



**Australian Government**

**Department of Health**

## **Application 1575:**

**Autologous Fat Grafting (AFG) by  
injection for defects arising from  
breast surgery for cancer  
treatment/prevention or congenital  
deformity**

**Amended Application Form**

# 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: Breast Surgeons of Australia and New Zealand  
ABN: 44 665 232 654  
Business trading name: BreastSurgANZ

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 defects arising from breast surgery for cancer treatment/prevention or congenital deformity

### 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:

- Breast reconstruction surgery after breast cancer excision and/or mastectomy for cancer or cancer risk reduction;
- Surgery for developmental breast disorders;

### 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)

Fat grafting has become an essential tool in the management of breast cancer patients yet currently has no item number and is often coded simply as “scar-revision”. 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, allows wider use of prosthetic breast reconstruction and can avoid the need for autologous reconstruction. It can minimise the need for extensive revisional surgery for defects after breast reconstruction.

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 treatment and prevention of breast cancer
- ii. Correction of developmental disorders of the breast

### 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):

**(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:**

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

**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

(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

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

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):

N/A

(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):

N/A

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

**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.

## 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:

N/A

- (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

N/A

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)  
 No

N/A

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

N/A

## 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.	Meta-Analysis: A literature search was performed in PubMed, Embase and the Cochrane Library on 1 September 2017, adhering to the PRISMA guidelines, to identify all relevant studies of patients with breast cancer exposed to autologous fat transfer. Fifty-nine studies and a total of 4292 patients were included.	Meta-analysis of the oncological safety of autologous fat transfer after breast cancer.	Despite its obvious clinical benefits, experimental research has demonstrated that autologous fat transfer potentially stimulates angiogenesis and tissue regeneration, with potential increase the risk of locoregional recurrence of breast cancer. This meta-analysis shows there is no evidence of this and that fat transfer appears safe after breast cancer.	Meta-analysis of the oncological safety of autologous fat transfer after breast cancer. ( <a href="https://www.bjs.co.uk/article/meta-analysis-of-the-oncological-safety-of-autologous-fat-transfer-after-breast-cancer/">https://www.bjs.co.uk/article/meta-analysis-of-the-oncological-safety-of-autologous-fat-transfer-after-breast-cancer/</a> )	June 5, 2018
2.	Cross Sectional Study. Retrospective review of 880 fat transplantation procedures performed over a 10 year period (1998 – 2009).	Fat Injection to the Breast: Technique, Results, and Indications Based on 880 Procedures Over 10 Years.	The authors report their experience with fat transplantation in the breast. They review their technique and results (including clinical follow-up at 15 days, 3 months and 1 year), and describe various indications for which they found lipomodelling to be appropriate.	Emmanuel Delay, Sebastian Garson, Gilles Tousson, Raphael Sinna; Fat Injection to the Breast: Technique, Results, and Indications Based on 880 Procedures Over 10 Years, Aesthetic Surgery Journal, Volume 29, Issue 5, 1 September 2009, Pages 360–376. ( <a href="https://doi.org/10.1016/j.asj.2009.08.010">https://doi.org/10.1016/j.asj.2009.08.010</a> )	Sep 1, 2009

	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.	Systematic Review - Every clinical trial and experimental study on AFT and its oncological influences was screened. Between September 2014 and September 2016, 856 articles from four databases were found. 105 core articles were selected.	Systematic review: The oncological safety of adipose fat transfer after breast cancer surgery.	Oncological concerns have risen around the safety of adipose fat transfer after breast cancer surgery. In this article, the authors present the clinical and molecular evidences, and discuss the current contradiction between them, offering support to the safety of fat transfer.	Systematic review: The oncological safety of adipose fat transfer after breast cancer surgery. The Breast, Volume 31, February 2017, Pages 128-136. <a href="https://doi.org/10.1016/j.breast.2016.11.001">https://doi.org/10.1016/j.breast.2016.11.001</a>	Feb, 2017
4.	Systematic Review - Electronic databases were searched from 1st January 1986 to 31st March 2014 including: PubMed, MEDLINE, EMBASE, SCOPUS, The Cochrane Library, and clinical trial registries. 35 studies were included (3624 patients). A protocol was published on PROSPERO (CRD42013005254). Types of studies: All original studies.	Use of autologous fat grafting for breast reconstruction: a systematic review with meta-analysis of oncological outcomes.	The primary objective was to determine the oncological, clinical, aesthetic and functional, patient reported, process and radiological outcomes of AFG. They demonstrated a high degree of patient and surgeon satisfaction. Meta-analysis of comparative studies showed no significant difference in oncological event rates between AFG and non-AFG groups.	Use of autologous fat grafting for breast reconstruction: A systematic review with meta-analysis of oncological outcomes. <a href="https://doi.org/10.1016/j.bjps.2014.10.038">https://doi.org/10.1016/j.bjps.2014.10.038</a>	Feb, 2015



	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.	A systematic review following the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement was conducted. Case series, cohort studies and randomized controlled trials (RCTs) reporting on relevant outcomes of breast reconstruction with supplemental AFG were included. In total, 43 studies were included reporting on 6260 patients with a follow-up period ranging from 12 to 136 months.	Autologous fat grafting in onco-plastic breast reconstruction: A systematic review on oncological and radiological safety, complications, volume retention and patient/surgeon satisfaction.	This study presents an up-to-date overview of the literature on autologous fat grafting (AFG) in onco-plastic breast reconstruction, with respect to complications, oncological and radiological safety, volume retention and patient/surgeon satisfaction. AFG in breast reconstruction is a promising technique. Safety is not compromised as cancer recurrence and complications are not observed.	Autologous fat grafting in onco-plastic breast reconstruction: A systematic review on oncological and radiological safety, complications, volume retention and patient/surgeon satisfaction. ( <a href="https://doi.org/10.1016/j.bjps.2016.03.019">10.1016/j.bjps.2016.03.019</a> )	June, 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***
6.	A Matched Controlled Study – Patients included those who underwent segmental or total mastectomy for breast cancer (719 breasts) or breast cancer risk reduction or benign disease (305 cancer-free breasts) followed by breast reconstruction with lipofilling as an adjunct or primary procedure between June 1981 and February 2014. Patients were then matched with identical breast cancer treatment followed by reconstruction without lipofilling (670 breasts).	Lipofilling of the Breast Does Not Increase the Risk of Recurrence of Breast Cancer: A Matched Controlled Study.	Although many plastic surgeons perform autologous fat grafting for breast reconstruction after oncologic surgery, it has not been established whether postoncologic lipofilling increases the risk of breast cancer recurrence. The authors assessed the risk of locoregional and systemic recurrence in patients who underwent lipofilling for breast reconstruction.	Lipofilling of the Breast Does Not Increase the Risk of Recurrence of Breast Cancer: A Matched Controlled Study. <a href="https://doi.org/10.1097/01.prs.0000475741.32563.50">10.1097/01.prs.0000475741.32563.50</a>	Feb, 2016
7.	Prospective Observational Study - 2001 to 2005, 74 autologous fat transfers were undertaken in 69 patients, with 5 patients receiving injections in both breasts, to improve the cosmetic appearance through resurfacing and to repair certain sequelae of conservative breast treatment. Pre- and postoperative imaging, including MRI, were undertaken to monitor viability	Autologous fat transfer in reconstructive breast surgery: indications, technique and results.	Reconstructive techniques have led to vast improvements in results of reconstructive breast surgery. The authors applied the technique of autologous fat transfer to reconstructive breast surgery, and to the treatment of certain cosmetic sequelae of conservative breast treatment to further improve cosmetic outcomes.	Autologous fat transfer in reconstructive breast surgery: indications, technique and results. <a href="https://doi.org/10.1016/j.ejso.2006.12.002">https://doi.org/10.1016/j.ejso.2006.12.002</a>	August, 2007

	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***
	of the fat grafts and detect any suspicious lesions.				
8.	Systematic Review: An online search of the Cochrane Library, MEDLINE, Embase and SciELO was conducted from July 1986 to June 2011. Studies included were original articles of autologous liposuctioned fat grafting to the female breast, with description of clinical complications and/or radiographic changes and/or local breast cancer recurrence. Review included 60 articles with 4601 patients. Thirty studies used fat grafting for augmentation and 41 for reconstructive procedures.	Applicability and safety of autologous fat for reconstruction of the breast.	Autologous fat grafting to the breast for cosmetic and reconstructive purposes is still controversial with respect to its safety and efficacy. The objective of this study was to conduct a systematic review of the clinical applicability and safety of the technique.	Applicability and safety of autologous fat for reconstruction of the breast ( <a href="https://doi.org/10.1002/bjs.8722">10.1002/bjs.8722</a> )	June, 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***
9	Meta-analysis: A comprehensive search of published studies that examined postoperative morbidity following immediate or delayed BR with combined radiotherapy was performed. Medical (MEDLINE & EMBASE) databases were searched and cross-referenced for appropriate studies where morbidity following BR was the primary outcome measured. A total of 1,105 patients were identified from 11 appropriately selected studies.	Radiotherapy and breast reconstruction: a meta-analysis.	Optimum sequencing of breast reconstruction (BR) in patients receiving post mastectomy radiation therapy (PMRT) is controversial. A comprehensive search of published studies examined postoperative morbidity following immediate or delayed BR with combined radiotherapy was performed. Reconstruction technique (including autologous reconstruction) was also examined with outcome when PMRT was delivered after BR.	Radiotherapy and breast reconstruction: a meta-analysis. ( <a href="https://doi.org/10.1007/s10549-011-1401-x">10.1007/s10549-011-1401-x</a> )	May, 2011
10	Cohort Study	A five year experience of measuring clinical effectiveness in a breast reconstruction service using the BREAST-Q patient reported outcomes measure: A cohort study.	To assess the clinical effectiveness of breast reconstruction and the utility of the BREAST-Q patient-reported outcomes measure for routine patient care.	A five year experience of measuring clinical effectiveness in a breast reconstruction service using the BREAST-Q patient reported outcomes measure: A cohort study. ( <a href="https://doi.org/10.1016/j.bjps.2016.08.015">10.1016/j.bjps.2016.08.015</a> )	November, 2016
11	Systematic Review and meta-analysis: Eighty-nine studies consisting of 5350 unique patients were included.	Efficacy of autologous fat transfer for the correction of contour deformities in the breast: A systematic review and meta-analysis.	Autologous fat transfer (AFT or lipofilling, has already become a part of clinical practice for treating contour deformities of the breast, even though evidence regarding its efficacy is still lacking. This meta-	Efficacy of autologous fat transfer for the correction of contour deformities in the breast: A systematic	Oct, 2018

	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***
			analysis is aimed to facilitate intuitive interpretation of the available data by clinicians, guideline committees and policy makers. AFT seems to be an effective procedure in breast reconstruction, reflected by the high patient and surgeon satisfaction and low incidence of clinical and radiological complications.	review and meta-analysis. ( <a href="https://doi.org/10.1016/j.bjps.2018.05.021">10.1016/j.bjps.2018.05.021</a> )	
12	A longitudinal, multicenter, prospective cohort study was conducted between February 1, 2012, and July 31, 2016, at the 11 sites associated with the Mastectomy Reconstruction Outcomes Consortium Study.	Association of Fat Grafting With Patient-Reported Outcomes in Postmastectomy Breast Reconstruction.	Research aims were to determine whether fat grafting is associated with patient-reported outcomes (PROs) in patients undergoing breast reconstruction. Our findings should bolster the ongoing assertion that fat grafting is an important tool in breast reconstruction and that this option should remain available to reconstructive surgeons and to the patients they serve	Association of Fat Grafting With Patient-Reported Outcomes in Postmastectomy Breast Reconstruction. ( <a href="https://doi.org/10.1001/jamasurg.2017.1716">10.1001/jamasurg.2017.1716</a> )	Oct 1, 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***
13	Retrospective cohort study: A database of all patients who underwent fat grafting after BCS and RT was prospectively maintained. Patient demographics, clinical and surgical characteristics and intra- and postoperative complications were analysed. Preoperative and 6-month postoperative photographs were evaluated by a four-member expert-panel assessing the aesthetic outcome.	Surgical Outcome and Cosmetic Results of Autologous Fat Grafting After Breast Conserving Surgery and Radiotherapy for Breast Cancer: A Retrospective Cohort Study of 222 Fat Grafting Sessions in 109 Patients.	Breast conserving surgery and radiotherapy often lead to breast deformity. Reconstruction of these defects is a surgical challenge. Lately, the popularity of autologous fat grafting in these patients is growing. The purpose of this study was to assess clinical outcomes and aesthetic results of autologous fat grafting after BCS and RT.	Surgical Outcome and Cosmetic Results of Autologous Fat Grafting After Breast Conserving Surgery and Radiotherapy for Breast Cancer: A Retrospective Cohort Study of 222 Fat Grafting Sessions in 109 Patients. ( <a href="https://doi.org/10.1007/s00266-017-0946-4">10.1007/s00266-017-0946-4</a> )	Dec, 2017
14	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.	The Use of Autologous Fat Grafting for Treatment of Scar Tissue and Scar-Related Conditions: A Systematic Review. ( <a href="https://www.ncbi.nlm.nih.gov/pubmed/26710059">https://www.ncbi.nlm.nih.gov/pubmed/26710059</a> )	Jan, 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***
1.	Nil	Nil	Nil	Nil	nil

*\* 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):**

BreastSurgANZ

Australian Society of Plastic Surgeons

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

As above

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

BCNA (Breast Cancer Network Australia)

Reclaim your Curves

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

Nil relevant

- 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**

*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:**

Define the medical condition (disease) that specifies the patient population that would benefit from the use of the proposed intervention.

The presenting medical conditions of the proposed populations suitable for and who would benefit from the AFG procedure include the following:

- Defects in shape, size and contour, or for pain, in patients who have undergone treatment for, or prevention of, breast cancer
- Breast developmental defects (Developmental breast asymmetry)

#### **1. Defects after treatment for breast cancer**

The mainstay of treatment for early breast cancer is breast conserving surgery (BCS), or mastectomy, to excise the primary tumour with or without lymph node dissection. In Australia around 40% of women with breast cancer will undergo mastectomy and up to 25% of these will have an immediate or delayed reconstruction. Mastectomy is also an important prevention option for women at high risk of breast cancer.

Patients undergoing both BCS and mastectomy + reconstruction will face issues with cosmetic deformity or requiring revision surgery. Autologous fat grafting (AFG), also known as lipofilling, uses patients' own fat, usually harvested from the abdomen or thighs, to correct contour defects and improve reconstruction outcomes by reinjecting adipocytes after processing.

#### **a) Mastectomy and reconstruction**

Mastectomy is performed in around 40-50% of women in Australia with early breast cancer, either because the lesion is too large or multifocal to allow breast conservation or due to other factors including patient choice. This leaves a flat chest in the breast area, with a longitudinal scar. Bilateral complete mastectomy will leave long scars on both sides of the chest with complete loss of the breast mounds. Therefore, breast cancer surgery can have long term effects on women's quality of life with adverse physical, emotional and psychological impacts, reduced self-esteem, diminished psychological well-being, a feeling of 'imbalance' and restricted freedom of dress. Breast reconstruction can ameliorate these consequences, although it is complex and different patients are suited to different types of procedures.

Research at Flinders Medical Centre<sup>1</sup> on the effectiveness of breast reconstruction in improving the health of women is demonstrated in Table 1. Table 1 is the data that represent paired pre-operative and post-operative BREAST-Q scores for 162 patients following breast mound reconstruction, which shows statistically significant improvements ( $p$  values) compared to the pre-operative condition.

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<sup>1</sup> Dean, NR, Crittenden T, A five-year experience of measuring clinical effectiveness in a breast reconstruction service using the BREAST-Q patient reported outcome measure: A cohort study. *Journal of Plastic, Reconstructive & Aesthetic Surgery* 2016. 69 (11) [1469-1477](#).

**Table 1: Health status pre-op and at 6 months after reconstructive breast surgery**

Timing of questionnaire	Satisfaction with breasts	Psychosocial well-being	Physical well-being (chest)	Sexual well-being
Pre-operative (95% CI)	44.99 (42.02-47.95)	55.44 (52.59 – 58.29)	69.83 (67.32 – 72.34)	38.74 (35.15 – 42.33)
Post-operative (95% CI)	64.92 (61.92-67.92)	71.47 (68.09 – 74.85)	74.78 (72.43 – 77.13)	54.17 (50.55 – 57.78)
SD between groups	p < 0.0001	p < 0.0001	p < 0.0001	p < 0.0001

Breast reconstruction may be immediate or delayed. An immediate breast reconstruction (IBR) is done during the same operation as a mastectomy. Benefits of an immediate reconstruction include:

- there is only one operation (although the surgery and recovery time is longer than for mastectomy alone);
- it may be possible to keep the skin, nipple and areola intact so that the look of the reconstructed breast is more natural.

A delayed breast reconstruction is done months or even years after a mastectomy. A benefit of delayed breast reconstruction is that the initial mastectomy surgery and recovery time is shorter, which is of considerable importance for patients who have a requirement or a wish to quickly progress to post-operative chemotherapy or radiotherapy.

Breast reconstruction may be undertaken as an autologous or prosthetic reconstruction. The main advantages of autologous reconstruction are that: the patient’s own tissue is used; the reconstructed breast looks and feels more natural over the long term; it tolerates radiation better; and usually requires no revision and is permanent. The main disadvantage in relation to autologous flap surgery is the complexity, length of surgery, and long recovery time.

Autologous breast reconstruction using a transverse rectus abdominus myocutaneous (TRAM) flap involves rebuilding the breast shape by moving skin, fatty tissue and part of the rectus abdominus muscle from the abdomen to the chest, without using implants. TRAM flap surgery may either be via a free or pedicled flap.

TRAM flap procedures are complex procedures, often involve microsurgery and have a typical operation time of 10 hours. As flap surgery involves transferring a whole block of skin, fat and sometimes muscle from a distant part of the body to the mastectomy defect it requires long incisions in the skin and interference with the normal anatomy of the muscles, nerves and blood vessels. It leaves long permanent scars and often some muscle weakness. Recovery time from these procedures is six to eight weeks. Fat necrosis rates are in the order of 15% in the free TRAM and 47% in the pedicled TRAM flaps and incidence of flap failure of 2-5%. Flap failure results in serious consequences for patients, including repeat surgery<sup>2</sup>.

Harvesting the rectus abdominis muscle inevitably causes abdominal muscle weakness. In order to reduce the abdominal morbidity, the deep inferior epigastric perforator (DIEP) flap for breast reconstruction was developed<sup>3</sup>. A DIEP flap breast reconstruction rebuilds a breast shape by moving skin and fatty tissue, but not muscle from the abdomen to the chest. This means that the risk of weakness or hernia in the abdomen is lower than after a TRAM flap breast reconstruction. Women usually return to regular activities faster than with a TRAM flap breast reconstruction. However, the muscles may still be

<sup>2</sup>Casey WJ, Silverman R, Macias A et al. Etiology of breast masses after autologous breast reconstruction. *Ann Surg Oncol*, 2013; 20, 607-14.

<sup>3</sup> Kroll SS, Reece GP, Miller MJ, et al. Comparison of cost for DIEP and free TRAM flap breast reconstructions. *Plast Reconstr Surg* 2001; 107:1413-6; discussion 1417-8.

weak in the short term because the operation involves some interference with the muscle. With advances in perforator anatomy, various other muscle-sparing flaps have also been developed<sup>4</sup>.

The disadvantage of DIEP surgery relates to the time it takes to dissect the vascular pedicle from the rectus muscle and the need for microsurgery. Bilateral DIEP flap operations can take up to 12 hours as care is needed not to damage the inferior epigastric vessels as they are being traced through the rectus abdominis combined with the time it takes for microsurgical anastomosis. Fat necrosis rate have been found to be 13.4% for DIEP flaps and 5.7% for the alternative SIEA flap<sup>5</sup>.

Silicone implant based reconstruction has the advantage of reduced surgical time and an ability to produce breast reconstructions of a variety of sizes, independently of the volume of donor tissue available. It is less complex, with a speedier recovery, but it looks and feels less natural. Once the prosthesis is implanted a fibrous capsule develops and forms around it. Capsular contracture results from tightening of the collagen fibres in the fibrous capsule causing distortion of the implant, shape deformity and pain. This requires surgical intervention such as capsulotomy or capsulectomy, with replacement of implants. Radiotherapy post reconstruction increases the rate of capsular contracture, deformity and implant loss. Implant-only reconstructions have very high levels of dissatisfaction and complications, with patients who have had radiotherapy having a complete failure of implant-only reconstruction in up to 18% of cases<sup>6</sup>. The average life of a breast implant is 10 years<sup>7</sup>. However, prosthetic reconstruction still has a strong role post mastectomy as many patients are medically unsuitable for the more complex autologous procedures or don't wish to undergo extensive surgery. These patients invariably require one or more revision surgeries in the future. Many patients with complications elect removal of their prosthesis in favour of a second (autologous) reconstruction.

Several studies have shown an association between irradiation and post-operative complications and poor cosmetic outcome<sup>8,9</sup>. Postoperative radiotherapy can have significant effects on the reconstructed breast, including high incidences of fat necrosis, volume loss and contracture. The effect on implant-based reconstruction is likely to be more significant than on autologous reconstruction, often leading to implant failure requiring removal but can have deleterious effects on all types of reconstruction. A meta-analysis<sup>10</sup> concluded that whichever type of reconstruction is used, radiotherapy increases the incidence of postoperative complications. Most surgeons are wary of operating on irradiated tissue and for many women with such defects, limiting the ability for many women to have a delayed reconstruction after radiotherapy.

Up to 30% of patients remain dissatisfied with their reconstructed breasts and may seek revisional surgery<sup>11</sup>.

Recent research and an extensive review of the literature<sup>12</sup> indicates that transferred fat can help the regeneration of irradiated tissue, with the action thought to be mediated through adipose stem cells.

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<sup>4</sup> Chevray PM. Breast reconstruction with superficial inferior epigastric artery flaps: a prospective comparison with TRAM and DIEP flaps. *Plast Reconstr Surg* 2004; 114:1077-83; discussion 1084-5.

<sup>5</sup> Casey WJ, Silverman R, Macias A et al. Etiology of breast masses after autologous breast reconstruction. *Ann Surg Oncol*, 2013; 20, 607-14.

<sup>6</sup> Lam TC, Hsieh F, and Boyages S. The Effects of Postmastectomy Adjuvant Radiotherapy on Immediate Two-Stage Prosthetic Breast Reconstruction: A Systematic Review. *Plastic and Reconstructive Surgery*, 2013. 132(3): p. 511-518.

<sup>7</sup> Yu, P. Breast reconstruction at the MD Anderson Cancer Center. *Gland Surg*. 2016 Aug; 5(4): 416-421.

<sup>8</sup> Whitfield, GA et al. Incidence of severe capsular contracture following implant-based immediate breast reconstruction with or without postoperative chest wall radiotherapy using 40 Gray in 15 fractions. *Radiotherapy and Oncology*, 2009; 90(1), pp.141-147.

<sup>9</sup> Crisera, CA et al. Immediate Free Flap Reconstruction for Advanced-Stage Breast Cancer: Is It Safe? *Plastic and Reconstructive Surgery*, 2013; 128(1), pp.32-41.

<sup>10</sup> Barry, M & Kell, MR. Radiotherapy and breast reconstruction: a meta-analysis. *Breast Cancer Research and Treatment*, 2011; 127(1), pp.15-22.

<sup>11</sup> Jeevan, R., Cromwell, D. & Browne, J., 2011. Fourth annual report of the national mastectomy and breast reconstruction audit. 2011. NHS Information Centre.

<sup>12</sup> Shukla, L Morrison, WA. & Shayan, R. Adipose-derived stem cells in radiotherapy injury: a new frontier. *Frontiers in surgery*, 2015; 2(4), 1-12.

There is accumulating evidence as to the effectiveness of fat grafting to the breast. Findings published his findings in 2005<sup>13</sup> assessed 47 fat injections, over a 10 year period, into 43 breasts in 37 women who had previously undergone breast reconstruction with implants (58%), TRAM (40%) or TRAM plus implant (2%). The authors identified an improvement in the contour of 85% of reconstructed breasts and no improvement in 15%, with a complication rate of 8.5%.

A 2018 meta-analysis<sup>14</sup> of eighty-nine studies on AFG, with 5350 included unique patients and a mean follow-up of 1.9 years revealed a very high overall patient and surgeon satisfaction rate of 94.3% and 95.7%, respectively, which was also confirmed by high satisfaction scores and Breast-Q scores. Overall, only 1.5 sessions were needed to achieve the desired result. Though evidence on the long-term volume retention is lacking, based on the current data it was calculated to be 52.4% at one year. Only 5.0% of procedures resulted in clinical complications and 8.6% of breasts required subsequent biopsy due to abnormal clinical or radiological findings. The authors concluded that AFG was an effective procedure in breast reconstruction, reflected by the high patient and surgeon satisfaction and low incidence of clinical and radiological complications.

A 2016 systematic review<sup>15</sup> of 43 studies (6260 patients) with a follow-up period ranging from 12 to 136 months found a total complication rate of 8.4% (95% CI 7.6-9.1) which was lower than those reported following other reconstructive breast procedures. The mean volume retention was 76.8% (range 44.7-82.6%) with a satisfaction rate of 93.4% for patients and 90.1% for surgeons.

In a 2017 multicentre, prospective cohort study of women<sup>16</sup> after breast reconstruction (implant or flap), who then subsequently had fat grafting (165 of 2048 [8.1%] found that prior to AFG these women reported significantly lower breast satisfaction (adjusted mean difference [AMD], -4.74; 95% CI, -8.21 to -1.28; P = .008), psychosocial well-being (AMD, -3.87; 95% CI, -7.33 to -0.40; P = .03), and sexual well-being (AMD, -5.59; 95% CI, -9.70 to -1.47; P = .008), compared with those who did not receive subsequent fat grafting. Following AFG the treated cohort reported similar breast satisfaction, psychosocial well-being, and sexual well-being two years postoperatively.

The 2015 guiding statement of the American Society of Plastic and Reconstructive Surgery Executive Committee guidance on AFG<sup>17</sup> now states that the evidence suggests AFG is an effective option in breast reconstruction following mastectomy while demonstrating moderate to significant aesthetic improvement and it is also a useful modality for alleviating post mastectomy pain syndrome. Furthermore, the evidence suggests AFG is a viable option for improving the quality of irradiated skin present in the setting of breast reconstruction. It also notes that based on available literature, complication rates associated with fat grafting are relatively low with cases of severe complications and death apparently extremely rare, with fat grafting to the post-mastectomy reconstructed breast not delaying breast cancer detection or increasing breast cancer recurrence. The guidance concludes that overall autologous fat grafting to the post mastectomy breast with no remaining native tissue yields aesthetic improvement and significant patient satisfaction.

AFG in reconstruction can also be used to alter the type of reconstruction employed post radiotherapy. With the increase in the use of post mastectomy radiotherapy, patients are experiencing more capsular contracture and volume loss post autologous reconstruction. Extensive revision surgery (including the use of prosthetic implants to augment volume) is becoming increasingly common. AFG is able to correct contour defects in these patients and provide sufficient volume in some to entirely avoid the use of a prosthesis, and their attendant long term complications. In patients having delayed reconstruction who have received post mastectomy radiotherapy, several sessions of AFG can be employed to enable the use

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<sup>13</sup>Spear SL, Wilson HB, Lockwood MD. Fat injection to correct contour deformities in the reconstructed breast. *Plast Reconstr Surg.* 2005 Oct;116(5):1300-5.

<sup>14</sup>Krastev TK, Alshaikh GAH, Hommes J et al. Efficacy of autologous fat transfer for the correction of contour deformities in the breast: A systematic review and meta-analysis *Journal of Plastic, Reconstructive & Aesthetic Surgery* (2018) 000, 1–18

<sup>15</sup>Groen JW, Negenborn VL, Twisk DJWR, et al Autologous fat grafting in onco-plastic breast reconstruction: A systematic review on oncological and radiological safety, complications, volume retention and patient/surgeon satisfaction *Journal of Plastic, Reconstructive & Aesthetic Surgery* (2016) 69, 742-764.

<sup>16</sup>Bennett KG, Qi J, Kim HM, et al Association of Fat Grafting With Patient-Reported Outcomes in Postmastectomy Breast Reconstruction. *JAMA Surg.* 2017 Oct 1;152(10):944-950

<sup>17</sup>American Society of Plastic Surgeons, Executive Committee 2015 Post-Mastectomy Fat Graft/Fat Transfer ASPS Guiding Principles

of prosthetic reconstruction instead of the traditional autologous reconstruction, hence avoiding a prolonged, complex surgery.

#### **b) Breast conservation surgery**

Breast conservation surgery entails removal of the tumour with a margin of healthy tissue and the space left in the breast is usually closed using the surrounding tissue. Removal of over 20% of volume is likely to lead to significant deformity<sup>18</sup>. This is exacerbated by the routine use of radiotherapy post BCS to reduce local recurrence rates. In the last decade, breast oncoplastic techniques have increasingly been employed to allow the removal of larger areas of breast tissue while achieving satisfactory cosmesis. However for some patients residual breast defects are large enough that further surgical revision is needed. Revision surgery in patients who have had radiotherapy has suboptimal results, therefore the default revision is usually completion mastectomy with autologous reconstruction, despite the fact the patient has no residual cancer.

A retrospective cohort study<sup>19</sup> assessed the clinical outcomes and aesthetic results of AFG after BCS and radiotherapy. 109 consecutive patients (114 breasts) underwent 222 fat grafting procedures. The mean clinical postoperative follow-up was 26 ± 19 months (range 10-97). The median number of fat grafting sessions sufficient for a satisfactory surgical result was two (range 1-6). Localised infections occurred in four patients, all treated effectively with oral antibiotics. Fat necrosis that required excision under local anaesthesia occurred once. The overall cosmetic appearance was rated 5.1/10 before and 7.2/10 after reconstruction (p < 0.01). A significant improvement was noted in breast symmetry, volume, shape and scarring. The researchers concluded that grafting after BCS and RT provides significant aesthetic improvement of the breast. It has a positive effect on the postsurgical scar and irradiated tissue and helps to restore the volume deficit.

The use of AFG to correct of defects in BCS patients means they can avoid mastectomy and reconstruction in favour of one or two sessions of smaller, more tolerable surgery.

#### **2. Developmental breast asymmetry defects**

Some degree of breast asymmetry is normal, but some women develop one breast that is significantly larger than the other or even fail to develop one side at all. The most common congenital condition with significant asymmetry is the tuberous breast deformity which characterised by breast base constriction, parenchymal hypoplasia, inferior breast skin deficiency, superior malposition of the inframammary fold, herniation of the breast into the areola with a constricted breast base, and asymmetry. These deformities are very variable, often with considerable discrepancies between both breasts in the same individual. Patients presenting for correction of breast and chest wall asymmetries may have undergone numerous thoracic procedures in early childhood and may have suffered significant psychosocial effects. Breast asymmetry has a negative impact on the psychological quality of life of adolescents with adolescents having decreases in emotional functioning, mental health, self-esteem, and eating behaviours and attitudes. Correction of breast asymmetry and hypomastia improved these assessments. Correction of developmental breast asymmetry by breast augmentation is therefore warranted on clinical grounds for some congenital and developmental conditions.

Clinical studies show that 1-2 grafting sessions are usually sufficient to establish long-term patient and surgeon satisfaction with outcomes, with no or few complications. The aesthetic outcome is natural, implant-free and long-lasting. AFG also decreases local fibrosis and helps, along with fasciotomies and mammary gland remodelling, modify the shape of the breast. The technique corrects the missing volume in a precise, personalised manner.

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<sup>18</sup> Bulstrode, NW, & Shrotria S. Prediction of cosmetic outcome following conservative breast surgery using breast volume measurements. *Breast* 2001; 10(2), pp.124–126.

<sup>19</sup> van Turnhout AA, Fuchs S, Lisabeth-Broné K, et al. Surgical Outcome and Cosmetic Results of Autologous Fat Grafting After Breast Conserving Surgery and Radiotherapy for Breast Cancer: A Retrospective Cohort Study of 222 Fat Grafting Sessions in 109 Patients. *Aesthetic Plast Surg*. 2017 Dec;41(6):1334-1341.

**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:**

Clearly describe the characteristics of the patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed service. Please consider age ranges, the severity of the medical condition, the presence of co-morbidities, and how the patient will be investigated, managed and referred to be eligible for the service.

Please also specify any other patients who would also use the proposed medical service that may need to be evaluated.

**1. Post mastectomy with reconstruction**

- AFG is applicable to patients who have a suitable donor site for fat harvest
- AFG is proposed for patients post reconstruction with tissue expanders/prosthesis and autologous reconstruction, with or without PMRT, for:
  - i. Correction of contour defects
  - ii. Rippling of prostheses
  - iii. Correction of breast asymmetry > 20% in differences to contralateral side
  - iv. Mastectomy skin flaps requiring further coverage of prosthesis
  - v. Up to 3 AFG sessions per breast unless significant volume or contour defects remain

**2. Post mastectomy without reconstruction**

- AFG is applicable to patients who have a suitable donor site for fat harvest
- AFG is proposed for patients who have had a simple mastectomy, or have had failure of a reconstruction and removal of the reconstruction for:
  - i. Improvement of skin flaps post mastectomy radiotherapy, prior to reconstruction with prosthesis
  - ii. Patients suitable for reconstruction with AFG alone without implant or autologous flap (a rare indication)
  - iii. Up to 3AFG sessions per breast unless significant volume or contour defects remain for (i) and up to 5 AFG session

**3. Post breast conservation surgery for benign or malignant neoplasms**

- AFG is applicable to patients who have a suitable donor site for harvesting fat
- AFG is proposed for patients treated with or without radiotherapy for:
  - i. Correction of contour defects
  - ii. Correction of breast asymmetry > 20% in difference to contralateral side
  - iii. Up to 3 AFG sessions per breast unless significant volume or contour defects remain

**4. Developmental breast asymmetry**

- AFG is applicable to patients who have a suitable donor site for harvesting fat
- AFG is proposed for patients with:
  - i. Congenital tuberous breasts
  - ii. Unilateral hypomastia causing asymmetry > 20% in difference to contralateral side
  - iii. Up to 3 AFG sessions per breast unless significant volume or contour defects remain or reconstruction is planned using AFG alone

**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):**

Explain the current clinical management pathway up to the point(s) where the proposed intervention would be appropriate.

**Clinical Pathway for Breast Surgery**

**Post mastectomy**

- Simple mastectomy or failed reconstruction
  - thin skin flaps or 6 months post mastectomy radiotherapy, prior to prosthetic or autologous reconstruction
  - scar associated with pain and discomfort secondary to tight/thin skin flap
  - patient reviewed by specialist breast surgeon or plastic surgeon and donor sites assessed and deemed suitable
- With prosthetic reconstruction
  - 6 months Post mastectomy radiotherapy
  - Patient with, or deemed at risk of, contour defect, rippling, asymmetry or inadequate prosthesis coverage
  - patient reviewed by specialist breast surgeon or plastic surgeon and donor sites assessed and deemed suitable
- With autologous reconstruction (with or without prosthesis)
  - 6 months Post mastectomy radiotherapy
  - Patient with, or deemed at risk of, contour defect or asymmetry
  - patient reviewed by specialist breast surgeon or plastic surgeon and donor sites assessed and deemed suitable
- Patients considered suitable for reconstruction with AFG alone
  - patient reviewed by specialist breast surgeon or plastic surgeon and donor sites assessed and deemed suitable
  - patient's body habitus considered suitable for adequate reconstruction using AFG alone and surgeon's assessment that this can be achieved in 5 sessions of AFG
- Post wide excision
  - patient 6 months post radiotherapy
  - Patient with contour defect or asymmetry
  - Patient with scar contracture causing pain
  - patient reviewed by specialist breast surgeon or plastic surgeon and donor sites assessed and deemed suitable
- Congenital breast defects
  - patient with congenital hypomastia or tuberous breast as assessed by specialist breast or plastic surgeon
  - patient assessed and deemed suitable for correction of asymmetry using AFG alone or in conjunction with prosthesis
  - patient reviewed by specialist breast surgeon or plastic surgeon and donor sites assessed and deemed suitable

## **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<sup>20</sup> (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<sup>21</sup>. The viability of adipocytes has been shown to decrease with increased suction, excessive handling, refrigeration or major trauma during tissue collection or processing<sup>22</sup>. 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<sup>23</sup>. Volumes grafted for breast reconstruction are typically in the range of 40-150 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<sup>24</sup>. There is no difference in the ability of these sites to produce proliferating cells in culture<sup>25</sup>.

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<sup>26</sup>.

### **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):**

Up to 3 procedures to correct breast/post-mastectomy contour abnormalities and up to 5 for total breast reconstruction with AFG only. Residual defects and asymmetry to be assessed by photos and preapproval obtained for further AFG sessions.

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<sup>20</sup>Coleman SR. Facial recontouring with lipostructure. *Clin Plast Surg*. 1997; 24, 347-67.

<sup>21</sup>Illouz YG, 2009. Autologous fat transplantation to the breast: a personal technique with 25 years of experience. *Aesthetic Plastic Surgery*, 2009; 33, 706-715.

<sup>22</sup>Chan CW, MacMillan RD. Autologous fat transfer: a review of the literature with a focus on breast cancer surgery. *Journal of Plastic, Reconstructive & Aesthetic Surgery*, 2008; 61, 1438-1448.

<sup>23</sup>Wetterau M, Szpalski C, Hazen A, Warren S. Autologous Fat Grafting and Facial Reconstruction. *Plast Reconstr Surg*. 2016; Jan 137(1):31e-43e.

<sup>24</sup>Markey AC & Glogau RG. Autologous fat grafting: comparison of techniques. *Dermatol Surg*, 2000; 26, 1135-9.

<sup>25</sup>Rohrich RJ, Sorokin ES, Brown SA. In search of improved fat transfer viability: a quantitative analysis of the role of centrifugation and harvest site. *Plast Reconstr Surg*, 2004; 113, 391-5; discussion 396-7.

<sup>26</sup> Wetterau M, Szpalski C, Hazen A, Warren S. Autologous Fat Grafting and Facial Reconstruction. *Plast Reconstr Surg*. 2016 Jan 137(1):31e-43e.



**31. If applicable, advise which health professionals will primarily deliver the proposed 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 whether the proposed medical service could be delegated or referred to another professional for delivery:**

N/A

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

Specialist surgeons

**34. 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 under supervision of a specialist surgeon

**35. (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:**

Fat grafting is a procedure that requires general anaesthetic or local anaesthetic +/- sedation, best carried out in a sterile and controlled environment suited to the above settings.

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

- Yes
- No – please specify below

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

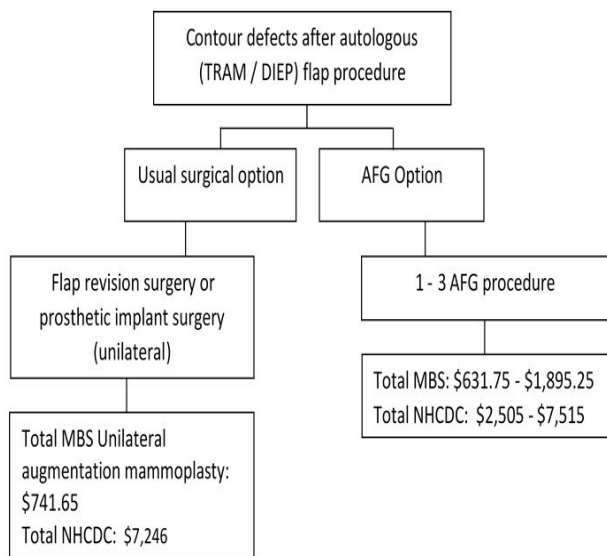
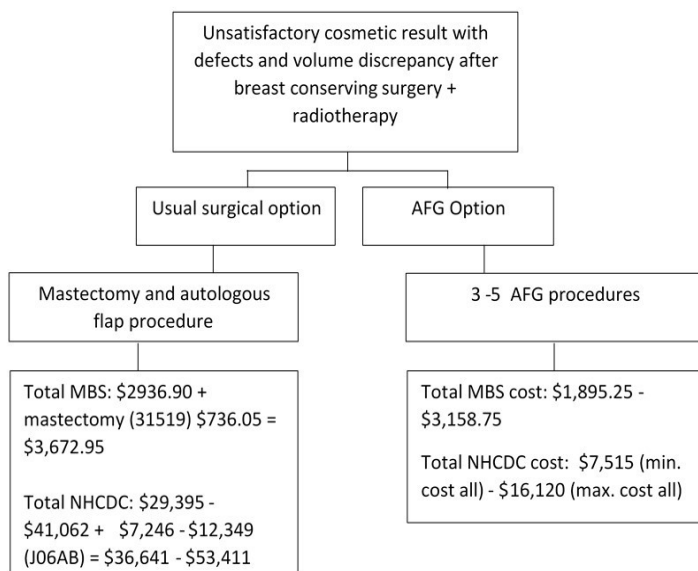
- 37. Nominate the appropriate comparator(s) for the proposed medical service, i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system (including identifying health care resources that are needed to be delivered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

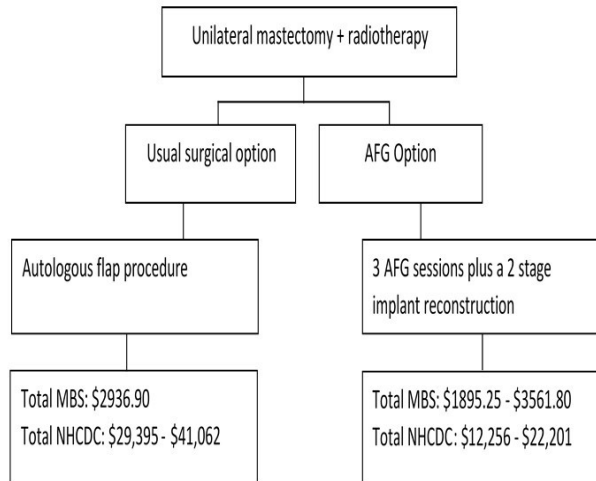
Outline the comparator (intervention) that is currently used to manage the patient population proposed in Part 6a and identify any healthcare resources (pharmaceuticals, diagnostic and investigational services, etc.) that are currently performed in association with the current comparator.

For an investigative medical service, please make the distinction between what is the comparator versus the reference standard. Please refer to the *Technical Guidelines for preparing assessment reports for the Medical Services Advisory Committee* for further details.

Breast procedures commonly have autologous reconstruction as the comparator (see Breast Flow charts).

We include flow charts for breast procedures (see below). These flow charts are for common clinical situations which occur after breast surgery which may be amendable to treatment with AFG.





**38. 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

AFG allows for the wider use of prosthetic breast reconstruction (45539/45542 or 45527) and can avoid the need for autologous reconstruction, (45564 or 45562/45504/45505) which is associated with significantly longer theatre utilisation, longer admissions, and greater comorbidity.

Patients with defects from prosthetic reconstruction requiring revisional surgery currently undergo extensive surgery to excise capsule and/or replace implants, (45552 or 45553) or even pursue autologous reconstruction (45562/45504/45505). AFG may entirely replace this surgery in suitable patients.

Patients who have had post mastectomy radiotherapy and require delayed reconstruction commonly undergo autologous reconstruction, (45564 or 45562/45504/45505). AFG can allow use of prosthetic reconstruction instead (45539/45542 or 45527).

Patients requiring treatment for breast defects after breast conservation surgery and radiotherapy previously would require completion mastectomy (31519 or 31524), and autologous reconstruction (45539/45542 or 45527). AFG can replace this.

Patients with developmental breast defects may undergo insertion of tissue expanders and exchange of implant (45539/45542) or breast augmentation (45524) for correction of asymmetry. AFG can replace this in suitable patients. The complications arising from prosthetic reconstruction also apply to this group (see above).

- 39. 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):**

AFG can be performed in an operating theatre as a day-case surgical procedure or part of a more extensive procedure requiring a longer admission. It usually takes 30-60 minutes of operating theatre time. Surgeons performing AFG must have received appropriate training. Members of BreastSurgANZ and the Australian Society of Plastic Surgeons will usually have met this training requirement.

More than one fat grafting procedure can be required to correct a breast defect, with a median of 2 fat grafting sessions for each patient. There is usually at least a 3 month interval between procedures.

Fat grafting may be performed as part of the primary breast cancer treatment or as a delayed procedure.

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

Will the proposed medical service replace or supplement the current medical service?

- Yes  
 No

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

If the proposed medical service is to replace the current medical service, describe how it will differ from what is currently available and its potential advantage.

In some cases of breast defects AFG will replace autologous breast reconstruction.

In some cases of breast defects AFG will replace autologous breast reconstruction in favour of prosthetic reconstruction, and completion mastectomy with reconstruction in patients with defects from wide excision.

- 41. 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):**

Referring to question 38, please summarise how the current clinical management pathways are expected to change as a consequence of introducing the proposed medical service. Please advise of any variation in health care resources (pharmaceuticals, diagnostic and investigational services, etc).

AFG will allow change in management of breast defects as referred to in the above flow charts.

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

### **42. 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):**

#### **Safety and efficacy of AFG**

##### **Safety**

Laboratory and clinical studies have confirmed the safety of AFG after cancer. Recent systematic and meta-analyses, and major case cohorts have shown that AFG does not result in an increased rate of local recurrence in patients with breast cancer. In relation to oncological risk from AFG after breast cancer surgery, there is now significant evidence as to its safety. Delay and colleagues (2009) found in a series of 880 fat transfer procedures over 10 years<sup>27</sup>, that there was no increased risk of loco-regional recurrence of cancer.

There was some concern that fat necrosis in AFG would make follow-up imaging of the tumour site difficult to interpret and delay diagnosis of recurrence. However fewer cysts and calcifications are seen on radiological images for this procedure than for other types of breast surgery. However, more biopsies were performed based on radiological findings (3.7% vs. 1.6%), and more cases of fat necrosis (9.0% vs 4.7%) were seen after treatment with AFG. The total complication rate of 8.4% (95% CI 7.6-9.1) is lower than those reported following other reconstructive breast procedures.

Moreover all breast procedures affect subsequent radiological imaging and present challenges in interpretation and the diagnosis of cancer recurrence, however advances in imaging technology now make the differentiation of benign and malignant changes straight forward.

There have recently been a significant number of major clinical studies, systematic reviews and meta-analyses about AFG. The American Society of Plastic and Reconstructive Surgeons have now completely revisited their earlier opposition to AFG, to where now their 2015 guiding statement states the evidence suggests AFG is an effective option in breast reconstruction following mastectomy while demonstrating moderate to significant aesthetic improvement and it is also a useful modality for alleviating post mastectomy pain syndrome. Furthermore, the evidence suggests AFG is a viable option for improving the quality of irradiated skin present in the setting of breast reconstruction. It also notes that based on available literature, complication rates associated with fat grafting are relatively low with cases of severe complications and death apparently extremely rare, with fat grafting to the post-mastectomy reconstructed breast not delaying breast cancer detection or increasing breast cancer recurrence. The guidance concludes that overall autologous fat grafting to the post mastectomy breast with no remaining native tissue yields aesthetic improvement and significant patient satisfaction.

##### **Efficacy**

Research has found that adipose tissue is easily harvestable, often in good supply, avoids risk associated with foreign bodies or large flap procedures, improves skin trophicity and AFG can be performed as a day case procedure. Adipose tissue is also particularly useful in the correction of small defects of the breast after breast reconstruction using a flap, when irregularities or asymmetry remain. There is lower donor site and recipient site morbidity with smaller incisions, reduced infection and haematoma rates compared with other breast reconstruction techniques.

The 2015 guiding statement of the ASPRS Executive Committee guidance on AFG<sup>28</sup> now states the evidence suggests AFG is an effective option in breast reconstruction following mastectomy while demonstrating moderate to significant aesthetic improvement and it is also a useful modality for alleviating post mastectomy pain syndrome. Furthermore, the evidence suggests AFG is a viable option for improving the quality of irradiated skin present in the setting of breast reconstruction. It also notes that based on available literature, complication rates associated with fat grafting are relatively low with cases of severe complications and death apparently extremely rare, with fat grafting to the post-mastectomy reconstructed breast not delaying breast cancer detection or increasing breast cancer recurrence.

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<sup>27</sup>Delay E, et al. Fat Injection to the Breast: Technique, Results, and Indications Based on 880 Procedures Over 10 Years. *Aesthetic Surgery Journal*, 2009; 29(5), 360–376.

<sup>28</sup>American Society of Plastic Surgeons, Executive Committee 2015 Post-Mastectomy Fat Graft/Fat Transfer ASPS Guiding Principles

Consequently, AFG has increasingly been used to correct contour defects after both mastectomy with reconstruction and BCS. A recent paper reported on the trends in autologous fat grafting to the breast as a national survey of American Plastic Surgeons<sup>29</sup>. Their questionnaire study of 2584 plastic surgeons revealed that 62% were using AFG for reconstructive breast surgery.

The guidance concludes that overall autologous fat grafting to the post mastectomy breast with no remaining native tissue yields aesthetic improvement and significant patient satisfaction.

AFG has been successfully used for the management of soft tissue volume deficiencies including the treatment of congenital volume deficits, whether used as a soft tissue filler alone or performed in conjunction with bony reconstruction, adipose transfer offers many advantages to the patient and clinician.

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

Briefly outline in this section whether the application is going to put forward an ‘overall’ claim that the proposed medical service is either non-inferior (no worse than the main comparator) or superior to its main comparator depending on the combined effect of the claims listed in Question 41. This has implications on the nature of the evidence that needs to be presented to the committee for consideration. This is expanded upon in the *Technical Guidelines for preparing assessment reports*.

- Superiority  
 Non-inferiority

**44. 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:**

Outcomes may include survival (mortality), clinical events (e.g. strokes or myocardial infarction), patient-reported outcomes (e.g. symptoms, quality of life), adverse events, burdens (e.g. demands on caregivers, frequency of tests, restrictions on lifestyle) and economic outcomes (e.g. cost and resource use). It is critical that outcomes used to assess adverse effects as well as outcomes used to assess beneficial effects are among those addressed by an application to MSAC.

Once a list of relevant outcomes has been compiled for the application, Applicants should prioritize the outcomes and select the main outcomes of likely relevance to the application. Applicants should broadly state which outcomes will be primary outcomes and which will be secondary outcomes. Primary outcomes are the main outcomes that would be expected to be analysed should the application identify relevant studies, and conclusions about the effects of the interventions under review will be based largely on these outcomes. There should in general be no more than three primary outcomes and they should include at least one desirable and at least one undesirable outcome (to assess beneficial and adverse effects respectively). Outcomes not selected as major outcomes would be expected to be listed as minor outcomes. In addition, minor outcomes may include a limited number of additional outcomes the application intends to address. These may be specific to only some applications. For example, laboratory tests and other surrogate measures may not be considered as main outcomes as they are less important than clinical endpoints in informing decisions.

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<sup>29</sup>Kling RE, Pusic AL, Young VL et al. Trends in autologous fat grafting to the breast: a national survey of the American Society of Plastic Surgeons. *Plast Reconstr Surg*, 2013; 132, 35-46.

**Safety Outcomes:**

Breast reconstruction surgery after breast cancer excision and mastectomy - Less invasive revision surgery, less immediate and long term local complications;

Surgery for developmental breast disorders - Less invasive revision surgery, less immediate and long term local complications;

**Clinical Effectiveness Outcomes:**

Breast surgery after breast cancer excision and mastectomy - Less invasive revision surgery, better quality of life, improved economic outcomes

Surgery for developmental breast disorders - Less invasive revision surgery, better quality of life, improved economic outcomes



## PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

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

Breast – post simple mastectomy a very rare indication (perhaps 20-30 cases pa); post mastectomy and prosthetic reconstruction may be needed in 10-20% of cases thus up to 2000 cases pa; post breast autologous reconstruction for up to 10% cases thus up to 1000 cases pa; congenital defects rare – up to 20-30 cases pa

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

As above in 45, up to 3 or 5 sessions per breast depending on indication, with average of 2 sessions.

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

Between one and five services in total, usually over a few months

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

See 45 above.

**49. 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:**

This may increase somewhat as reconstruction rates increase and availability of this may encourage use of lower burden implant type reconstructions rather than Autologous (e.g. DIEP) reconstruction over time. The training in the technique is important and is offered to both plastic and breast surgeons (see 45 above).

## PART 8 – COST INFORMATION

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

Please provide an indicative fee of providing the proposed service. Please identify any equipment and consumable costs separately.

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.

### 51. Specify how long the proposed medical service typically takes to perform:

Please provide information on the time taken to perform the proposed medical service. It is useful to the Department to separate and explain the time to prepare for the service (pre-service time), the time taken to perform the 'actual' service (intra-service) and the time taken post service (after care).

Thirty minutes to one hour in the operating theatre per service.

### 52. 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.

For each proposed MBS listing, please provide details in the outlined table.

Category
<p><b>Proposed item descriptor:</b> Autologous fat grafting (i.e. harvesting, preparation and injection of adipocytes) as an independent procedure or in conjunction with another procedure for:</p> <ul style="list-style-type: none"> <li>i. Correction of defects arising from treatment and prevention of breast cancer in patients with, or who are deemed at risk of, contour defects, &gt;=20% volume asymmetry, post treatment pain and poor prosthetic coverage up to 3 sessions per side</li> <li>ii. Preparation of post mastectomy thin/irradiated skin flaps in patients intending to have breast reconstruction up to 3 sessions per side</li> <li>iii. Breast reconstruction using AFG alone in suitable patients up to 5 sessions per side</li> <li>iv. Correction of developmental disorders of the breast up to 3 sessions per side</li> </ul> <p>Fee: \$631.75</p>