



**Australian Government**

**Department of Health**

# **Application Form**

## **MSAC Application 1475**

### **Ablative fractional laser resurfacing for burn scar treatment**

**(New and Amended Requests for Public Funding)**

**(Version 0.1)**

This application form is to be completed for new and amended requests for public funding (including but not limited to the Medicare Benefits Schedule (MBS)). It describes the detailed information that the Australian Government Department of Health requires in order to determine whether a proposed medical service is suitable.

Please use this template, along with the associated Application Form Guidelines to prepare your application. Please complete all questions that are applicable to the proposed service, providing relevant information only. Applications not completed in full will not be accepted.

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

Phone: +61 2 6289 7550

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Website: <http://www.msac.gov.au>

## **PART 1 – APPLICANT DETAILS**

### **1. Applicant details (primary and alternative contacts)**

Corporation / partnership details <i>(where relevant):</i> Corporation name: ABN: Business trading name:	Redacted
Primary contact name:	Redacted
Primary contact numbers: Business: Mobile: Email:	Redacted
Alternative contact name:	Redacted
Alternative contact numbers: Business: Mobile: Email:	Redacted

### **2. (a) Are you a lobbyist acting on behalf of an Applicant?**

Yes:   
No:

### **(b) If yes, are you listed on the Register of Lobbyists?**

Yes:   
No:

## **PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE**

### **3. Application title**

Proposal for MBS item numbers for ablative fractional laser resurfacing for burn scar treatment

### **4. Provide a succinct description of the medical condition relevant to the proposed service (*no more than 150 words – further information will be requested in Part 6 of the Application Form*)**

Scarring remains a major clinical outcome of severe burn wound healing and other medical conditions where large areas of skin are affected. Despite assiduous efforts in traditional scar management, severe scars often persist to significantly diminish quality of life by disfigurement, pain, itchiness, inability to sweat, abnormal heat sensitivity, and by contractures restraining the motion of body and joints of affected patients.

Traditionally burn scars are treated with non-surgical therapeutic options and a great variety of surgical techniques. However, most of these surgical approaches are associated with considerable morbidity, involve a lengthy painful process, time off work, and admission(s) to the hospital.

### **5. Provide a succinct description of the proposed medical service (*no more than 150 words – further information will be requested in Part 6 of the Application Form*)**

The advent of fractional ablative resurfacing represents a milestone in burn and reconstructive surgery to restore the functional and aesthetical integrity of a burnt body and has recently been added to the routine treatment for burn scar reconstruction. The laser should especially help fill the cleft between occupational therapy and surgical intervention, in some cases replace reconstructive procedures or be used before surgery to soften scars and improve surgical outcomes. Its use can positively influence immature scars, hence limits morbidity and accelerates rehabilitation. By including this approach into the standard practice, burn scars can be treated holistically and minimize the extent or sometimes even avoid reconstructive surgery.

### **6. (a) Is this a request for MBS funding?**

Yes:

No:

### **(b) If yes, is the medical service(s) proposed to be covered under an existing MBS item number(s) or is a new MBS item(s) being sought altogether?**

Amendment to existing MBS item(s):

New MBS item(s):

### **(c) If an amendment to an existing item(s) is being sought, please list the relevant MBS item number(s) that are to be amended to include the proposed medical service:**

N/A

**(d) If an amendment to an existing item(s) is being sought, what is the nature of the amendment(s)?**

- i. An amendment to the way the service is clinically delivered under the existing item(s)
- ii. An amendment to the patient population under the existing item(s)
- iii. An amendment to the schedule fee of the existing item(s)
- iv. An amendment to the time and complexity of an existing item(s)
- v. Access to an existing item(s) by a different health practitioner group
- vi. Minor amendments to the item descriptor that does not affect how the service is delivered
- vii. An amendment to an existing specific single consultation item
- viii. An amendment to an existing global consultation item(s)
- ix. Other (please describe below)


N/A

**(e) If a new item(s) is being requested, what is the nature of the change to the MBS being sought?**

- i. A new item which also seeks to allow access to the MBS for a specific health practitioner group
- ii. A new item that is proposing a way of clinically delivering a service that is new to the MBS (in terms of new technology and / or population)
- iii. A new item for a specific single consultation item
- iv. A new item for a global consultation item(s)

X

**(f) Is the proposed service seeking public funding other than the MBS?**

Yes:   
 No:

**(g) If yes, please advise:**

N/A

**7. What is the type of service:**

- Therapeutic medical service
- Investigative medical service
- Single consultation medical service
- Global consultation medical service
- Allied health service
- Co-dependent technology
- Hybrid health technology

**8. For investigative services, advise the specific purpose of performing the service (which could be one or more of the following):**

- i To be used as a screening tool in asymptomatic populations
- ii. Assists in establishing a diagnosis in symptomatic patients
- iii. Provides information about prognosis
- iv. Identifies a patient as suitable for therapy by predicting a variation in the effect of the therapy
- v. Monitors a patient over time to assess treatment response and guide subsequent treatment decisions


**9. Does your service rely on another medical product to achieve or to enhance its intended effect?**

Pharmaceutical / Biological  
 Prosthesis or device  
 No

X (fractional ablative CO2 laser)

**10. (a) If the proposed service has a pharmaceutical component to it, is it already covered under an existing Pharmaceutical Benefits Scheme (PBS) listing?**

Yes   
 No

**(b) If yes, please list the relevant PBS item code(s)?**

N/A
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**(c) If no, is an application (submission) in the process of being considered by the Pharmaceutical Benefits Advisory Committee (PBAC)?**

Yes (please provide PBAC submission item number below)   
 No

N/A
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**(d) If you are seeking both MBS and PBS listing, what is the trade name and generic name of the pharmaceutical?**

Trade name	N/A
Generic name	N/A

**11. (a) If the proposed service is dependent on the use of a prosthesis, is it already included on the Prostheses List?**

Yes   
 No

**(b) If yes, please provide the following information (where relevant):**

Billing code(s)	
Trade name of prostheses	
Clinical name of prostheses	
Other device components delivered as part of the service	

**(c) If no, is an application in the process of being considered by a Clinical Advisory Group or the Prostheses List Advisory Committee (PLAC)?**

Yes	<input type="checkbox"/>
No	<input type="checkbox"/>

**(d) Are there any other sponsor(s) and / or manufacturer(s) that have a similar prosthesis or device component in the Australian market place which this application is relevant to?**

Yes	<input type="checkbox"/>
No	<input checked="" type="checkbox"/>

**(e) If yes, please provide the name(s) of the sponsor(s) and / or manufacturer(s).**

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**12. Please identify any single and / or multi-use consumables delivered as part of the service?**

Single use consumables	Approximately 170.- AUD per patient per 3% total body surface area (TBSA) treated (consumables, local anaesthetic cream, etc.)
Multi-use consumables	N/A

**PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS**

13. (a) If the proposed medical service involves the use of a medical device, in-vitro diagnostic test, pharmaceutical product, radioactive tracer or any other type of therapeutic good, please provide the following details:

Type of therapeutic good	Ablative fractional CO <sub>2</sub> Ultrapulse® laser
Manufacturer's name	Lumenis Limited
Sponsor's name	

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

Class III	no
AIMD	no
N/A	

14. (a) Is the therapeutic good to be used in the service exempt from the regulatory requirements of the *Therapeutic Goods Act 1989*?

Yes	<input type="checkbox"/>	If yes, please provide supporting documentation as an attachment to this application form
No	<input checked="" type="checkbox"/>	

(b) If no, has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

Yes (please provide details below)	<input checked="" type="checkbox"/>
No	<input type="checkbox"/>

ARTG listing, registration or inclusion number:	ARTG Identifier: 182239 Class IIb
TGA approved indication(s), if applicable:	N/A
TGA approved purpose(s), if applicable:	Laser is used for the coagulation, ablation, vaporization and incision of soft tissue in number of dermatological and surgical procedures

15. If the therapeutic good has not been listed, registered or included in the ARTG, is the therapeutic good in the process of being considered for inclusion by the TGA?

Yes (please provide details below)	<input type="checkbox"/>
No	<input type="checkbox"/>

Date of submission to TGA	
Estimated date by which TGA approval can be expected	
TGA Application ID	

TGA approved indication(s), if applicable  
TGA approved purpose(s), if applicable




**16. If the therapeutic good is not in the process of being considered for listing, registration or inclusion by the TGA, is an application to the TGA being prepared?**

Yes (please provide details below)

No

Estimated date of submission to TGA

Proposed indication(s), if applicable

Proposed purpose(s), if applicable

**PART 4 – SUMMARY OF EVIDENCE**

17. Provide an overview of all key journal articles or research published in the public domain related to the proposed service that is for your application (limiting these to the English language only). *Please do not attach full text articles, this is just intended to be a summary.*

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
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	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
1.	Prospective Before and After Cohort	Ablative fractional CO <sub>2</sub> laser for burn scar reconstruction: An extensive subjective and objective short-term outcome analysis of a prospective treatment cohort	Extensive analysis of 47 patients with 118 burn scars, treated with the ablative fractional CO <sub>2</sub> Ultrapulse® laser.  At 6-8 weeks follow-up after one treatment only → highly statistically significant improvement in objective and subjective outcome parameters, including Vancouver Scar Assessment Score, Patient and Observer Scar Assessment Score, standardized Ultrasound measurement of scar thickness, neuropathic pain, pruritus, and burn specific quality of life.	BURNS 2016; in press; available online on: <a href="https://www.ncbi.nlm.nih.gov/pubmed">https://www.ncbi.nlm.nih.gov/pubmed</a>	October 2016

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
2.	Prospective Before and After Cohort	Laser resurfacing and remodelling of hypertrophic burn scars	147 burn patients with hypertrophic scars included, treated with the ablative fractional CO <sub>2</sub> Ultrapulse® laser, 57 patients with a 2 year follow-up:  Significant improvement in the Vancouver Scar Assessment Score & the UNC4P-Score (pain, pruritus, paraesthesia, pliability),  Overall excellent outcome	Annals of Surgery 2014; Volume 260, Number 3, Pages 519-532  <a href="https://www.ncbi.nlm.nih.gov/pubmed">https://www.ncbi.nlm.nih.gov/pubmed</a>	September 2014

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
3.	Consensus Report	Laser treatment of traumatic scars with an emphasis on ablative fractional laser resurfacing: consensus report	The advent of fractional photothermolysis and its application to scar treatment represents a significant breakthrough in the realm of trauma rehabilitation. Laser scar therapy, particularly fractional ablative laser resurfacing deserves a prominent role in scar treatment, with the possible inclusion of early intervention for contracture avoidance and assistance with wound healing. The report suggests the routine addition of ablative fractional resurfacing to existing trauma scar treatment paradigms.	JAMA Dermatology 2014; Volume 150, Number 2, Pages 187-93  <a href="https://www.ncbi.nlm.nih.gov/pubmed">https://www.ncbi.nlm.nih.gov/pubmed</a>	December 2013

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
4.	Prospective Study	Evaluation of clinical results, histological architecture, and collagen expression following treatment of mature burn scars with fractional carbon dioxide laser	18 patients included, 10 patient completed entire treatment protocol. Histopathological analysis of scar tissue before and after 3 treatment cycles with the ablative fractional CO <sub>2</sub> Ultrapulse® laser → Significant histological improvement in dermal collagen; Statistically significant increase in Type III collagen expression and a decrease in Type I collagen expression. Further, statistically significant improvement noted in clinical evaluation of patients before and after 3 treatments (Vancouver Scar Assessment Score, Patient and Observer Scar Assessment Score).	JAMA Dermatology; Volume 149, Number 1, Pages 50-57  <a href="https://www.ncbi.nlm.nih.gov/pubmed">https://www.ncbi.nlm.nih.gov/pubmed</a>	January 2013

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
5.	Case Series	Functional improvements in traumatic scars and scar contractures using ablative fractional laser protocol	<p>4 patients with hypertrophic, contracted scars included &amp; treated with the ablative fractional CO2 Ultrapulse® laser;</p> <p><u>Patient 1:</u> complete hand function regained at 4mt follow-up;</p> <p><u>Patient 2:</u> normalization of walking at 6mt follow-up &amp; persisted improvement at 2y follow-up;</p> <p><u>Patient 3:</u> excellent scar pliability, durability, full participation in prosthetic rehabilitation at 3mt follow-up;</p> <p><u>Patient 4:</u> scar flattening, resolving pain &amp; improved mobility at 9mt follow-up</p>	<p>J Trauma Acute Care Surgery; Volume 73, Number 2, Supplement 1, Pages S116 – S121.</p> <p>Available online on: <a href="https://www.ncbi.nlm.nih.gov/pubmed">https://www.ncbi.nlm.nih.gov/pubmed</a></p>	November 2012

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
6.	Case Series	Rapid healing of scar-associated chronic wounds after ablative fractional resurfacing	3 patients with multiple scars related to blast injuries with contraction, poor pliability, textural irregularity & chronic focal wounds, treated with the ablative fractional CO2 Ultrapulse® laser; all patients experienced incidental rapid healing of their chronic wounds within 2weeks of their initial laser treatment. Healing was sustained throughout the treatment course and beyond & was associated with gradual enhancement in scar pliability, texture, durability, and range of motion.	Arch Dermatology; Volume 148, Number 11: Pages 1289 – 1293  Available online on:  <a href="https://www.ncbi.nlm.nih.gov/pubmed">https://www.ncbi.nlm.nih.gov/pubmed</a>	November 2012
7.					
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9.					
10.					



	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
11.					
12.					
13.					
14.					
15.					

\* Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.

\*\*Provide high level information including population numbers and whether patients are being recruited or in post-recruitment, including providing the trial registration number to allow for tracking purposes.

\*\*\* If the publication is a follow-up to an initial publication, please advise.

**18. Identify yet to be published research that may have results available in the near future that could be relevant in the consideration of your application by MSAC (limiting these to the English language only). Please do not attach full text articles, this is just intended to be a summary.**

	Type of study design*	Title of research (including any trial identifier if relevant)	Short description of research (max 50 words)**	Website link to research (if available)	Date***
1.					
2.					
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\* Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.

\*\*Provide high level information including population numbers and whether patients are being recruited or in post-recruitment.

\*\*\*Date of when results will be made available (to the best of your knowledge).

**PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION**

**19. List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the service (please attach a letter of support for each group nominated).**

Given the highly technical and complex nature of the ablative fractional CO2 laser in burn scar management of this very vulnerable patient cohort, only qualified burn specialists, trained in laser medicine & having obtained a laser safety certificate, should treat burn patients with the ablative fractional CO2 laser. Besides the different settings, which have to be tailored to each patient, an adaptive combination of different handpieces (each with different treatment effects) is required to achieve optimal treatment outcomes. It is thus pertinent that the treating surgeon acquires a sufficient caseload to establish the optimal treatment algorithm for each individual patient.

Please find attached letter of support from the Australian and New Zealand Burn Association (ANZBA).

**20. List any professional bodies / organisations that may be impacted by this medical service (i.e. those who provide the comparator service).**

N/A

**21. List the relevant consumer organisations relevant to the proposed medical service (please attach a letter of support for each consumer organisation nominated).**

N/A

**22. List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed medical service.**

N/A

**23. Nominate two experts who could be approached about the proposed medical service and the current clinical management of the service(s):**

Name of expert 1	Redacted
Telephone number(s)	Redacted
Email address	Redacted
Justification of expertise	Redacted
Name of expert 2	Redacted
Telephone number(s)	Redacted
Email address	Redacted
Justification of expertise	Redacted

*Please note that the Department may also consult with other referrers, proceduralists and disease specialists to obtain their insight.*



**PART 6 – POPULATION (AND PRIOR TESTS), INDICATION, COMPARATOR, OUTCOME (PICO)**

**PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION**

**24. Define the medical condition, including providing information on the natural history of the condition and a high level summary of associated burden of disease in terms of both morbidity and mortality.**

Burn Scars:

Our skin is the largest organ in our body keeping us in touch with the outside world. It is an avenue to our most intimate selves physically and psychologically and its complexity thus far has not been replicated.

When lost by way of a severe burn, the skin does not heal itself by regeneration but rather by scarring. With improvements in the management of burn patients and the associated improved survival rates, these scars may create significant morbidity for millions of people worldwide. Besides the stigma, which can result in reduced quality of life with extensive psychological and emotional problems, patients frequently suffer from symptoms such as itchiness, chronic pain, increased heat-sensitivity, inability to sweat, and restricted range of motion. Particularly burn scars in the face, neck, hands, and over joints, may have detrimental physical, aesthetic, and social consequences associated with substantial financial costs for modern health-care systems, mental health, and time off work. Rehabilitation of a severe burn injury is a process over years and the sequelae of severe scarring is life-changing.

Thus, effective scar management is of utmost importance to reduce symptoms, improve function, cosmesis, hence psychology and accelerate re-integration into society and work.

References:

1. Mustoe, T.A., *Scars and keloids*. *BMJ*, 2004. **328**(7452): p. 1329-30.
2. Waibel, J. and K. Beer, *Ablative fractional laser resurfacing for the treatment of a third-degree burn*. *J Drugs Dermatol*, 2009. **8**(3): p. 294-7.
3. Issler-Fisher, A.C., et al., *Ablative fractional CO2 laser for burn scar reconstruction: An extensive subjective and objective short-term outcome analysis of a prospective treatment cohort*. *Burns*, 2016.

**25. Specify any characteristics of patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed medical service, including any details of how a patient would be investigated, managed and referred within the Australian health care system in the lead up to being considered eligible for the service.**

Patient population:

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 (amongst others pruritus, pain, stigma, and contracture).

Rendering practitioners:

Qualified Burn Specialist (Medical Doctors/Surgeons)

Referring practitioners:

- Medical practitioners (surgeons, GPs etc.)
- Occupational therapists/physiotherapists specialised in chronic scar management

**26. Define and summarise the current clinical management pathway *before* patients would be eligible for the proposed medical service (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway up to this point).**

**Treatment with the ablative fractional CO2 laser is already included in the current clinical management plan!**

Patients suffering from the consequences of burn scars, and scars following other medical conditions where large areas of skin are affected, are referred to the regular burns/scar clinics, where a plan for their scar management is elaborated including occupational therapy, physiotherapy, treatment with the ablative fractional CO2 laser, and other reconstructive surgical procedures. Depending on the individual requirements, a holistic scar management plan will be discussed with the patient and planned.

The laser treatment itself is performed as a day-only-procedure under local or general anaesthesia. Depending on the location and extent of the scar other small surgical reconstructive procedures might be performed during the same operation.

3-6 treatment sessions with the ablative fractional CO2 laser are required with an interval of 6-24 weeks to achieve an optimal outcome. However, depending on patient factors (skin type, ethnicity, etc.) and scar characteristics, the number of treatments and treatment-intervals may be altered.

Patients are re-evaluated in a consultation-setting as a follow-up before their subsequent treatment.

(Please find flow-chart attached)

**PART 6b – INFORMATION ABOUT THE INTERVENTION**

**27. Describe the key components and clinical steps involved in delivering the proposed medical service.**

The provided treatment service includes a novel laser technology, which has been developed for effective scar treatment. This laser technique, which is also called “Fractional Photothermolysis”, is the hallmark of the so-called ablative fractional CO2 lasers [1].

The difference to conventional lasers is, that high energy is delivered in a small grid, in punching hundreds of micro-channels in the skin/scar to cause minor injuries, leaving the surrounding area unharmed [2]. The healing process of these micro-injuries induces the change of the scar tissue as a whole. Rapid improvement can be noticed in pliability, pigmentation changes, followed by gradual enhancement of the texture, and consecutive improvement of pain, itchiness, improved heat-sensitivity and physical mobility within days to weeks after each treatment. Latest research has even proved a significant increase in quality of life. [3-5].

The procedure room or theatre has to be equipped according to the laser safety guidelines. Personnel resources include: proceduralist (burn surgeon), laser safety nurse, and an anaesthetic nurse / anaesthetist (if a general anaesthesia is required).

The treatment with the ablative fractional CO2 laser will be performed under local or general anaesthesia.

**References:**

1. Manstein, D., et al., Fractional photothermolysis: a new concept for cutaneous remodeling using microscopic patterns of thermal injury. *Lasers Surg Med*, 2004. **34**(5): p. 426-38.
2. Anderson, R.R., et al., Laser treatment of traumatic scars with an emphasis on ablative fractional laser resurfacing: consensus report. *JAMA Dermatol*, 2014. **150**(2): p. 187-93.
3. Jesitus, J. Ablative fractional resurfacing restores form, function after scarring. *Dermatology Times* 2013; Dec 1 2013:[Available from: <http://dermatologytimes.modernmedicine.com/dermatology-times/news/ablative-fractional-resurfacing-restores-form-function-after-scarring>; accessed 26 May 2014.]
4. Issler-Fisher, A.C., et al., Ablative fractional CO2 laser for burn scar reconstruction: An extensive subjective and objective short-term outcome analysis of a prospective treatment cohort. *Burns*, 2016.
5. Hultman, C.S., et al., Laser resurfacing and remodeling of hypertrophic burn scars: the results of a large, prospective, before-after cohort study, with long-term follow-up. *Ann Surg*, 2014. **260**(3): p. 519-29; discussion 529-32.

**28. Does the proposed medical service include a registered trademark component with characteristics that distinguishes it from other similar health components?**

A registered trademark for an ablative fractional CO2 laser per se does not exist, although so far the technology of the ablative fractional UltraPulse® CO2 laser is specific to the company distributing the laser (Lumenis), providing different handpieces for specific treatment for scars. The SCAAR FX™ has the unique combination of short pulse durations and high energy, which enables deep, precise and effective treatment. Contrary to other ablative fractional lasers, the UltraPulse's® SCAAR FX™ reaches a penetration depth of up to 4.0mm, which is 4x the depth of penetration of any other CO2 laser, with an optimal ablation/coagulation ratio. The technology enables the proceduralist to tailor parameters to individual patient's needs. An important feature – and the reason why this belongs in the hands of trained medical specialists – is that besides its very powerful effect, it can also cause a lot of damage if used incorrectly. This is also supported by observational data suggesting, that complication rates may be higher when laser treatments are performed by non-specialists [1].

If other powerful ablative fractional devices (for example erbium lasers) are similarly effective for pathological scars is currently topic of debate amongst specialists in this field.

References:

1. Hammes, S., et al., Treatment errors resulting from use of lasers and IPL by medical laypersons: results of a nationwide survey. *J Dtsch Dermatol Ges*, 2013. **11**(2): p. 149-56.

**29. If the proposed medical service has a prosthesis or device component to it, does it involve a new approach towards managing a particular sub-group of the population with the specific medical condition?**

No

**30. If applicable, are there any limitations on the provision of the proposed medical service delivered to the patient (i.e. accessibility, dosage, quantity, duration or frequency).**

Depending on the patient's skin type, ethnicity, nature & type of scar, maturation status of scar, the settings (dosage, etc.) have to be chosen accordingly to treat a patient safely. The treatment interval can also vary according to these factors, which is why it is important that the patients are assessed for suitability and arrangement of a treatment plan in a specialised scar clinic. The procedure itself should be undertaken by a specialist for burn scars.

**31. If applicable, identify any healthcare resources or other medical services that would need to be delivered at the same time as the proposed medical service.**

Required personnel: proceduralist (burn surgeon), laser safety nurse, scrub nurse, and an anaesthetic nurse / anaesthetist (if a general anaesthesia is required).

No other healthcare resources required.

**32. If applicable, advise which health professionals will primarily deliver the proposed service.**

Burn & Scar Specialists (Medical Doctors/Surgeons)



**33. If applicable, advise whether the proposed medical service could be delegated or referred to another professional for delivery.**

No, the procedure should only be undertaken by a specialist for burn scars.

**34. If applicable, specify any proposed limitations on who might deliver the proposed medical service, or who might provide a referral for it.**

As previously mentioned, the indication, application and treatment planning belongs in to the hands of a specialist (medical doctor/surgeons) with exquisite expertise with the nature of burn scars.

Patients demographics, information about the trauma mechanism, as well as information about the nature, type, quality and age of the scar, the treatment has to be tailored to each patient individually.

Added to that, as elucidated in point 28, besides the very powerful effect of the ablative fractional Ultrapulse®, it can also cause a lot of damage if used incorrectly and by unqualified personnel [1].

References:

1. Hammes, S., et al., Treatment errors resulting from use of lasers and IPL by medical laypersons: results of a nationwide survey. *J Dtsch Dermatol Ges*, 2013. **11**(2): p. 149-56.

**35. If applicable, advise what type of training or qualifications would be required to perform the proposed service as well as any accreditation requirements to support service delivery.**

- Qualified Burn Specialist (Medical doctor/Surgeon)
- Laser Safety Certificate

**36. (a) Indicate the proposed setting(s) in which the proposed medical service will be delivered (select all relevant settings)**

Inpatient private hospital	<input type="checkbox"/>
Inpatient public hospital	<input checked="" type="checkbox"/>
Outpatient clinic	<input checked="" type="checkbox"/>
Emergency Department	<input type="checkbox"/>
Consulting rooms	<input type="checkbox"/>
Day surgery centre	<input type="checkbox"/>
Residential aged care facility	<input type="checkbox"/>
Patient's home	<input type="checkbox"/>
Laboratory	<input type="checkbox"/>
Other – please specify	<input type="checkbox"/>

**(b) Where the proposed medical service is provided in more than one setting, please describe the rationale related to each.**

The majority of the burn patients presenting with pathological burn scars are seen in the outpatient clinic and subsequently treated with the ablative fractional CO2 laser as a day-only procedure. However, we do also treat patients who are hospitalized for their initial burn injury and are already developing hypertrophic scars and contractions, or are admitted for more complex reconstructive procedures in conjunction with the treatment with the ablative fractional CO2 laser.

**37. Is the proposed medical service intended to be entirely rendered in Australia?**

Yes

No (please specify below)

**PART 6c – INFORMATION ABOUT THE COMPARATOR(S)**

**38. Nominate the appropriate comparator(s) for the proposed medical service, i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system (including identifying health care resources that are needed to be delivered at the same time as the comparator service).**

**As this is a new treatment modality (in addition to the traditional scar management and reconstructive options), there are no comparators as such.**

Treatment with the ablative fractional CO2 laser provides a novel treatment modality which was previously not available avenue for early intervention to positively influence young immature scar, as well as a late scar improvement of old, mature scars. This treatment should serve as an addition to the traditional scar management, limit the extent of required reconstructive procedures, or sometimes even avoid a more complex reconstructive procedure.

At Concord Repatriation General Hospital, we have had an annual increase in the number of outpatient visits of 17% and an annual increase in the number of admissions of 39% since 2013. However, at the same time we could observe a decrease of the number of elective reconstructive procedures of 57%, and a reduction of the length of stay at the hospital following elective reconstructive surgical procedures of 74% (from a mean of 5.2days pre-laser era to 1.85 days since we have the ablative fractional CO2 Ultrapulse® laser).

**39. Does the medical service that has been nominated as the comparator have an existing MBS item number(s)?**

Yes (please provide all relevant MBS numbers below)

No

**40. Define and summarise the current clinical management pathways that patients may follow *after* they receive the medical service that has been nominated as the comparator (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway that patients may follow from the point of receiving the comparator onwards including health care resources).**

Surgery remains the main therapeutic approach for contracted scars and aims to relieve tension ultimately improving the range of motion of the affected areas. However, by its very nature it causes additional scarring, especially in people prone to hypertrophic scars, and hence has little place to play in the improvement of cosmesis, structure, and sometimes, even function of the scar. Further, surgery usually does not influence patient-debilitating factors such as chronic, neuropathic pain and itching. Various non-surgical therapeutic options exist to improve burn scar management, ranging from physical therapy, use of compression garment, topical medical therapy to other types of laser treatments. However, there remains a significant gap between these traditionally conservative measures and the surgical therapy, which although sometimes highly effective, is associated with considerable morbidity, high recurrence rates, and very often also treatment delays [1-3].

The treatment with the ablative fractional CO2 laser complements current scar management. As previously mentioned, current scar treatment paradigms generally indicate a scar to be fully mature (>1year post trauma) to allow for spontaneous improvement before surgical intervention for restrictive or cosmetically disfiguring scars are applied [3-6]. However, with the ablative fractional CO2 laser it is possible to start treatment as early as several weeks after the injury has occurred [7,8]. It requires between 3-6 treatment sessions with an interval of 6weeks to 6months in between each treatment session to achieve an optimal outcome. This early treatment intervention positively influences scar formation, improves early mobility, enhances, and hereby accelerates the entire rehabilitative process [7]. Evidence also suggests that old, mature scars can profit from the treatment with this laser modality. The laser does not replace surgery, but will decrease the extent of surgery & prepares the scar for an optimal outcome.

Please see flow-chart Point 6, Number 25.

Currently, for treatment with the ablative fractional CO2 laser MBS item numbers #45515 (*Scar, other than on face or neck, not more than 7cms in length, revision of, as an independent procedure, where undertaken in the operating theatre of a hospital, or where performed by a specialist in the practice of his or her specialty*) and #45518 (*Scar, other than on face or neck, more than 7cms in length, revision of, as an independent procedure, where undertaken in the operating theatre of a hospital, or where performed by a specialist in the practice of his or her specialty*) are routinely used. However, these item numbers do neither grasp the whole extent of the procedure, nor account for the extent of the treated areas (please see explanations in Part 8). Therefore, given the highly technical and complex nature of this new minimally invasive approach in burn victims, we submit that there should be a benefit by way of a clearly defined and separated MBS item numbers that only be used by designated specialists within burn units.

References:

1. Mustoe, T.A., *Scars and keloids. BMJ, 2004. 328(7452): p. 1329-30.*
2. Anderson, R.R., et al., *Laser treatment of traumatic scars with an emphasis on ablative fractional laser resurfacing: consensus report. JAMA Dermatol, 2014. 150(2): p. 187-93.*
3. Manstein, D., et al., *Fractional photothermolysis: a new concept for cutaneous remodeling using microscopic patterns of thermal injury. Lasers Surg Med, 2004. 34(5): p. 426-38.*
4. Smith, M.A., A.M. Munster, and R.J. Spence, *Burns of the hand and upper limb--a review. Burns, 1998. 24(6): p. 493-505.*
5. Motamed, S., et al., *Treatment of flexion contractures following burns in extremities. Burns, 2006. 32(8): p. 1017-21.*
6. [Wainwright, D.J., Burn reconstruction: the problems, the techniques, and the applications. Clin Plast Surg, 2009. 36\(4\): p. 687-700.](#)
7. [Shumaker, P.R., et al., Functional improvements in traumatic scars and scar contractures using an ablative fractional laser protocol. J Trauma Acute Care Surg, 2012. 73\(2 Suppl 1\): p. S116-21](#)
8. [Jesitus, J. Ablative fractional resurfacing restores form, function after scarring. Dermatology Times 2013; Dec 1 2013:\[Available from: <http://dermatologytimes.modernmedicine.com/dermatology-times/news/ablative-fractional-resurfacing-restores-form-function-after-burns>](#)

**41. (a) Will the proposed medical service be used in addition to, or instead of, the nominated comparator(s)?**

Yes	<input checked="" type="checkbox"/>
No	<input type="checkbox"/>

**(b) If yes, please outline the extent of which the current service/comparator is expected to be substituted.**

Several studies have been published, looking at the efficacy of treatment with the ablative fractional CO2 laser for scar management, revealing substantial improvement of functional, symptomatic, and cosmetic outcome, including improved wound healing in chronically instable scars [1-7].

Added to that, at the Burns Unit of Concord Repatriation General Hospital several subjective (patient questionnaires) and objective outcome parameters of burn victims treated with the ablative fractional CO2 laser are prospectively collected, revealing significant improvement, especially in pruritus, pain and most importantly patient quality of life. Patients are rehabilitated earlier, and, hence, can be re-integrated earlier in their work environment. The short-term results of this data collection has just been published in October 2016.

References:

1. Waibel, J. and K. Beer, Ablative fractional laser resurfacing for the treatment of a third-degree burn. *J Drugs Dermatol*, 2009. **8**(3): p. 294-7.
2. Anderson, R.R., et al., Laser treatment of traumatic scars with an emphasis on ablative fractional laser resurfacing: consensus report. *JAMA Dermatol*, 2014. **150**(2): p. 187-93.
3. Uebelhoer, N.S., E.V. Ross, and P.R. Shumaker, Ablative fractional resurfacing for the treatment of traumatic scars and contractures. *Semin Cutan Med Surg*, 2012. **31**(2): p. 110-20.
4. Hultman, C.S., et al., Laser resurfacing and remodeling of hypertrophic burn scars: the results of a large, prospective, before-after cohort study, with long-term follow-up. *Ann Surg*, 2014. **260**(3): p. 519-29; discussion 529-32.
5. Shumaker, P.R., et al., Functional improvements in traumatic scars and scar contractures using an ablative fractional laser protocol. *J Trauma Acute Care Surg*, 2012. **73**(2 Suppl 1): p. S116-21.
6. Shumaker, P.R., et al., Rapid healing of scar-associated chronic wounds after ablative fractional resurfacing. *Arch Dermatol*, 2012. **148**(11): p. 1289-93.
7. Issler-Fisher, A.C., et al., Ablative fractional CO2 laser for burn scar reconstruction: An extensive subjective and objective short-term outcome analysis of a prospective treatment cohort. *Burns*, 2016.

**42. Define and summarise how current clinical management pathways (from the point of service delivery onwards) are expected to change as a consequence of introducing the proposed medical service including variation in health care resources (Refer to Question 39 as baseline).**

Specialists for scar management - especially in burns - reported their findings of this new technique, revealing substantial improvement of functional and cosmetic outcome, especially in pliability, texture, durability, range of motion, and patient satisfaction [1-7].

Other evidence indicates, that patients who presented with hairless scars, had a new-onset of hair growth, and even regained the ability to sweat (which is usually a problem in burn scars, as the skins natural accessory sweat glands are destroyed by the burn injury) has been described, resulting in an improvement in heat sensitivity, which is one of the most limiting symptoms of burn victims [1,8].

A significant reduction in other symptoms such as pruritus and also pain can be observed in patients treated with this modality – symptoms which have traditionally been very difficult to manage Patients are frequently on chronic pain medication and often enrolled in specialized pain clinics for years. Thus, limiting or even completely distinguish pain and pruritus has a substantial positive impact on patients and healthcare.

It has been shown that treatment with the ablative fractional CO2 laser results in a substantial increase in quality of life, regardless of the maturation status of the scars [1].

And finally, reports exist, demonstrating that the CO2 ablative fractional laser can induce rapid healing of chronic wounds and ulcerations [7,9].

Conventional paradigms suggested that scars have to be mature, which takes approximately 1-2 years post-injury before an intervention for scar improvement should be initiated [10,11]. However, with the ablative fractional CO2 laser it is possible to start treatment once the acute burn wound has healed and already show first signs of pathological scarring [6,12]. This early treatment intervention positively influences scar formation, improves early mobility, enhances, and hereby accelerates the entire rehabilitative process [6]. Added to that, there is evidence that scars as old as 50 years can be successfully treated with the ablative fractional CO2 laser [2]. The treatment with the ablative fractional CO2 laser does not replace surgical scar releases, but it decreases the extent of surgery, leading to reduced postoperative morbidity, thus fasten the process of workplace-reintegration and improved overall outcome.

#### References:

1. Issler-Fisher, A.C., et al., *Ablative fractional CO2 laser for burn scar reconstruction: An extensive subjective and objective short-term outcome analysis of a prospective treatment cohort*. *Burns*, 2016.
2. Waibel, J. and K. Beer, *Ablative fractional laser resurfacing for the treatment of a third-degree burn*. *J Drugs Dermatol*, 2009. **8**(3): p. 294-7.
3. Cervelli, V., et al., *Ultrapulsed fractional CO2 laser for the treatment of post-traumatic and pathological scars*. *J Drugs Dermatol*, 2010. **9**(11): p. 1328-31.
4. Uebelhoer, N.S., E.V. Ross, and P.R. Shumaker, *Ablative fractional resurfacing for the treatment of traumatic scars and contractures*. *Semin Cutan Med Surg*, 2012. **31**(2): p. 110-20.
5. Hultman, C.S., et al., *Laser resurfacing and remodeling of hypertrophic burn scars: the results of a large, prospective, before-after cohort study, with long-term follow-up*. *Ann Surg*, 2014. **260**(3): p. 519-29; discussion 529-32.
6. Shumaker, P.R., et al., *Functional improvements in traumatic scars and scar contractures using an ablative fractional laser protocol*. *J Trauma Acute Care Surg*, 2012. **73**(2 Suppl 1): p. S116-21.
7. Shumaker, P.R., et al., *Rapid healing of scar-associated chronic wounds after ablative fractional resurfacing*. *Arch Dermatol*, 2012. **148**(11): p. 1289-93.
8. Beachkofsky, T.M., J.S. Henning, and C.M. Hivnor, *Induction of de novo hair regeneration in scars after fractionated carbon dioxide laser therapy in three patients*. *Dermatol Surg*, 2011. **37**(9): p. 1365-8.
9. Anderson, R.R., et al., *Laser treatment of traumatic scars with an emphasis on ablative fractional laser resurfacing: consensus report*. *JAMA Dermatol*, 2014. **150**(2): p. 187-93.
10. Smith, M.A., A.M. Munster, and R.J. Spence, *Burns of the hand and upper limb--a review*. *Burns*, 1998. **24**(6): p. 493-505.
11. Motamed, S., et al., *Treatment of flexion contractures following burns in extremities*. *Burns*, 2006. **32**(8): p. 1017-21.
12. Jesitus, J. *Ablative fractional resurfacing restores form- function after scarring*. *Dermatology Times* 2013; Dec 1 2013; [Available from: <http://dermatologytimes.modernmedicine.com/dermatology-times/news/ablative-fractional-resurfacing-restores-form-function-after-scarring>; accessed 26 May 2014.

**PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME**

**43. Summarise the clinical claims for the proposed medical service against the appropriate comparator(s), in terms of consequences for health outcomes (comparative benefits and harms).**

As previously mentioned it has been shown in several studies that treatment of burn scars with the ablative fractional CO2 laser improves functionality (increased range of motion, improved pliability, closure of chronic wound breakdown), symptoms (such as neuropathic pain & itchiness), decreases the thickness of the scar, dramatically improves cosmesis, and hence reduces the stigma and alters the psychology of affected patients[1-4]. Latest research even demonstrated a significant improvement in patients' quality of life, hence accelerating rehabilitation and re-integration into society and work [1].

In the burns community it is accepted that treatment with the ablative fractional CO2 laser might reduce the extent of complex reconstructive surgical procedures or sometimes even avoid it. Severe burn scarring is a complex and heterogenic medical condition. Depending on various factors such as skin types, location and scar characteristics, some patients require reconstructive surgical procedures ranging from simple small surgical excisions, grafting, local flaps, but can also include complex reconstructive procedures such as free flaps, rhinoplasties and others. **Therefore, a single comparator as such does not exist without listing the full range of plastic surgical procedures performed in these patients.** Moreover, current data suggest that treatment with the ablative fractional CO2 laser complements traditional treatment strategies, and may reduce the number and extent of the whole range of plastic surgical procedures for burn scar management.

References:

1. Issler-Fisher, A.C., et al., *Ablative fractional CO2 laser for burn scar reconstruction: An extensive subjective and objective short-term outcome analysis of a prospective treatment cohort.* Burns, 2016.
2. Hultman, C.S., et al., *Laser resurfacing and remodeling of hypertrophic burn scars: the results of a large, prospective, before-after cohort study, with long-term follow-up.* Ann Surg, 2014. **260**(3): p. 519-29; discussion 529-32.
3. Shumaker, P.R., et al., *Functional improvements in traumatic scars and scar contractures using an ablative fractional laser protocol.* J Trauma Acute Care Surg, 2012. **73**(2 Suppl 1): p. S116-21.
4. Shumaker, P.R., et al., *Rapid healing of scar-associated chronic wounds after ablative fractional resurfacing.* Arch Dermatol, 2012. **148**(11): p. 1289-93.

**44. Please advise if the overall clinical claim is for:**

Superiority	X
Non-inferiority	

**45. List the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be specifically measured in assessing the clinical claim of the proposed medical service versus the comparator:**

**Safety Outcomes**



Treatment with the ablative fractional CO2 laser is minimally invasive and the risks of the procedure itself are absolutely minimal (eye-hazard, burn, pigment-changes, small risk for infection).
<b>Clinical Effectiveness Outcomes</b>
Improvement in scar pliability, colour, thickness, contour, symptoms, functionality, quality of life.

## **PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION**

### **46. Estimate the prevalence and/or incidence of the proposed population.**

Patients suffering from the consequences of burn scars, and scars following other medical conditions where large areas of skin are affected, who require treatment and are eligible for laser scar intervention. Over a 13 months' course, we have treated 89 patients with over 118 scars. However, the number of patients treated is also reflected by the available theatre time and might increase if there is more surgical time available.

Since the introduction of the ablative fractional CO2 laser into our routine scar management, the number of more complex elective reconstructive surgeries could be reduced by 57% and the length of stay at the hospital of patients undergoing elective reconstructive procedures could be reduced by 74% (a drop from a mean of 5.2days pre-laser-era to a mean of 1.8days since the introduction of the ablative fractional CO2 laser).

### **47. Estimate the number of times the proposed medical service(s) would be delivered to a patient per year.**

Each patient who is treated with the ablative fractional CO2 laser requires approximately 3-6 treatment sessions, with an interval of 6weeks up to 6months in between each treatment sessions. However, the treatment plan (frequency & interval) has to be adapted to each patients needs individually and can therefore also be different (more or less treatments, with longer or shorter intervals). Summarizing it would be around 3-5 treatments per patient per year.

### **48. How many years would the proposed medical service(s) be required for the patient?**

It takes approximately around 1-2 years for a patient to complete the laser treatment unless there are substantial areas involved, which can't be treated all at once during the same treatment session.

### **49. Estimate the projected number of patients who will utilise the proposed medical service(s) for the first full year.**

Over the last year we have treated a mean of 2.8 patients per week. As there is quite a long wait list for patients with pathologic burn scars booked for laser surgery, we are currently planning to expand our theatre time, which should enable us to treat up to 5 patients per week with the ablative fractional CO2 laser. Thus, we estimate to treat approximately 200-250 patients with the ablative fractional CO2 laser in 2017.

### **50. Estimate the anticipated uptake of the proposed medical service over the next three years factoring in any constraints in the health system in meeting the needs of the proposed population (such as supply and demand factors) as well as provide commentary on risk of 'leakage' to populations not targeted by the service.**

Since the introduction of the ablative fractional CO2 laser into our routine scar management, the numbers were steadily increasing. We do expect a further increase due to the high demand during the next three years, however, we will have to analyse the numbers over the next year to make a conclusive statement about this and it highly depends on availability of theatre time. Depending on the workload of acutely burnt patients, the number of elective reconstructive procedures (including laser treatment) may be limited.

**PART 8 – COST INFORMATION**

**51. Indicate the likely cost of providing the proposed medical service. Where possible, please provide overall cost and breakdown.**

<p><u>Purchase of machine:</u> Laser machine (Ablative fractional UltraPulse® CO2 laser): <b>\$237'300</b> (purchase price November 2014)</p> <p><u>Annual warranty:</u> (preventive maintenance, labor, parts, travel) for the machine, including the handpieces: <b>\$20'700</b></p> <p><u>Costs for a treated area of 3% total body surface area (TBSA):</u></p> <ul style="list-style-type: none"><li>- Anaesthesia (general anaesthesia or local anaesthesia with sedation) with or without anaesthetist (depending on patient and scar factors)</li><li>- Consumables include syringes, needles, dressings, chlorhexidine and suction tubing. All together (including anaesthetic compound cream) the total average cost for a laser procedure on a 3% burn scar is <b>\$170 per procedure.</b></li><li>- Treatment time (excluding anaesthesia): approximately 40min for an area of 3% TBSA</li><li>- Personnel (40min): surgeon, recovery nurse, scrub scout, orderly, +/- anaesthetist (hospital employees)</li></ul>
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**52. Specify how long the proposed medical service typically takes to perform.**

Approximately 40min for an area of 3% TBSA scar
-------------------------------------------------

**53. If public funding is sought through the MBS, please draft a proposed MBS item descriptor to define the population and medical service usage characteristics that would define eligibility for MBS funding.**

Category (proposed category number) – (proposed category description)
-----------------------------------------------------------------------

Proposed item descriptor

Existing item numbers:

- 45025: *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) – limited to 1 aesthetic area*  
→ Medicare 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*  
→ Medicare Fee \$398.55
- 45506: *Scar, of face or neck, not more than 3cm in length, revision of, where undertaken in the operating theatre of a hospital, or where performed by a specialist in the practice of his or her specialty.*  
→ Medicare Fee \$219.95
- 45512: *Scar, of face or neck, more than 3cm in length, revision of, where undertaken in the operating theatre of a hospital, or where performed by a specialist in the practice of his or her specialty.*  
→ Medicare Fee \$295.70
- 45515: *Scar, other than on face or neck, not more than 7cms in length, revision of, as an independent procedure, where undertaken in the operating theatre of a hospital, or where performed by a specialist in the practice of his or her specialty)*  
→ Medicare Fee \$186.50
- 45518: *Scar, other than on face or neck, more than 7cms in length, revision of, as an independent procedure, where undertaken in the operating theatre of a hospital, or where performed by a specialist in the practice of his or her specialty*  
→ Medicare Fee \$225.70
- 45519: *Extensive burn scars of skin (more than 1 percent of body surface area), excision of, for correction of scar contracture.*  
→ Medicare Fee \$429.05
- 14100: *Laser photocoagulation using laser light within the wave length of 510-1064nm in the treatment of vascular lesions of the head or neck where abnormality is visible from 3 metres, including any associated consultation, up to a maximum of 6 sessions (including any sessions to which items 14100 to 14118 and 30213 apply) in any 12month period*  
→ Medicare Fee \$152.50
- 14106: *Laser photocoagulation photocoagulation using laser light within the wave length of 510-1064nm in the treatment of port wine stains, haemangiomas of infancy, cafe-au-lait macules and naevi of Ota, other than melanocytic naevi (common moles), where the abnormality is visible from 3 metres, including any associated consultation, up to a maximum of 6 sessions (including any sessions to which items 14100 to 14118 and 30213 apply) in any 12 month period-area of treatment up to 50cm<sup>2</sup>.*  
→ Medicare Fee \$152.50
- 14109: *Laser photocoagulation (same as 14106)... more than 50cm<sup>2</sup> and up to 100cm<sup>2</sup>.*  
→ Medicare Fee \$187.35
- 14112: *Laser photocoagulation (same as 14106)... more than 100cm<sup>2</sup> and up to 150cm<sup>2</sup>*

→ Medicare Fee \$221.70

- 14115: *Laser photocoagulation (same as 14106)... more than 150cm<sup>2</sup> and up to 250cm<sup>2</sup>*  
→ Medicare Fee \$256.5
- 14118: *Laser photocoagulation (same as 14106)... more than 250cm<sup>2</sup>*  
→ Medicare Fee \$325.75
- 14124: *Laser photocoagulation using laser light within the wave length of 510-1064nm in the treatment of haemangiomas of infancy, including any associated consultation – where a 7th or subsequent session (including any sessions to which items 14100 to 14118 and 30213 apply) is indicated in a 12 month period.*  
→ Medicare Fee \$152.50

Fee: \$(proposed fee)

As we are dealing with burn scars we suggest to calculate the treatment areas according to the percentage of total body surface area (TBSA), which is affected by the scar. TBSA is the standardised and validated assessment metric for burn patients. The treatment of scars on the face/neck should be considered as a separate item number and the treated area calculated by aesthetic areas (same as existing item numbers 45025 & 45026 (definition see above).

Proposed fees calculated according the following:

- Face or neck: fee of existing item numbers for scar revision
- Areas other than face or neck: fee of existing item numbers for laser photocoagulation + 30%:

We propose an addition of approximately 30% because:

1. *Specialized training and education for safe and competent application of laser medicine in burn patients required*
2. *Extra capital required for purchase and maintenance of machine, e.g.:*
  - *Ablative fractional CO2 Ultrapulse®: \$237'300 (excluding GST*
  - *Pulsed Dye laser (standard device for laser photocoagulation using laser light to treat burn scars): \$126'435 (excluding GST)*
3. *Compared to laser photocoagulation using laser light within the wavelength of 510-1064nm, treatment with the ablative fractional CO2 laser is more invasive, hence more painful/higher postoperative morbidity, which requires general anaesthesia for treatment of a larger surface area.*

As per calculations of Point 5.f) per treated area of 3% TBSA (surgical time approx. 40min) on one body localization and extrapolated from the above existing item numbers:

#### **Proposed definitions & fees**

- Scar revision with ablative fractional CO2 laser in the treatment of burn scars or scars following other medical conditions where large areas of skin are affected, resulting in detrimental physical, aesthetic and social sequelae; Resurfacing of the face or neck – limited to 1 aesthetic area.  
→ proposed Medicare Fee \$ 219.95 (*same fee as item no 45506*)
- Scar revision with ablative fractional CO2 laser in the treatment of burn scars or scars following other medical conditions where large areas of skin are affected, resulting in detrimental physical, aesthetic and social sequelae; Resurfacing of the face or neck – more than 1 aesthetic area.  
→ proposed Medicare Fee \$ 295.79 (*same fee as item no 45512*)

- Scar revision with ablative fractional CO2 laser in the treatment of burn scars or scars following other medical conditions where large areas of skin are affected, resulting in detrimental physical, aesthetic and social sequelae; Resurfacing of the face or neck – whole of face or whole of neck.  
→ proposed Medicare Fee \$ 700 (*complexity of procedure if whole face is treated*)
- Scar revision/resurfacing with ablative fractional CO2 laser in the treatment of burn scars or scars following other medical conditions where large areas of skin are affected, resulting in detrimental physical, aesthetic and social sequelae; other than face or neck, involving not more than 3% of total body surface.  
→ proposed Medicare Fee \$ 198.25 (*same fee as item no 14106 & 30%*)
- Scar revision/resurfacing with ablative fractional CO2 laser in the treatment of burn scars or scars following other medical conditions where large areas of skin are affected, resulting in detrimental physical, aesthetic and social sequelae; other than face or neck, involving 3% or more but less than 6% of total body surface.  
→ proposed Medicare Fee \$ 243.55 (*same fee as item no 14109 & 30%*)
- Scar revision/resurfacing with ablative fractional CO2 laser in the treatment of burn scars or scars following other medical conditions where large areas of skin are affected, resulting in detrimental physical, aesthetic and social sequelae; other than face or neck, involving 6% or more but less than 9% of total body surface.  
→ proposed Medicare Fee 288.21\$ (*same fee as item no 14112 & 30%*)
- Scar revision/resurfacing with ablative fractional CO2 laser in the treatment of burn scars or scars following other medical conditions where large areas of skin are affected, resulting in detrimental physical, aesthetic and social sequelae; other than face or neck, involving 9% or more but less than 12% of total body surface.  
→ proposed Medicare Fee \$ 333.45 (*same fee as item no 14115 & 30%*)
- Scar revision/resurfacing with ablative fractional CO2 laser in the treatment of burn scars or scars following other medical conditions where large areas of skin are affected, resulting in detrimental physical, aesthetic and social sequelae; other than face or neck, involving more than 12% of total body surface.  
→ proposed Medicare Fee \$ 423.48 (*same fee as item no 14118 & 30%*)

## PART 9 – FEEDBACK

The Department is interested in your feedback.

### 54. How long did it take to complete the Application Form?

3,5 full days (35h) (with old completed form as a template)

### 55. (a) Was the Application Form clear and easy to complete?

Yes

No

### (b) If no, provide areas of concern.

Old form was easier to fill out.

### 56. (a) Are the associated Guidelines to the Application Form useful?

Yes

No

### (b) If no, what areas did you find not to be useful?

### 57. (a) Is there any information that the Department should consider in the future relating to the questions within the Application Form that is not contained in the Application Form?

Yes

No

### (b) If yes, please advise:

There is no section for the applicant to write why he/she is submitting this application.