



**Australian Government**

**Department of Health**

# Application Form

## Autologous Fat Grafting by injection for treatment of burns scars and for treatment of facial defects due to craniofacial abnormalities

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 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.

Email: [hta@health.gov.au](mailto:hta@health.gov.au)

Website: [www.msac.gov.au](http://www.msac.gov.au)

# PART 1 – APPLICANT DETAILS

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

Corporation / partnership details (where relevant): Breast Surgeons of Australia & New Zealand Incorporated

Corporation name: Australian Society of Plastic Surgeons

ABN: 78 823 025 148

Business trading name: Australian Society of Plastic Surgeons Inc

**Primary contact name:** REDACTED

Primary contact numbers

Business:

Mobile:

Email:

**Alternative contact name:** REDACTED

Alternative contact numbers

Business:

Mobile:

Email:

## 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

Autologous Fat Grafting (AFG) by injection for treatment of burns scars and for treatment of facial defects due to craniofacial abnormalities.

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

AFG (proposed service) is relevant for defects arising from the following medical conditions:

- Craniofacial disorders with facial asymmetry requiring reconstruction and recontouring
  - These include congenital craniofacial syndromes
  - Acquired defects due to disorders including Parry – Rhombert disease
- Burns scars and contractures
  - These include major burns where thin split thickness skin graft has been used

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

Autologous fat grafting (AFG) is the harvesting, preparation, and re-injection of autologous fat, with or without specialised fat grafting equipment. It includes live fat cells being harvested from a donor site on the patient, prepared in theatre by a variety of methods to separate and purify the fat cells, and injected back into the defective area. It relies on the fat stem cells remaining viable in the transferred site. Fat transfer, or fat grafting, or lipo-filling, or lipo-modelling, can be extremely useful for recontouring congenital facial deformities and serious burns scars.

AFG is more complex than scar revision and an item number will improve resource allocation and monitoring of use.

The proposed service is for autologous fat grafting (i.e. harvesting, preparation and injection of adipocytes) as an independent procedure or in conjunction with another procedure for

- i. Correction of defects arising from craniofacial disorders
- ii. Correction of burns scars and associated contractures

### 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:

Insert relevant MBS item numbers here

**(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):

Insert description of 'other' amendment here

**(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)

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

- Yes
- No

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

Insert description of other public funding mechanism here

**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

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):

Insert PBS item code(s) here

(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

Insert PBAC submission item number here

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

Trade name: Insert trade name here

Generic name: Insert generic name here

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): Insert billing code(s) here

Trade name of prostheses: Insert trade name here

Clinical name of prostheses: Insert clinical name here

Other device components delivered as part of the service: Insert description of device components here

(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  
 No

(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  
 No

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

Insert sponsor and/or manufacturer name(s) here

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

Single use consumables: **Single use consumables:**

1, 5, 10 and 20cc syringes

Infiltration set up (local anaesthetic, saline, tubing, three way tap)

Collection canister

Suction tubing

Most fat grafting systems involve the use of consumables but these vary between systems. A typical system would have a disposable fat aspiration cannula and suction canister with associated tubing, syringes and 3 way taps.

Multi-use consumables: Insert description of multi use consumables here.

## 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: N/A

Manufacturer's name: Insert description of single use consumables here

Sponsor's name: Insert description of single use consumables here

- (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  
 AIMD  
 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?**

n/a

- Yes (If yes, please provide supporting documentation as an attachment to this application form)  
 No

- (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 (if yes, please provide details below)  
 No

ARTG listing, registration or inclusion number: Insert ARTG number here

TGA approved indication(s), if applicable: Insert approved indication(s) here

TGA approved purpose(s), if applicable: Insert approved purpose(s) here

- 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?**

n/a

- Yes (please provide details below)  
 No

Date of submission to TGA: Insert date of submission here

Estimated date by which TGA approval can be expected: Insert estimated date here

TGA Application ID: Insert TGA Application ID here

TGA approved indication(s), if applicable: If applicable, insert description of TGA approved indication(s) here

TGA approved purpose(s), if applicable: If applicable, insert description of TGA approved purpose(s) here

- 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?**

n/a

- Yes (please provide details below)  
 No

Estimated date of submission to TGA: Insert date of submission here

Proposed indication(s), if applicable: If applicable, insert description of proposed indication(s)

Proposed purpose(s), if applicable: If applicable, insert description of proposed purpose(s) here

## 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***
1.	Systematic review : A total of 746 studies were found and 23 studies (from 2008 to 2016) were included: A total of 1158 patients were assessed for improvement in scar characteristics including colour, thickness, volume, pain and restoration of function at affected sites, following treatment.	Autologous fat grafting for scars, healing and pain: a review.	To explore the current evidence regarding the use of AFG in hypertrophic and painful scars.	<a href="https://doi.org/10.1177/2059513117728200">10.1177/2059513117728200</a>  Riyat, H., et al. (2017). "Autologous fat grafting for scars, healing and pain: a review." <u>Scars, burns &amp; healing</u> 3: 2059513117728200.	Sep 18, 2017

	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.	Systematic Review: Twenty-six clinical articles were included, reporting on 905 patients in total.	The Use of Autologous Fat Grafting for Treatment of Scar Tissue and Scar-Related Conditions: A Systematic Review.	This systematic review aims to evaluate the available evidence regarding the effectiveness of autologous fat grafting for the treatment of scar tissue and scar-related conditions.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/26710059">https://www.ncbi.nlm.nih.gov/pubmed/26710059</a>  Negenborn, V. L., et al. (2016). "The Use of Autologous Fat Grafting for Treatment of Scar Tissue and Scar-Related Conditions: A Systematic Review." <i>Plast Reconstr Surg</i> <b>137</b> (1): 31e-43e.	Jan, 2016
3.	Retrospective Clinical Study	Early experience with fat grafting as an adjunct for secondary burn reconstruction in the hand: Technique, hand function assessment and aesthetic outcomes	Retrospective study of 13 burns patients using standardised outcomes measures for assessment of range of motion and function of hands following fat grafting. Statistically significant improvements in Total Active Movement scores and in burns scar appearance were found.	<a href="http://elsevier.com">elsevier.com</a>  Byrne, M., et al. (2016). "Early experience with fat grafting as an adjunct for secondary burn reconstruction in the hand: Technique, hand function assessment and aesthetic outcomes." <i>Burns</i> <b>42</b> (2): 356-365.	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***
4.	Systematic Review	Fat grafting and adipose-derived regenerative cells in burn wound healing and scarring: a systematic review of the literature	Systematic review of literature including 6 murine and 12 human studies. Some evidence to suggest fat grafting improves skin texture and function as well as neuropathic pain for treatment of burns scars.	<a href="https://journals.lww.com/plasreconsurg/pages/default.aspx">https://journals.lww.com/plasreconsurg/pages/default.aspx</a> Condé-Green, A., et al. (2016). "Fat grafting and adipose-derived regenerative cells in burn wound healing and scarring: a systematic review of the literature." <u>Plastic and Reconstructive Surgery</u> <b>137</b> (1): 302-312.	2016
5.	Prospective Cohort Study	Facial Contour Symmetry Outcomes after Site-Specific Facial Fat Compartment Augmentation with Fat Grafting in Facial Deformities	A population of 167 patients with unilateral facial deformities (Parry-Rhombert disease, Craniofacial macrosomia or traumatic unilateral deformities) were prospectively enrolled and underwent computerized photogrammetric facial symmetry analysis. They then had AFG and were reassessed 12 months later. Significant improvements in facial symmetry were demonstrated.	<a href="https://journals.lww.com/plasreconsurg/pages/default.aspx">https://journals.lww.com/plasreconsurg/pages/default.aspx</a> Denadai, R., et al. (2019). "Facial Contour Symmetry Outcomes after Site-Specific Facial Fat Compartment Augmentation with Fat Grafting in Facial Deformities." <u>Plastic and Reconstructive Surgery</u> <b>143</b> (2): 544-556.	2019

	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.	Prospective cohort study with blinded outcome assessment	Complementary Fat Graft Retention Rates Are Superior to Initial Rates in Craniofacial Contour Reconstruction	115 patients with unilateral facial deformity from disorders including Parry-Rhombert disease and craniofacial macrosomia underwent post-primary AFG to the face and had blinded ultrasound measurement of thickness of fat using ultrasound up to 12 months post-op. Complementary fat retention rates were higher than initial retention rates.	<a href="https://journals.lww.com/plasreconsurg/pages/default.aspx">https://journals.lww.com/plasreconsurg/pages/default.aspx</a>  Denadai, R., et al. (2019). "Complementary Fat Graft Retention Rates Are Superior to Initial Rates in Craniofacial Contour Reconstruction." <u>Plastic and Reconstructive Surgery</u> <b>143</b> (3): 823-835	2019
7.	Prospective cohort study	Predictors of Autologous Free Fat Graft Retention in the Management of Craniofacial Contour Deformities	142 patients similar to above cohort having AFG to the face. Conclusion – fat graft retention 67.7% mean at 12 months, but varies between conditions	<a href="https://journals.lww.com/plasreconsurg/pages/default.aspx">https://journals.lww.com/plasreconsurg/pages/default.aspx</a>  Denadai, R., et al. (2017). "Predictors of Autologous Free Fat Graft Retention in the Management of Craniofacial Contour Deformities." <u>Plastic and Reconstructive Surgery</u> <b>140</b> (1): 50e-61e	2017

	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***
8.	Retrospective case review	Fat grafting for neuropathic pain after severe burns	7 burns patients with severe neuropathic pain following burns underwent autologous fat grafting. They were followed up for 12 months. 6 of the 7 patients had a significant improvement in neuropathic pain as measured by a standardised patient reported outcomes questionnaire (PROMIS)	<a href="https://journals.lww.com/annalsplasticsurgery/Abstract/2016/06004/Fat_Grafting_for_Neuropathic_Pain_After_Severe.9.aspx">https://journals.lww.com/annalsplasticsurgery/Abstract/2016/06004/Fat_Grafting_for_Neuropathic_Pain_After_Severe.9.aspx</a>  Fredman, R., et al. (2016). "Fat grafting for neuropathic pain after severe burns." <u>Annals of Plastic Surgery</u> <b>76</b> : S298-S303.	2016

\* 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***
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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 statement of clinical relevance from each group nominated):**

ANZBA (Australian and New Zealand Burns Association)

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

ANZBA (Australia and New Zealand Burns Association)

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

List relevant consumer organisations here

- 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

Name of expert 2: REDACTED

# 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:**

- 1) **Craniofacial abnormalities with facial asymmetry.** A number of congenital craniofacial disorders including craniosynostosis syndromes, craniofacial clefts and craniofacial macrosomia as well as disorders such as Parry Romberg disease represent a significant health burden in terms of facial expression, social ostracization and functional problems.
- 2) **Burns scarring and contractures.** Patients with major burns require excision of burned tissue and usually split skin grafting to reconstruct defects. Split skin grafts are thin and have no associated sub-cutaneous tissue. This results in tethering of skin to underlying muscles and fascia with associated functional problems. In addition, split skin grafts contract and when across joints, can limit movement. Finally, the appearance of engrafted skin is often “abnormal” resulting in social isolation and prejudice against patients with this condition. Overall, these problems present a significant health burden to survivors of major burns.

### **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:**

- 1) **Craniofacial abnormalities with facial asymmetry.** These patients would be required to have had a formal diagnosis of a craniofacial disorder, and be assessed by a specialist as having a significant facial asymmetry or contour defect. Diagnosis of the disorder is outside of the scope of this document, but the contour defect or asymmetry would be identified by clinical evaluation by a specialist and documented by clinical photography. Laser scanning or MRI scanning may be ordered but should not be a pre-requisite, as making it so would add an additional cost-burden, where the benefit to the patient may not be a tangible one. Referral would be from GP or other specialist (e.g. paediatrician) to a specialist in the field (likely Plastic and Reconstructive Surgeon or Oromaxillofacial Surgeon).
- 2) **Burns scarring and contractures.** These patients would be required to have had a diagnosis of a burn as a prerequisite and would need to be assessed by a specialist as having a burns scar (or skin graft for replacement of a burn) which was causing a significant mobility problem, pain or deformity in an aesthetically prominent area. Referral would be from a GP or other specialist to a specialist with expertise in burns (Plastic and Reconstructive Surgeon, General Surgeon or Paediatric Surgeon).

It should be noted that in the Australian Healthcare system most craniofacial patients and most major burns patients are treated within the public hospital system and therefore the number of referrals occurring to generate item numbers would be relatively few.

### **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):**

- 1) **Craniofacial abnormalities with facial asymmetry.** These patients would be monitored in a multidisciplinary specialist team, including paediatricians, speech pathologists, plastic surgeons and nutritionists. For some, significant craniofacial surgery would be indicated as first line treatment for correction of craniofacial abnormalities, for others, autologous fat grafting may be a first line treatment of choice as it presents significantly less morbidity and risk than major surgery. At a minimum, prior to surgery patients would be required to have had monitoring of their condition over a period of at least 6 months, with clinical assessment and clinical photography and not have had facial surgery within 6 months of treatment.
- 2) **Burns scarring and contractures.** These patients would be monitored by a specialist surgeon in burns for a period of at least 6 months following completion of healing of burn wounds / associated skin grafts. There would be a requirement for scar associated with significant contour deformity causing disfigurement, and/ or dysaesthesias (e.g. pain and/or itch) or movement limitation. The patient would be required to have undergone a minimum of 3 months of topical therapies, including silicone and pressure therapy, with no improvement to be eligible.

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

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

Autologous fat grafting consists of harvesting fat from a patient's thigh, lower abdomen or flank and transferring fat or adipose tissue harvested from one site to another in the same patient via injection. Coleman (1997) established a method for autologous fat transfer (AFT) involving harvesting fat with atraumatic liposuction, purifying adipocytes with centrifugation and then injection in another body site (breast, face, burn or scar). Other methods have been developed, that refine some of these core elements such as additional washing of the aspirate, or which propose the use of additives including insulin, platelet rich plasma, endogenous stem cells, and thyroid hormone, or harvesting of the fat at multiple sessions. The viability of adipocytes has been shown to decrease with increased suction, excessive handling, refrigeration or major trauma during tissue collection or processing. Whilst the preparation can be performed manually there is now commercially available technology that uses systems to streamline the graft preparation process by selectively washing lipoaspirate while draining any unwanted tumescent fluid, free lipid, and debris has been developed. These systems can prepare 50 to 250 ml of graft in a closed, sterile environment in less than 15 minutes and allow the user to define the hydration level of the final graft. Volumes grafted for burns scars are typically in the range 0.5-80 mls. The harvest and transplant procedures can usually be completed within two hours. Donor sites used are usually from the lower abdomen or the outer or inner thigh, with the thigh more resistant to weight fluctuation. There is no difference in the ability of these sites to produce proliferating cells in culture.

In positioning the graft most surgeons use a blunted-tip cannula to deliver the processed fat in multiple passes. The technique is designed to deliver thin layers of fat that will survive by imbibition until inosculation and neovascularization occur. Recipient site studies have demonstrated that mobile areas, such as the lips, are less amenable to correction when compared to less mobile areas.

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

No

**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):**

Craniofacial defects and burns may require up to 6 procedures, but most will require 1 -2 treatments. As fat resorption occurs preferentially in the first 3 months, there should be a limit that fat grafting cannot be repeated within 3 months of each treatment. Reassessment by the treating specialist and monitoring with clinical photography between each treatment should also be mandatory.

**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:**

This service will be delivered by specialist surgeons. Regardless of whether the proposed patient population are to undergo the proposed intervention or the current comparator, if they are undergoing surgery, they will have the same staffing composition of a nursing team, a surgeon and an anaesthetist. During delivery of the proposed intervention of AFG, there will be no additional staff beyond the staff members normally present in theatre for the relevant surgery.

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

Specialist surgeons

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

N/A

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

Specialist surgeons

**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:**

Specialist surgeon holding FRACS or equivalent or medical practitioner under the supervision of a specialist surgeon

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

- Inpatient private hospital
- Inpatient public hospital
- Outpatient clinic
- Emergency Department
- Consulting rooms
- Day surgery centre
- Residential aged care facility
- Patient's home
- Laboratory
- Other – please specify below

Specify further details here

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

Many burns and craniofacial patients are under the care of a major public teaching hospital. Those who are privately insured may choose to attend private hospitals. They would normally have this treatment as a daycase but due to the intrinsic complexities of both of these patient groups from an anaesthetic point of view, some would be kept in hospital overnight.

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

- Yes
- No – please specify below

Specify further details here

**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):**

- 1) **Craniofacial abnormalities with facial asymmetry.** Comparative treatments are varied, but a typical case of Parry Rhombberg Disease would require treatment with a free autologous flap. E.g. Item numbers 45564 and 45565. This would usually be performed with an anaesthetic of longer than 6 hours and an inpatient hospital stay of 7 days. For this group of patients, ICU stay would be common for the first 24 –48 hours of post-operative care. Equipment and disposables costs would be significant. Revision of the free flap years down the track is very common and would need further anaesthetics and 45496 item number.
- 2) **Burns scarring and contractures.** Comparative treatment for this group is difficult to quantify as the prerequisite set is that the scars are those where surgical treatments are deemed unlikely to work. However, in the absence of other measures, patients and surgeons do often attempt further surgery, which would either be release of scar contracture (Item number 45519) or repeat skin grafting (Item number 45451) or sometimes pedicled flap (Item number 45203). Alternatively, some patients may be asked to persist with conservative measures such as physiotherapy and compression garments. Each of the surgical comparators would be more resource intensive as duration of surgery would be longer than for autologous fat grafting. In addition for the surgical comparators, patient would have a higher risk of post-operative bleeding and other complications and therefore may require an inpatient stay in hospital overnight. Equipment and disposable costs would probably be similar for existing services and the proposed service.

**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 item numbers below)  
 No

- 1) 45564 & 45565 plus 45496 at a later date
- 2) 45519 or 45451 or 45203

**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):**

- 1) **Inpatient stay as above. Most would attend between 2 and 5 follow-up appointments**
- 2) **Inpatient stay as above. Most would attend 1 -4 follow-up appointments**

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

- Yes  
 No

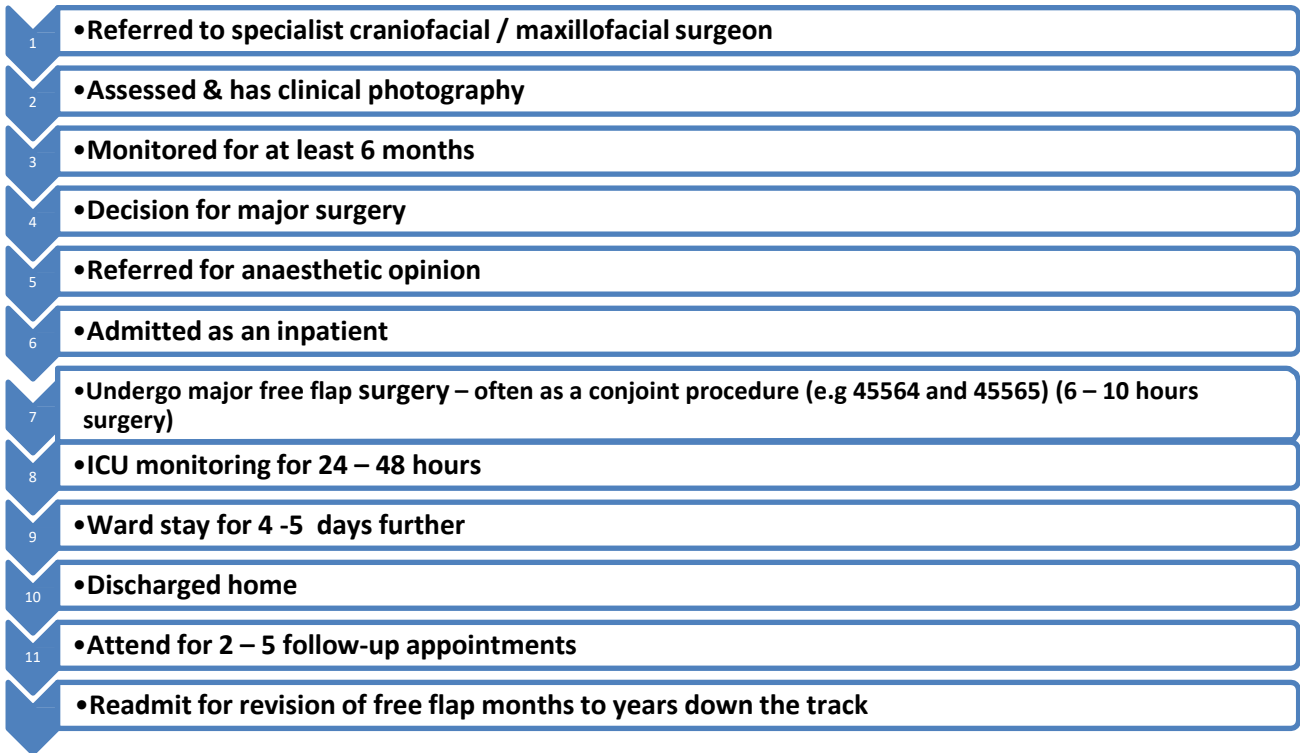
**(b) If yes, please outline the extent of which the current service/comparator is expected to be substituted:**

- 1) **Craniofacial abnormalities with facial asymmetry.** For this group, the hope is that the proposed medical service will be used **instead** of the comparator. It is likely that this will be the case for around 80% of patients. However, 20% may not get a satisfactory result with AFG alone and then will need the comparator intervention as a second line treatment.
- 2) **Burns scarring and contractures.** For this group, the proposed treatment will only be used for those refractory to existing treatments, so it is likely that 80% of these patients will already have had other surgical interventions (listed as comparator). 20% may be assessed a priori as being unlikely to benefit from existing surgical interventions. All will have had conservative treatments such as scar therapy and physiotherapy.

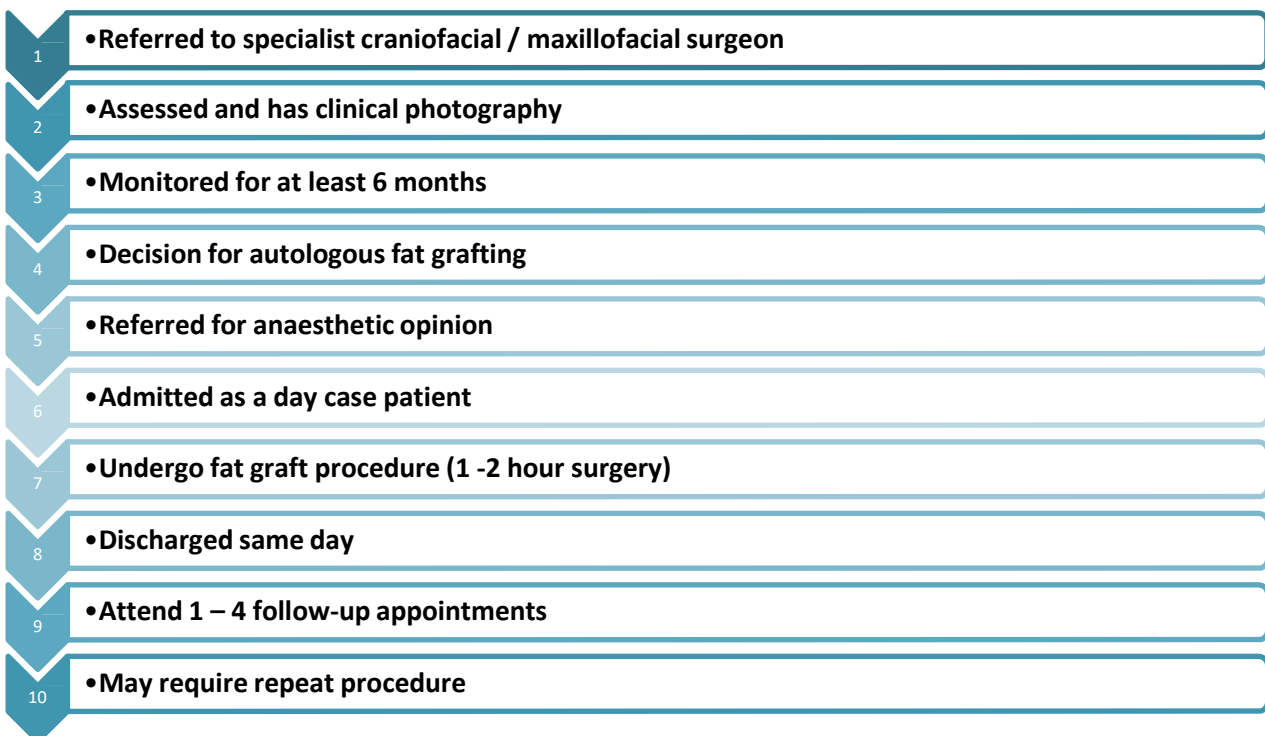


42. Define and summarise how current clinical management pathways (from the point of service delivery onwards) are expected to change as a consequence of introducing the proposed medical service including variation in health care resources (Refer to Question 39 as baseline):

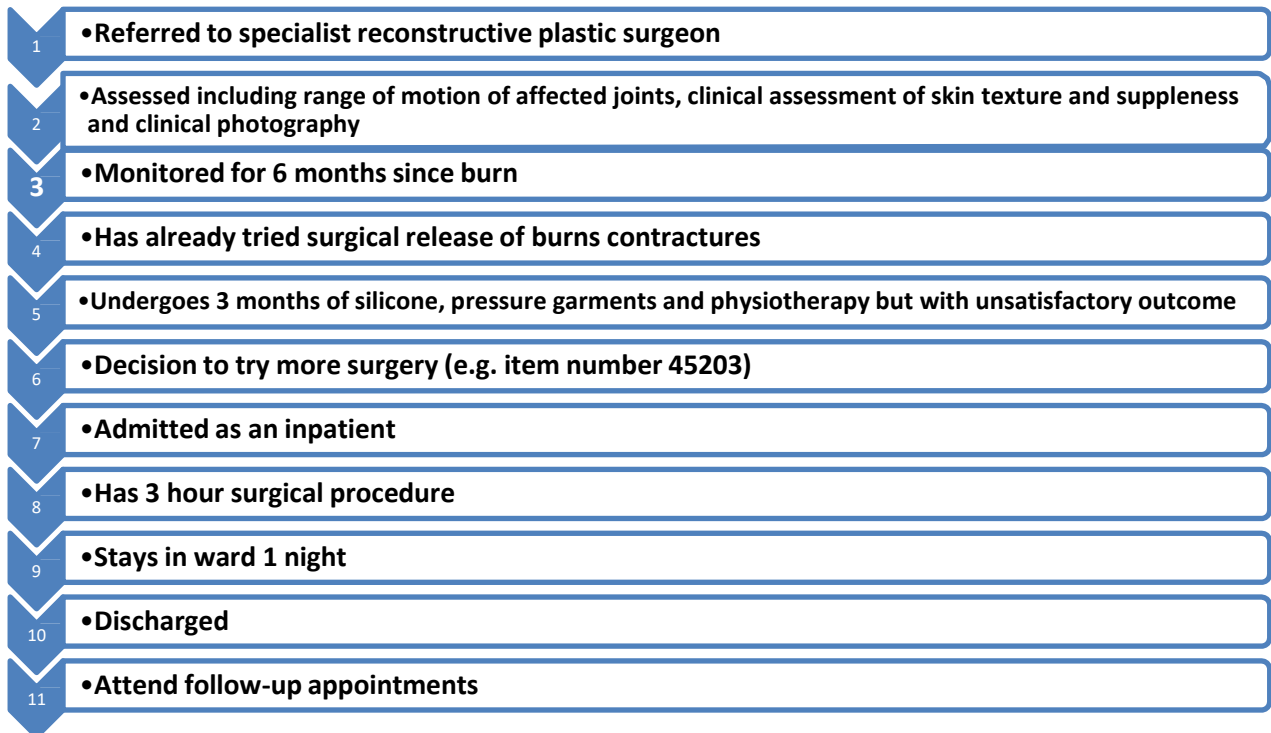
- 1) Craniofacial abnormalities with facial asymmetry
  - a. Existing pathway



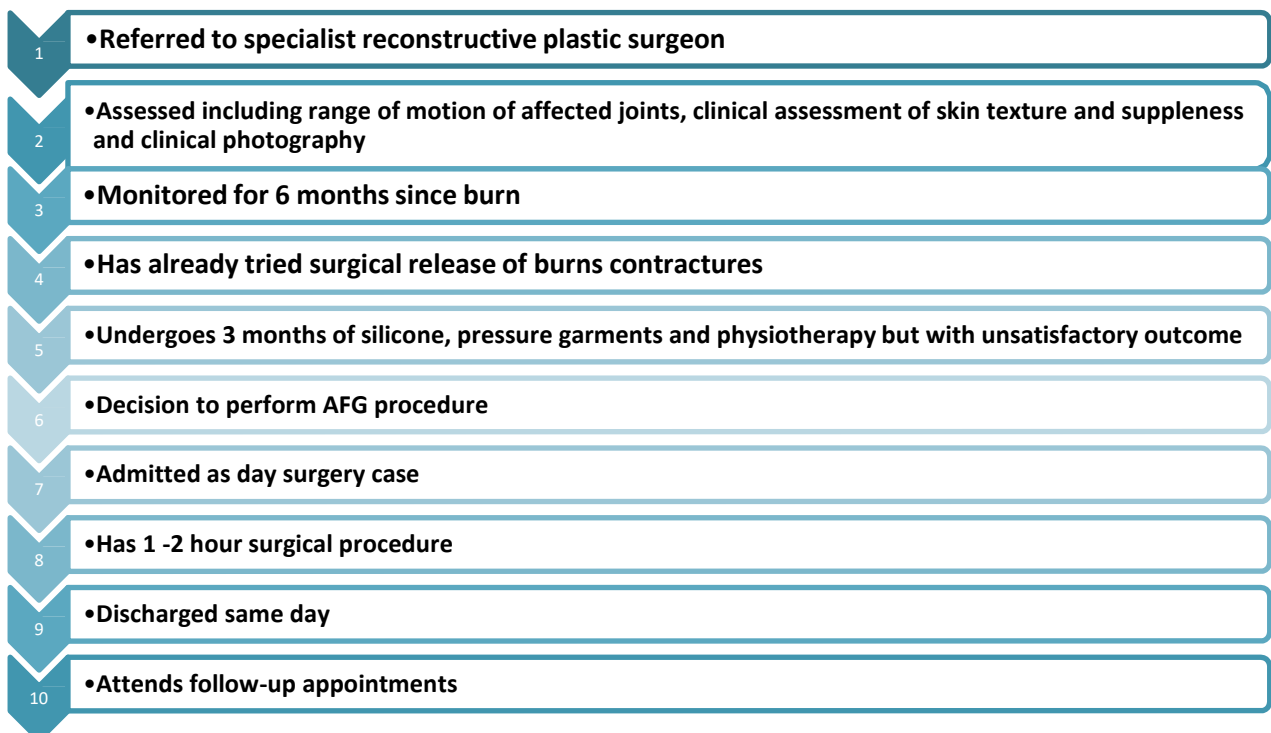
- b. Proposed pathway



2) Burns scars and contractures  
a. Existing pathway



b. Proposed pathway



**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):**

- 1) Craniofacial abnormalities with facial asymmetry.** The proposed service is expected to achieve the same result as comparator services, but with significantly less patient morbidity, fewer resources used and less risk for patients. Free tissue transfer, especially in children is a highly invasive undertaking with donor site pain and scarring, risks of surgical complications such as microvascular thrombosis, infections and haematoma. Whilst the proposed procedure is not risk free, the invasiveness of the procedure is considerably less and will cause less pain and risk. The down side of the proposed procedure is that amount of fat resorption is variable and this means that many patients will require more than one procedure and it is difficult to predict, who will need multiple procedures and who will require only one.
- 2) Burns scars and contractures.** The proposed service for this group of patients offers further remediation of the pain, deformity and functional deficit associated with major burns scarring, over and above what is currently available. Currently, surgeons may be offering repeat surgical procedures with diminishing returns, where what is required is a different strategy. Comparator procedures are major surgical procedures involving pain and scarring at donor sites and significant periods of recovery. They also entail risks of haematoma, graft or flap failure and prolonged treatment. The proposed service is not risk free but involves less scarring and risk than comparator procedures.

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

- Superiority  
 Non-inferiority

See above as it differs slightly between groups.

**45. Below, 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:**

- Infection at site of fat harvesting
- Infection at site of fat grafting

**Clinical Effectiveness Outcomes:**

- Restoration of contour as assessed clinically and by clinical photography
- Improvement in appearance as assessed by patient (PROMS could be used)
- Improvement of range of motion of affected joint (in burns)
- Overall improved quality of life relating to function and appearance.

## PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

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

Craniofacial defects up to 200 cases per year

Burns up to 100 cases per year

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

As above

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

Between 1 and 5

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

150 via the MBS

**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:**

500

This service is not likely to have "leakage" as the conditions are well defined and are mostly treated in major public hospitals, not claiming via the MBS.

## PART 8 – COST INFORMATION

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

The additional cost of AFG should include the consumables as detailed in 12 above. There are specific devices on the market which assist with this procedure, however we have not included all product details in this application as their use varies widely in Australia, with some surgeons/hospitals using only basic consumables and some choosing to purchase specific devices to aid in the procedure.

There is also an additional theatre time cost of about 30 minutes per procedure, which includes theatre time, and personnel including nursing, surgical and anaesthetic. Procedures can largely be performed as a day case, unless combined with another more extensive procedure.

This application seeks to make the use of AFG more accessible for those patients who would benefit most from the procedure, thereby EITHER achieving a better quality of life from the procedure OR avoiding more morbid and costly surgery.

Although the procedure is currently in routine clinical use, its use is not properly documented due to a lack of Item number, thus its use is often currently recorded as scar revision which is not compatible with the extent of expertise and time it takes to perform this procedure.

Our current proposed fee and estimates of economic benefit uses the comparator 45584 (liposuction for pseudolipoma), as a reasonable estimate of the fee for AFG, although AFG does require slightly more time and use of additional equipment for the re-injection of fat.

A private institution in Sydney has costed the procedure for patients having AFG as a day stay < 60 minute procedure at \$1800 including theatre staff and equipment.

**52. Specify how long the proposed medical service typically takes to perform:**

One to two hours.

**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 T8 – Plastic and Reconstructive Surgery

**Proposed item descriptor:** Autologous fat grafting (i.e. harvesting, preparation and injection of adipocytes) as an independent procedure or in conjunction with another procedure for:

- i. Correction of volume and contour defects arising from craniofacial disorders
- ii. Treatment of burns scar or associated skin graft in the context of scar contracture, contour deformity or neuropathic pain.

Fee: \$631.75