to treat the vascularity of immature scars rather than for reconstructive purpose. Hence, they are also not a suitable comparator.

Outcomes

A range of patient and health system related outcomes were identified from the extant literature and discussion with the applicant (Table 4). All studies measured outcomes using a combination of rating scales.

Table 4: Patient and health system related outcomes commonly used in clinical research

Outcomes	Common measures used in clinical research
Patient related outcomes Therapeutic effectiveness • Scar functionality: range of motion, pliability and elasticity, closure of chronic wound breakdown • Symptomatic control: neuropathic pain and itchiness • Scar appearance: colour, thickness, cosmesis	• Vancouver Scar scale (VSS) • Patient and Observer scar assessment scale (POSAS) and modified POSAS • University of North Carolina Scar Scale • Manchester Scale • Visual Analogue Scale (VAS) with scar rating • Stony Brook Scar Evaluation Scale • Phaseshift Rapid In Vivo Measurement of the Skin • Matching Assessment of Photographs and Scars
Safety	

Outcomes	Common measures used in clinical research
• Local side effects • Adverse events	• Erythema, swelling, exudate, bleeding, pruritus, scabbing, superficial epidermal loss • Blindness, infection, worsening scarring, dyschromia, transient increased pruritus, neuropathic pain
Health related Quality of life	Burns Specific Health Scale – Brief (BSHS-B)
Health system related outcomes • Reconstructive surgical procedures • Duration of hospitalisation • Resources used to manage side effects and adverse events • Cost effectiveness • Financial implications	 • Number or complexity • Average length of stay • Incidence and standard of care for adverse events • Cost per quality adjusted life year • Number of patients treated • capital cost of equipment • Reduction in surgical intervention and/or hospitalisation

Source: Brusselaers et al 2010; Tyack et al 2012

Rationale

Patient-related outcomes

The evidence base identified by the applicant includes two prospective before and after cohort studies, one clinical consensus report, one prospective study and two case series reports. It is commonly reported in the literature and confirmed by the applicant that limited evidence exists on ablative fractional laser treatment, particularly randomised controlled trials given practical and ethical limitations. Before and after cohort studies whereby the patient acts as their own control and case series will likely form the majority of the evidence base for this intervention.

A non-randomised controlled clinical study assessing ablative fractional CO_2 laser in thermal burn scars in fifteen patients has been published in the literature (El-Zawahdry et al 2015). In this study, half of the scar was untreated as a control. Two additional case reports of ablative fractional CO_2 laser was used to treat thermal burn scars are also reported in the literature (Waibel et al 2008; Haedersdal 2009).

Commonly used outcomes assessed for this intervention in burn scars include scar functionality (i.e. increased range of motion, improved pliability, closure of chronic wound breakdown), symptoms (e.g. neuropathic pain and itchiness), decreases the thickness of the scar, dramatically improves cosmesis, and hence reduces the stigma and alters the psychology of affected patients. Latest research has demonstrated a significant improvement in patients' quality of life.

The applicant reports that common local side effects of treatment include erythema, swelling, exudate/ discharge, pinpoint bleeding, pruritus, scabbing for a few days up to weeks, superficial epidermal loss. Adverse effects can include blindness (if laser light hits cornea/retina), infection (<1%), burn injury with worsening scarring, dyschromia, transient increased pruritus and neuropathic pain (up to months). Contraindications to fractional laser treatment include cultured epithelial autografts, active infections, and the presence of unstable epithelium within the early weeks of injury (Anderson et al 2014).

Routine adverse effects reported in the clinical literature similarly identify immediate onset of transient erythema and localised swelling, pinpoint bleeding and mild serous discharge (Anderson et

al 2014). Rare adverse effects include prolonged erythema, post-procedure pain requiring medications, scar exfoliation, and transient post-inflammatory hyperpigmentation (Anderson et al 2014). Reports of new scarring in the setting of cosmetic applications and worsening of scarring after resurfacing exist in the literature (Anderson et al 2014). On the basis of the above information, patient relevant outcomes for consideration include:

- Therapeutic effectiveness: Improved scar functionality (range of motion, pliability), symptoms (neuropathic pain, itchiness), scar thickness, cosmesis, quality of life; and
- Safety: Treatment-associated adverse events.

Of note, subjective parameters include the assessment of scar-related outcomes such as neuropathic pain and pruritus, as well as evaluation of improvement of quality of life following treatment with ablative fractional laser therapy. Some of the most commonly used measures are presented in Table 5.

Table 5: Name of instruments commonly used to measure outcomes for burn scar treatment

Name of instrument	**Scope of measurement**
Vancouver Scar scale (VSS)	Vascularity, pigmentation, pliability and height
Patient and Observer scar assessment scale (POSAS)	**Patient component**: Painfulness, itchiness, colour, stiffness, thickness, irregular appearance **Observer component:** Vascularisation, pigmentation, thickness, relief, pliability
University of North Carolina Scar Scale (UNC4P)	Pruritus , paraesthesia, pain and pliability
Manchester Scale	VAS plus scar colour, skin texture, relationship to surrounding skin, texture, margins, size, multiplicity
Visual Analogue Scale (VAS) with scar rating	vascularity, pigmentation, acceptability, observer comfort plus contour and summing the individual scores
Stony Brook Scar Evaluation Scale	VAS plus width, height, color, presence of suture/staple marks
Phaseshift Rapid In Vivo Measurement of the Skin (PRIMOS)	Skin microtopography, surface roughness.
Modified POSAS	ultrasound and histological assessment to supplement the existing POSAS
Douleur Neuropathique 4 Questions (DN4)	Neuropathic pain
5-D Pruritus Scale	Duration, degree, direction, disability and distribution of pruritus
Burn Specific Health Scale (BSHS-B) quality of life instruments	Simple abilities, hand function, affect, body image, interpersonal relationship, sexuality, heat sensitivity, treatment regimens, and work

Health care system-related outcomes

Ablative fractional CO_2 laser therapy combined with surgical scar revision may decrease the need for early burn excision and grafting in selected cases (Anderson et al 2014). This would have an important healthcare system impact in terms of reducing costly surgical intervention and hospital stay.

Based on clinical experience, the applicant estimates that introduction of the ablative fractional CO_2 laser into routine scar management could:

- reduce the number of more complex elective reconstructive surgeries by 57%; and
- reduce the length of stay at the hospital for patients undergoing elective reconstructive procedures by 74% (a drop from a mean of 5.2 days pre-laser-era to a mean of 1.8 days since introduction of the ablative fractional CO_2 laser).

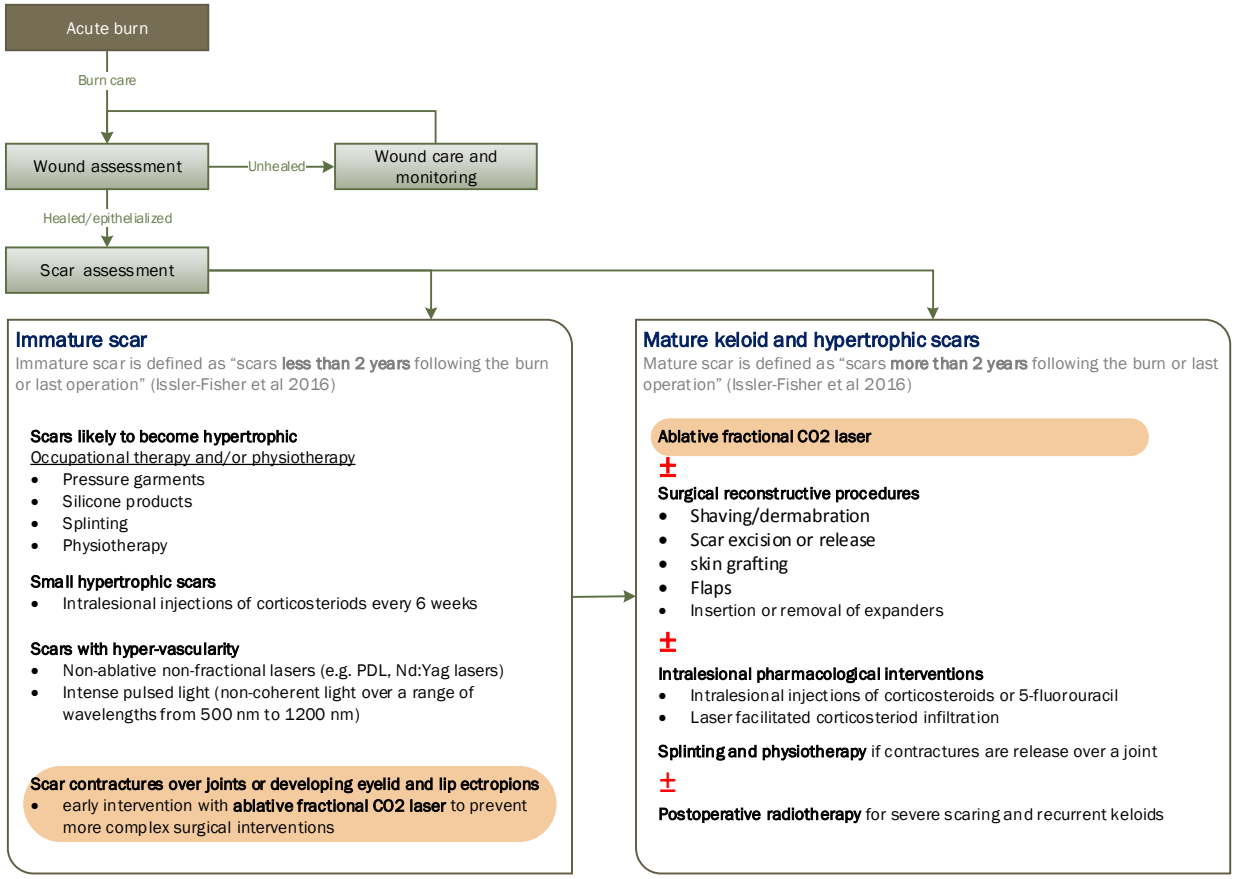
The applicant further indicated that, in some circumstances, the laser may completely replace the necessity for any of these procedures.

In order to objectively measure the outcome of ablative fractional CO_2 laser therapy on scar rehabilitation, ultrasound measurements of thickness of the scar before and after intervention could be measured (Issler-Fisher et al 2016). This will have a healthcare system impact in terms of ultrasound service use, which will need to be measured and included in the economic evaluation of the intervention for listing on the MBS.

Current / proposed clinical management algorithms for identified population

The clinical approach to treatment of burn scars largely depends on characteristics of the scar (Anderson et al 2014). As noted, ablative fractional CO_2 laser therapy is currently being routinely used at burn centres in conjunction with other non-surgical and surgical interventions. Figure 2 outlines the current clinical management algorithm for the proposed patient population. As noted in 'Comparator', patients would use surgical procedures for reconstructive purposes more extensively in the absence of ablative fractional CO2 laser. Other treatments would be the same.

Figure 2: Current clinical management algorithm for the management of burn scars



Proposed economic evaluation

The applicant submitted a claim of superiority of ablative fractional CO_2 laser therapy in terms of clinical effectiveness and safety outcomes in patients with severe scars resulting from burn injuries, compared to usual care.

Specifically, the applicant noted the following claims:

- Ablative fractional laser therapy offers cosmetic and functional enhancement for patients with severe burn scars.
- Ablative fractional laser therapy is minimally invasive, with fewer side effects.
- When combined with surgical scar revision, ablative fractional laser therapy may eventually decrease the need for early burn excision and grafting in selected cases.
- Improvement in therapeutic outcomes with ablative fractional laser therapy may have follow on effects in improving quality of life for patients with severe burn scars.

Based on this assessment, the appropriate economic evaluation is either a cost-utility analysis or a cost-effectiveness analysis. A cost-utility analysis, which presents the outcome in terms of life-years gained, is generally preferred by the Medical Services Advisory Committee (as outlined in the Guidelines). Studies reporting outcomes on quality of life will be important in this type of analysis and the advent of a Burns specific Quality of Life Scale will be advantageous in this respect.

The economic evaluation of this intervention will need to consider the availability of comparative evidence given the limited availability of randomised trials. Evidence will need to be extrapolated from the available non-randomised and observational studies, with the limitations of such evidence clearly documented. The assessment would also need to consider the extent of usual care (the comparator) and its associated resource use.

Proposed item descriptors

For consistency with existing MBS items for laser resurfacing, the following item descriptors are proposed. Item descriptors are based on total body surface area as proposed by the applicant. Given the difficulty in measuring physical aesthetic and social sequelae, the patient population is set out to align with existing MBS items and the proposed patient population.

In proposing the fees set out below, the applicant intends the fee to incorporate the costs of specialised training and education for safe and competent application of the proposed intervention, as well as the capital required for purchase and maintenance of the laser machine, in comparison to existing MBS items for laser therapy resurfacing.

Category 3 – Therapeutic Procedures **OPERATIONS | PLASTIC & RECONSTRUCTIVE**
FRACTIONAL ABLATIVE CARBON DIOXIDE LASER resurfacing of the face or neck for hypertrophic and keloid burn scars that are associated with significant functional or psychological impairment - limited to 1 aesthetic area (Anaes.) MBS Fee: $219.95 (same fee as item 45506)
FRACTIONAL ABLATIVE CARBON DIOXIDE LASER resurfacing of the face or neck for hypertrophic and keloid burn scars that are associated with significant functional or psychological impairment - more than 1 aesthetic area (Anaes.) MBS Fee: $295.70 (same fee as item 45512)
ABLATIVE FRACTIONAL CARBON DIOXIDE LASER resurfacing of the face or neck for hypertrophic and keloid burn scars that are associated with significant functional or psychological impairment – whole of face or whole of neck (Anaes.) MBS Fee: $700
ABLATIVE FRACTIONAL CARBON DIOXIDE LASER resurfacing of areas other than the face or neck for hypertrophic and keloid burn scars that are associated with significant functional or psychological impairment - area of treatment up to 3% of total body surface (Anaes.) MBS Fee: $198.25 (same fee as item 14106, plus 30%)
ABLATIVE FRACTIONAL CARBON DIOXIDE LASER resurfacing of areas other than the face or neck hypertrophic and keloid burn scars that are associated with significant functional or psychological impairment - area of treatment between 3% and up to 6% of total body surface (Anaes.) MBS Fee: $243.55 (same fee as item 14109, plus 30%)
ABLATIVE FRACTIONAL CARBON DIOXIDE LASER resurfacing of areas other than the face or neck hypertrophic and keloid burn scars that are associated with significant functional or psychological impairment - area of treatment between 6% and up to 9% of total body surface (Anaes.) MBS Fee: $288.25 (same fee as item 14112, plus 30%)
ABLATIVE FRACTIONAL CARBON DIOXIDE LASER resurfacing of areas other than the face or neck hypertrophic and keloid burn scars that are associated with significant functional or psychological impairment - area of treatment between 9% and up to 12% of total body surface (Anaes.) MBS Fee: $333.45 (same fee as item 14115, plus 30%)
ABLATIVE FRACTIONAL CARBON DIOXIDE LASER resurfacing of areas other than the face or neck

hypertrophic and keloid burn scars that are associated with significant functional or psychological impairment - area of treatment greater than 12% of total body surface (Anaes.)

MBS Fee: $423.50 (same fee as item 14118, plus 30%)

Up to a maximum of 6 sessions (including any sessions to which any of the above items apply) in any 12 month period.

References

Albert C 2017, Fractional vs Non-Fractional Laser: Where are we and where are we going? Congress Handout. Geneva: Schweizerische Gesellschaft für medizinische Laseranwendungen (SGML). www.rosenfluh.ch/media/dermatologie-aesthetische-medizin/2017/02/Fractional-vs-Non-Fractional-Laser.pdf [Accessed May 2017]

Anderson R, Donelan M, Hivnor C, Gleeson E, Ross V, Shumaker P, Uebelhoer N & Waibel J 2014, 'Laser treatment of traumatic scars with an emphasis on ablative fractional laser resurfacing: Consensus Report', *JAMA Dermatology*, 150(2):187-93.

Australia and New Zealand Burn Association 2017, Burn Units, available at: http://anzba.org.au/care/burn-units/, accessed 6 March 2017.

Australian Institute of Health and Welfare & Flinders University 2016, *Hospitalised burn injuries Australia 2013-14*, Injury Research and Statistics Series 102, Cat. no. INJCAT 178, AIHW, Canberra.

Brusselaers N, Pirayesh A, Hoeksema H, Verbelen J, Blot S, Monstrey S 2010. Burn scar assessment: a systematic review of different scar scales. J Surg Res. 164(1):e115-23.

Chan CYS, Metelitsa A, Dover JS 2015. Non-ablative fractional laser rejuvenation. https://clinicalgate.com/non-ablative-fractional-laser-rejuvenation/ [Accessed May 2017]

El-Zawahry B, Sobhi R, Bassiouny D & Tabak S 2015, 'Ablative CO_2 fractional resurfacing n treatment of thermal burn scars: an open-label controlled trial and histopathological study', *Journal of Cosmetic Dermatology*, 14:324-31.

Falder S, Browne A, Edgar D, Staples E, Fong J, Rea S, Wood F 2009, 'Core outcomes for adult burn survivors: a clinical overview' Burns. 35(5):618-41.

Fiona Wood Foundation 2017, *Current Statistics*, available at: http://www.fionawoodfoundation.com/our-challenge/current-statistics/, accessed 21 February 2017.

Gold MH, McGuire M, Mustoe TA, Pusic A, Sachdev M, Waibel J, Murcia C; International Advisory Panel on Scar Management. Updated international clinical recommendations on scar management: part 2- algorithms for scar prevention and treatment. Dermatol Surg. 2014; 40(8):825-31.

Hultman C, Friedstat J, Edkins R, Cairns B & Meyer A 2014, 'Laser resurfacing and remodelling of hypertrophic burn scars', *Annals of Surgery*, 260(3):519-32.

Issler-Fisher A, Fisher O, Smialkowski A, Li F, van Schalkwyk C, Haertsch P & Maitz P 2016, 'Ablative fractional CO2 laser for burn scar reconstruction: an extensive subjective and objective short-term outcome analysis of a prospective treatment cohort', *Burns*, in-press.

Lee KC, Dretzke J, Grover L, Logan A, Moiemen N. 2016. A systematic review of objective burn scar measurements. Burns Trauma. 27;4:14.

Medical Services Advisory Committee 2016. Technical Guidelines for preparing assessment reports for MSAC – Medical services type: Therapeutic (Version 2.0). Canberra: MSAC. http://www.msac.gov.au/internet/msac/publishing.nsf/Content/9C7DCF1C2DD56CBECA25801000123C32/$File/TherapeuticTechnicalGuidelines-Final-March2016-Version2.0-accessible.pdf [Accessed May 2017]

Ozog D, Liu A, Chaffins M, Ormsby A, Fincher E, Chipps L, Mi Q, Grossman P, Pui J & Moy R 2013, 'Evaluation of clinical results, histological architecture, and collagen expression following treatment of mature burn scars with a fractional carbon dioxide laser', *JAMA Dermatology*, 149(1):50-57.

Shumaker P, Kwan J, Landers J & Uebelhoer N 2012, 'Functional improvements in traumatic scars and scar contractures using an ablative fractional laser protocol', *Journal of Trauma and Acute Care Surgery*, 73;2(1):S116-121.

Shumaker P, Kwan J, Badiavas E, Waibel J, Davis S & Uebelhoer N 2012b, 'Rapid healing of scar-associated chronic wounds after ablative fractional resurfacing', *Archives of Dermatology*, 148(11):1289-93.

Tanna N and Hopping S 2015. Skin Resurfacing - Laser Surgery. Medscape: http://emedicine.medscape.com/article/838501-overview [Accessed May 2017]

Tarijian A & Goldberg D 2011, 'Fractional ablative laser skin resurfacing: a review', *Journal of* Cosmetic and Laser therapy, 13(6):262-64.

Tyack Z, Simons M, Spinks A, Wasiak J. A systematic review of the quality of burn scar rating scales for clinical and research use. Burns.38 (1):6-18.

Waibel J & Beer K, 2008, 'Fractional laser resurfacing for thermal burns', Journal of Drugs in Dermatology, 7(1):59-61