



Australian Government

Department of Health

Application Form

(New and Amended

Requests for Public Funding)

(Version 2.4)

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

Please use this template, along with the associated Application Form Guidelines to prepare your application. Please complete all questions that are applicable to the proposed service, providing relevant information only. Applications not completed in full will not be accepted. Should you require any further assistance, departmental staff are available through the Health Technology Assessment Team (HTA Team) on the contact numbers and email below to discuss the application form, or any other component of the Medical Services Advisory Committee process.

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Fax: +61 2 6289 5540

Email: hta@health.gov.au

Website: www.msac.gov.au

PART 1 – APPLICANT DETAILS

1. Applicant details (primary and alternative contacts)

Corporation / partnership details (where relevant):

Corporation name: AUSTRALIAN SOCIETY OF PLASTIC SURGEONS INC.

ABN: REDACTED

Business trading name: AUSTRALIAN SOCIETY OF PLASTIC SURGEONS

Primary contact name: REDACTED

Primary contact numbers

Business: REDACTED

Mobile: REDACTED

Email: REDACTED

Alternative contact name: REDACTED

Alternative contact numbers

Business: REDACTED

Mobile: REDACTED

Email: REDACTED

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

Yes

No

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

Yes

No

PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

3. Application title

Abdominoplasty with repair of rectus diastasis (aka rectus divarication) following pregnancy

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)

The medical condition concerned is the combination of low back pain, truncal instability and abdominal discomfort +/- urinary incontinence associated with significant rectus abdominis diastasis. This constellation of symptoms is not currently named as a syndrome but meets the criterion of a syndrome (Oxford English Dictionary definition of a syndrome “a collection of symptoms that consistently occur together, or a condition characterised by a consistent set of symptoms”) and could be named “Rectus diastasis syndrome”. There is peer-reviewed literature establishing that rectus diastasis of greater than 3cm (most commonly as a result of pregnancy) is associated with deterioration in the function of the abdominal wall with an associated muscular imbalance, chronic back pain and discomfort at the level of the defect. There is some evidence that rectus diastasis contributes to urinary incontinence.

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)

The medical service proposed is the surgical repair of a symptomatic rectus diastasis which is over the threshold distance of 3cm and where the patients have a recognised and documented pattern of symptoms - low back pain, daily abdominal discomfort on functional use and/or urinary incontinence. The repair would involve suturing the musculoaponeurotic layer of the abdominal wall and including associated excision of redundant skin and fat and transposition of the umbilicus (radical abdominoplasty). It would not be performed within 12 months of pregnancy.

The service would normally be performed under general anaesthesia in an accredited hospital and would include a 1 to 4 night inpatient stay with 6 weeks of aftercare. Restriction to accredited hospitals would be appropriate.

If it was felt to be appropriate by Medicare, Patient Reported Outcomes Measures for low back pain and incontinence, with evidence-based thresholds, could be incorporated into the item descriptor.

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:

30176

(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):

Currently this service (item 30176) is restricted to those who have rectus diastasis secondary to “surgical removal of large intra-abdominal or pelvic tumours”, without apparent peer-reviewed evidence for this restriction. The existence of this item acknowledges that Medicare recognises “rectus diastasis syndrome” but excludes the condition of pregnancy being the large mass within the pelvis. This does not appear to be a consistent approach. The argument that pregnancy is a physiological condition, rather than a pathological condition is not valid, as the majority of pregnancies do not result in rectus diastasis syndrome and so this post-pregnancy syndrome cannot be seen as “natural” or physiological. Furthermore, Medicare supports the treatment of significant symptoms arising from other physiological conditions, such as ablation of the uterine endometrium for menorrhagia (35616) which occurs within the context of the physiological condition of menopause or treatment of urinary problems secondary to benign prostatic hyperplasia (37245) occurring in the context of male ageing. Another example of a defined condition arising secondary to the physiological event of pregnancy would be post-partum depression. Not funding treatment of depression when it arises in this context would not be acceptable to the general community.

Abdominoplasty, including repair of rectus diastasis, used to be possible for women with rectus diastasis syndrome under the descriptor 30177, until that descriptor was changed and the new version of the descriptor was implemented in 2016. Item 30177 is now focussed on those who have had massive weight loss and are suffering the sequelae of this. The Australian Society of Plastic Surgeons agrees with the Department of Health that this is a separate, distinct population with a different set of symptoms and it is not appropriate to place the patients with rectus diastasis syndrome back into this item, as per the principle of being pathology – focussed within the schedule. Item 30176 is focussed on the repair of the abdominal wall, acknowledging that this is a valid procedure for those with abdominal wall defects, so this is the appropriate item for amendment.

(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 Protheses 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: Sutures are required to be used during the surgery

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: Insert description of single use consumables here

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*?

- 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?

- 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?

- 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.	Review	A systematic review on the outcomes of correction of diastasis of the recti. Hickey F, Finch JG, Khanna A.	Seven studies report that patient satisfaction was high following abdominal rectus repair surgery	https://www.ncbi.nlm.nih.gov/pubmed/21688021	Hernia 2011
2.	Review	A systematic review of outcomes of abdominoplasty. Staalesen T, Elander A, Strandell A, Bergh C.	One small controlled study on abdominoplasty was found indicating a positive effect on quality-of-life	https://www.ncbi.nlm.nih.gov/pubmed/22747350	J Plastic Surgery and Hand Surgery 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***
3.	Prospective analysis	Correlation between abdominal rectus diastasis width and abdominal muscle strength Gunnarsson U, Stark B, Dahlstrand U, Strigård K	57 patients underwent rectus diastasis repair and there was a strong correlation between intraoperatively measured rectus diastasis width below the umbilicus and flexion and isometric abdominal muscle strength	https://www.ncbi.nlm.nih.gov/pubmed/25766128	<i>Dig Surg.</i> 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***
4.	Review	Rectus Abdominis diastasis Akram J. Matzen SH	28 studies were included, representing 3725 patients. Post surgical repair the patient-satisfaction was high and long-term recurrence was zero.	https://www.ncbi.nlm.nih.gov/pubmed/24256310	J Plas. Surg Hand Surg. 2014

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
5.	Summary & case study	Stability, continence and breathing Lee DG, Lee LJ, McLaughlin L	Pregnancy-related pelvic girdle pain (PRPGP) has a prevalence of approximately 45% during pregnancy and 20-25% in the early postpartum period. Most women become pain free in the first 12 weeks after delivery, however, 5-7% do not. This study presents a possible physiological explanation for fascial changes.	https://www.ncbi.nlm.nih.gov/pubmed/19083692	Journal of Bodywork and Movement Therapies 2008

	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.	Surgical technique	Abdominoplasty and abdominal wall rehabilitation: a comprehensive approach Ramirez OM	104 patients undergoing a 4 stage surgical approach. 1 required re tightening.	https://www.ncbi.nlm.nih.gov/pubmed/10627012	<i>Plast Reconstr Surg</i> 2000
7.	Retrospective analysis	An aesthetic classification of the abdomen based on the myoaponeurotic layer Nahas FX.	Classification of myoaponeurotic deformities. 88 patients reviewed to evaluate the best surgical option	https://www.ncbi.nlm.nih.gov/pubmed/11711966	<i>Reconstr Surg.</i> 2001
8.	Cross sectional study	The normal width of the linea alba in nulliparous women Beer GM, Shuster A, Seifert B et al	Measurement of normal linea alba width in 150 nulliparous women.	https://www.ncbi.nlm.nih.gov/pubmed/19637295	<i>Clin Anat.</i> 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***
9.	Prospective randomised trial	Alternatives in the treatment of abdominal rectus muscle diastasis: an evaluation. Karolinska Institute, Dept of Clinical Science, Intervention and Technology	56 patients with a rectus diastasis wider than 3 cm have physical symptoms and poorer quality of life than an age-matched population. Surgical intervention improves patient comfort and improves quality of life.	https://openarchive.ki.se/xmlui/handle/10616/42245	2014

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
10.	Cross sectional study	Prevalence, potential risk factors and sequelae of diastasis recti abdominis Gitta S, Maygar Z, Tardi P et al	200 post partum women had 46.5% prevalence of rectus diastasis. There was a significant difference in quality of life, in presence of low back pain and urinary incontinence between the normal and the abnormal group.	https://www.ncbi.nlm.nih.gov/pubmed/28328249	<i>Orv. Hetil.</i> , 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***
11.	Prospective, randomized, clinical, 2-armed trial	Operative correction of abdominal rectus diastasis (ARD) reduces pain and improves abdominal wall muscle strength: a randomized prospective trial comparing retromuscular mesh repair to double-row self-retaining sutures Emanuelsson P. Dahlstrand UG. Strigard K. Stark B	86 patients with rectus divarication studied. Surgery improved functional ability and quality of life.	https://www.ncbi.nlm.nih.gov/pubmed/27475817	<i>Surgery</i> , 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***
12.	Prospective randomised control trial	Early complications, pain and quality of life after reconstructive surgery for abdominal rectus muscle diastasis: A three-month follow-up Emanuelsson P. Gunnarson U. Strigard K. Stark B.	>3cm rectus divarication repair in 57 patients comparing 2 techniques. Both techniques reliable with similar post operative pain. Mesh repair produced improved muscle strength.	https://www.ncbi.nlm.nih.gov/pubmed/24880577	J Plas. Reconstr. Aesth Surg 2014;
13.	Prospective trial	Abdominoplasty Improves Low Back Pain and Urinary Incontinence Taylor DA, Merten SL, Sandercoe GD, Gahanakari D et al	214 patients following abdominoplasty & rectus diastasis repair. At 6 months showed significant improvement in low back pain & urinary incontinence.	https://insights.ovid.com/crossref?an=00006534-201803000-00013	2016 conference paper Australasian Society of Aesthetic Plastic Surgeons Gold Coast, Australia.

	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***
14.	Prospective study	The relief of low back pain with the WARP abdominoplasty Toranto IR	Back pain alleviated in 24 of 25 patients following wide abdominal rectus plication abdominoplasty. Increase in muscle strength & intervertebral disc space.	https://www.ncbi.nlm.nih.gov/pubmed/2138335	Plast Reconstr Surg. 1990
15.	Prospective trial	Wide abdominal rectus plication abdominoplasty for the treatment of chronic intractable low back pain Oneal RM, Mulka JP, Shapiro P, et al	8 patients had long term alleviation of their chronic back pain following wide abdominal rectus plication.	https://www.ncbi.nlm.nih.gov/pubmed/21200216	Plast Reconstr Surg. 2011

	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***
16.	Case study	Functional Improvement Following Diastasis Rectus Abdominus Repair in an Active Duty Navy Female Gallus KM, Golberg KF, Field R	Restored abdominal function (in an active navy female) following abdominoplasty and imbrication of the abdominal wall diastasis.	https://www.ncbi.nlm.nih.gov/pubmed/27483541	<i>Mil Med.</i> 2016 Aug
17.	Prospective controlled longitudinal study	The relationships between inter-recti distance measured by ultrasound imaging and abdominal muscle function in postpartum women: a 6-month follow-up study Liaw LJ, Hsu MJ, Liao CF, Liu MF, Hsu AT	40 post partum women (& 20 nulliparous women) had inter rectus distance & abdominal muscle function assessed. At 6 months post partum diastasis & muscle function had not returned to normal.	https://www.ncbi.nlm.nih.gov/pubmed/21289454	<i>J Orthop Sports Phys Ther.</i> 2011

	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***
18.	Prospective trial	Correlation between Abdominal Diastasis Width and Abdominal Muscle Strength. Gunnarsson U, Stark B, Dahlstrand U, Strigard K.	57 patients underwent abdominal rectus diastasis repair. There was a strong correlation between the diastasis width & abdominal muscle strength.	https://www.ncbi.nlm.nih.gov/pubmed/25766128	Dig Surg 2015
19.	Opinion	Is the lumbodorsal fascia necessary Gracovetsky S	The lumbodorsal fascia is an important structure in spinal kinetics	https://www.unboundmedicine.com/medline/citation/19083674/	Journal of Bodywork and Movement Therapies 2008
20.	Prospective trial	A study of postural changes after abdominal rectus abdominoplasty Mazzocchi M, Dessy LA, Di Ronza S, Iodice P, Saggini R, Scuderi N	46 patients undergoing abdominoplasty & rectus diastasis repair. Improvement in posture & psychological factors & quality of life.	https://www.ncbi.nlm.nih.gov/pubmed/23132640	Hernia 2014

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
21.	Case series	Intra-abdominal pressure increases stiffness of the lumbar spine. Hodges PW, Eriksson AE, Shirley D, Gandevia SC.	Analysis of spinal stiffness in 3 patients in relationship to intra-abdominal pressure. There was a correlation.	https://www.ncbi.nlm.nih.gov/pubmed/16023475	J Biomech. 2005
22.	Lab research	Intra-abdominal pressure mechanism for stabilising the lumbar spine Cholewicki J, Juluru K, McGill SM.	They designed a model to imitate an intra abdominal pressure mechanism for stabilizing the lumbar spine. It appears preferable in tasks that demand trunk extensor moment such as lifting or jumping to increase intra-abdo pressure.	https://www.ncbi.nlm.nih.gov/pubmed/10050947	J Biomech. 1999

	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***
23.	Retrospective series	Improvement in stress urinary incontinence after abdominoplasty Carruthers KH, Kocak E, Hulsen JH, McMahon JD.	250 patients who had undergone abdominoplasty were reviewed for improvement in urinary incontinence. 60% of 50 patients with prior stress incontinence improved.	https://www.ncbi.nlm.nih.gov/pubmed/25073582	Aesthet Surg J. 2014

* 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.	For yet to be published research that may have results relevant to your application, insert the type of study design in this column and columns below	For yet to be published research that may have results relevant to your application, insert the title of research (including any trial identifier if relevant) in this column and columns below	For yet to be published research that may have results relevant to your application, insert a short description of research (max 50 words) in this column and columns below	For yet to be published research that may have results relevant to your application, insert a website link to this research (if available) in this column and columns below	For yet to be published research that may have results relevant to your application, insert date in this column and columns below
2.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
3.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
4.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
5.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
6.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
7.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
8.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
9.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
10.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
11.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
12.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
13.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
14.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date

	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***
15.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date

* *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):**

General Surgeons Australia

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

N/A

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

Australian Physiotherapy Association
Multiple Births Australia
Centre of Perinatal Excellence

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

N/A

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

Name of expert 1: REDACTED
Telephone number(s): REDACTED
Email address: REDACTED
Justification of expertise: REDACTED

Name of expert 2: REDACTED
Telephone number(s): REDACTED
Email address: REDACTED
Justification of expertise: REDACTED

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

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

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

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

Diastasis of the rectus abdominis muscles is the separation of the rectus muscles usually as a result of the linea alba thinning and stretching. Rectus diastasis results from increased intra-abdominal pressure most commonly following pregnancy; however, large abdominal and pelvic tumours, and prior abdominal operations can also be the cause. Most women who develop rectus diastasis do so after pregnancy, particularly those pregnancies involving multiple gestations or sequential, large infants. Female pattern rectus diastasis is centred at the level of the umbilicus, but can extend up to the xiphoid and down to the symphysis pubis. Male pattern rectus diastasis more frequently develops as a result of increased intra-abdominal fat volume and occurs primarily above the umbilicus in the fifth to sixth decades of life.

Significant rectus diastasis causes a decrease in abdominal wall pressure and function. Researchers have found a strong correlation between the measured rectus diastasis width below the umbilicus and flexion and isometric abdominal muscle strength. Exercise and physical therapy may allow a patient to compensate for the diastasis, but the rectus muscles will not re-approximate spontaneously.

Post-partum patients often struggle with a lack of core muscle strength which contributes to repetitive musculoskeletal injuries stemming from pelvic instability. The synergistic action of all the trunk muscles carries load and function through the lumbopelvic region. Because of overuse of the back musculature to compensate for lost abdominal wall stability, low back pain is frequent in cases of significant rectus diastasis. Rectus diastasis may therefore produce deterioration in the function of the abdominal wall with an associated muscular imbalance, urinary incontinence, chronic back pain and discomfort at the level of the defect. The appearance of the abdominal wall is often noticeably distorted in women with rectus diastasis. The midline bulge is exacerbated with muscle contraction and is common in multiparous women.

- 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:**

The proposed patient population would have rectus diastasis evident on clinical exam (and confirmed via an ultrasound or other appropriate diagnostic radiology to measure inter-rectus distance). They would suffer from lower back pain, pain at the level of the abdominal wall defect and/or urinary incontinence. Referral would likely be from their GP or obstetrician.

- 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):

Currently post-partum patients with abdominal rectus diastasis are not covered by the MBS (unless they have had an intra-abdominal tumour). These patients would be assessed by their GP initially for severity and consistency of symptoms and if indicated would be sent for diagnostic ultrasound of the abdominal wall. Those found to have significant diastasis would then be referred to a specialist surgeon. The surgeon would take a full history & examination and check that the criterion of a diastasis of greater than 3cm on medical imaging had been met (as well as checking that they were at least 12 months post-partum). Patients meeting symptomatic and imaging criteria and thus considered suitable for surgery would then have the pros and cons of this procedure discussed and with informed consent they would be booked for surgery.

There are no non-invasive procedures that are able to repair rectus diastasis and hence no effective clinical management pathway at present.

It should be noted that although the requiring for diagnostic radiology is proposed for the item descriptor and that this could theoretically result in an increase in ultrasounds performed, in reality, GPs often perform at least one ultrasound in the pursuit of trying to diagnose and then monitor the patient's condition anyway, so in fact an increase in imaging requests is unlikely.

PART 6b – INFORMATION ABOUT THE INTERVENTION

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

Identify appropriate patients (adequate history & examination).
Obtain informed financial consent.
Admission to an accredited hospital.
Pre-operative surgical markings.
General anaesthesia – administered by a specialist anaesthetist
Excision of excess skin, repair of the rectus diastasis (by suturing the musculoaponeurotic layer with absorbable or non-absorbable sutures), repositioning of the umbilicus, closure of abdomen.
Post-operative care in hospital usually for 1-4 nights.

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?

N/A

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):

The service must be provided within an accredited surgical hospital facility.

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:

General anaesthesia.

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

An FRACS qualified surgeon (usually a plastic surgeon or a general surgeon).

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:

A surgical specialist adequately trained in abdominoplasty must perform the procedure.

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:

FRACS (Fellowship of Royal Australasian College of Surgeons) – Plastic Surgery or General surgery. The surgeon would need to have accreditation at the relevant surgical facility that the procedure is taking place in.

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:

The service can only be performed in a licenced operating theatre.

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):**

This population is currently only treated on a private self-funded basis (costs would vary but likely range from \$10000-20000, including hospital, surgical and anaesthetic costs - the patient incurs these entirely). The service is not available in any public hospital setting. The only other option for these patients is no treatment and living with their abdominal dysfunction and pain. Many are unable to afford this procedure and thus are unable to have treatment.

Untreated women with rectus diastasis syndrome are likely to put strain on health care resources in an attempt to control their symptoms. Cost of analgesia for low back pain, consultations with GPs and management of incontinence are likely to have significant health economic costs, but these are difficult to measure due to the fact that women will seek help from a disparate variety of sources – pharmacies, GPs and public hospitals. The health burden of these symptoms has a follow-on effect in terms of productivity. Women who have problems with incontinence and back pain are less likely to return to full-time employment.

- 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

Specify item number/s here

- 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):**

Currently these patients either have no treatment (live with their abdominal dysfunction and pain and possibly urinary incontinence) or self fund for their surgical treatment.

Many are unable to afford this procedure and thus are unable to have treatment.

If they have surgery, then they would have on average a 1-4 night stay in hospital and then follow up with the surgeon in their rooms for up to 4 months. On average 5 post operative visits for review would be required.

- 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:**

The inclusion of this procedure within the 30176 item number would allow those patients suitable to be included to have their surgery covered by medicare and/or private health funds. There would still be some patients requiring this surgery that don't meet the requirements and thus would still need to self fund or have no treatment.

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):

Those suitable patients would still undergo the same procedure and same post operative care, but would be subsidized, thus allowing greater access to this procedure for post-partum women.

PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME

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

There is no MBS comparator that treats this clinical problem.

There is evidence that repair of rectus diastasis relieves rectus diastasis syndrome (low back pain, abdominal wall pain at the site of the defect +/- urinary incontinence following child birth. This is outlined in section 45 below.

This procedure is the same as for descriptor 30176 (but this only includes intra abdominal or pelvic tumours, not including babies/pregnancy)

The procedure offers superiority over no treatment at all.

The procedure offers equivalence to having the procedure entirely self funded.

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

- Superiority
 Non-inferiority

- 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: List safety outcomes here

Clinical Effectiveness Outcomes: Patient reported outcomes of improvement in quality of life, improvement in low back and abdominal pain and improvement in urinary incontinence have been proven in several clinical papers.

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

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

The incidence of chronic back pain greater than two years following pregnancy has been reported between 5% to 21.1%.

Persistent urinary incontinence rates 10 to 12 years after pregnancy range between 25% to 37.9%.

Vaginal delivery is associated with a higher incidence of long term stress incontinence. The Australian female population is approximately 11million. 24% of Australian women are childless in their lifetime. A 20% incidence of chronic back pain and a 35% incidence of urinary incontinence in the remaining 8.36m childbearing women would mean up to 1.67m Australian women are suffering chronic back pain and 3.2m stress incontinence. Both these conditions negatively affect the quality of life and are usually under reported.

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

Approximately 1000 patients per year.

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

1 (one procedure per patient)

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

1000

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:

Numbers per year would possibly increase as the awareness and accessibility improves. This is very difficult to quantify.

PART 8 – COST INFORMATION

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

As per current item number 30176. The surgical procedure and post operative care would be very similar

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

2-3 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 3 – THERAPEUTIC PROCEDURES. Group T8 – surgical operations. Subgroup 1 - general
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Amend item 30176

Rectus diastasis, surgical repair of, where the patient has had a massive intra-abdominal or pelvic tumour, or pregnant uterus and where the diastasis is 3cm or more (as measured by appropriate diagnostic radiology) and where there are documented functional symptoms in the case notes with at least two of the following symptoms: low back pain, urinary incontinence and daily abdominal discomfort on functional use, by suturing of the musculoaponeurotic layer of the abdominal wall and including associated excision of redundant skin and fat and transposition of the umbilicus, not being a service performed within 12 months after the end of a pregnancy (Anaes, Assist)

Fee: \$985.70

PART 9 – FEEDBACK

The Department is interested in your feedback.

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

16 hours

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

Yes

No

(b) If no, provide areas of concern:

(c) Some of the wording of the questions is very difficult to understand. The form obviously encompasses many types of applications and many questions are difficult to relate to a surgical procedure.

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

Yes

No

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

Insert feedback here

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

Yes

No

(b) If yes, please advise:

Insert feedback here