Australian Government

Medical Services Advisory Committee

Public Summary Document

Application 1546.1 - Abdominoplasty with surgical repair of rectus diastasis following pregnancy

Applicant: Australian Society of Plastic Surgeons

Date of MSAC consideration: 82nd MSAC Meeting, 29-30 July 2021

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, visit the MSAC website

1. Purpose of application

A resubmission requesting Medicare Benefits Schedule (MBS) listing of abdominoplasty for surgical repair of postpartum rectus diastasis (aka rectus divarication; RD) was received from the Australian Society of Plastic Surgeons (ASPS) by the Department of Health.

2. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness and cost-effectiveness, MSAC supported creation of a new Medicare Benefits Schedule (MBS) item to reinstate abdominoplasty with repair of rectus diastasis following pregnancy. MSAC considered there were uncertainties in the evidence base, but advised that abdominoplasty had inferior but acceptable safety, superior effectiveness that was sustained over five years, and acceptable cost-effectiveness compared with no treatment.

MSAC advised that a review be conducted 2 years following implementation to ensure that use of the item does not extend beyond the intended population or to purely cosmetic purposes.

The MSAC supported item descriptor and draft explanatory note are summarised below:

Category 3017X – Category 3 – Therapeutic Procedures
Group T8 – surgical operations Subgroup 1 – general Radical abdominoplasty, with repair of rectus diastasis, excision of skin and subcutaneous tissue, and transposition of umbilicus, not being a laparoscopic procedure, not being a service associated with a service to which item 30165, 30651, 30655, 30168, 30171, 30172, 30176, 30177, 30179, 45530, 45564 or 45565 applies, and where it can be demonstrated, that the patient has an abdominal wall defect as a consequence of pregnancy and must: a) not be receiving this service within 12 months after the end of a pregnancy; b) have a diastasis of at least 3cm measured by diagnostic imaging; and c) have documented symptoms of at least moderate severity of pain or discomfort at the site of the diastasis in the abdominal wall during functional use and/or low back pain or urinary symptoms likely due to rectus diastasis; and d) have failed to respond to non-surgical conservative treatment including physiotherapy Applicable once per lifetime (H) Multiple Operation Rule (Anaes.) (Assist.) See para TN.8.X of explanatory notes to this Category)
Fee: $1,025.60 Benefit: 75% = $769.20

TN.8.XX
In the context of eligibility for item XXXXX, acceptable examples of conservative non-surgical treatment include symptomatic management with pain medication, lower back braces, lifestyle changes, physiotherapy and/or exercise. Diagnostic imaging, documented symptoms of pain and discomfort, and documented failure to respond to non-surgical conservative treatment must all be documented in patient notes.

Consumer summary

The Australian Society of Plastic Surgeons applied for public funding through the Medicare Benefits Schedule (MBS) for surgery to repair separation of the abdominal muscles after pregnancy, a condition known as rectus diastasis (or rectus divarication). In this surgery (abdominoplasty), the central muscles are "sewn" back together and if necessary extra skin is removed. Letters of support for funding rectus diastasis were received from many consumers.

The application was for funding of abdominoplasty after someone has been pregnant and has unsuccessfully tried to improve their symptoms with exercise, physiotherapy or weight loss. This procedure is not intended for cosmetic use. It is sometimes difficult to tell if rectus diastasis has happened directly because of pregnancy or some other cause – for example, significant weight loss before pregnancy.

The evidence shows that abdominoplasty after pregnancy to treat rectus diastasis is not as safe as no treatment, but that it is just as safe as abdominoplasty performed after weight loss or the removal of a tumour, both of which are currently accepted and funded on the MBS.

The evidence showed that abdominoplasty is more effective at treating rectus diastasis

Consumer summary
compared with no treatment, and that the effect was maintained over 5 years. It was also considered to be cost-effective compared with no treatment. **MSAC's advice to the Commonwealth Minister for Health** MSAC considered there were uncertainties in the evidence base, but advised that abdominoplasty had inferior but acceptable safety, superior effectiveness that was sustained over 5 years, and acceptable cost-effectiveness compared with no treatment. MSAC recommended creating a new MBS item for abdominoplasty with repair of rectus diastasis after pregnancy.

3. Summary of consideration and rationale for MSAC's advice

MSAC noted that this resubmission seeks to create a new MBS item for abdominoplasty with repair of rectus diastasis following pregnancy. MSAC recalled that the previous submission, considered by MSAC in November 2019, was not supported at that time based on uncertainty around the benefit of the intervention relative to best supportive care (physiotherapy and/or exercise) and uncertainty regarding the incremental cost-effectiveness of the intervention. MSAC also raised concerns about the effectiveness of abdominoplasty to alleviate back pain.

In considering the resubmission, MSAC noted strong, ongoing support from consumers and surgeons for reinstatement of Medicare funding for the procedure including comments that it is unfair that patients can access MBS rebates for abdominoplasty following massive weight loss or the removal of a tumour but not for post-partum rectus diastasis.

MSAC noted the clinical need is for a small subset of women who have rectus diastasis post-partum and are symptomatic.

MSAC noted the clinical management algorithm, but considered that the box "RD (i.e. rectus diastasis) resolved" could be amended to "symptoms related to RD resolved" to more accurately reflect that it is the symptoms associated with the rectus diastasis that is being treated.

MSAC noted that the comparator in the resubmission is best supportive care, which may include symptomatic management with pain medication, lower back braces, lifestyle changes, physiotherapy and/or exercise. Physiotherapy and/or exercise are acknowledged by the applicant as representing the preferred first-line treatment option for post-partum women with abdominal rectus diastasis. However, non-physiotherapy/exercise program interventions such as pain medicines, lower back braces and lifestyle changes would be considered as part of the overall management of any patient with abdominal rectus diastasis and not as direct alternatives/comparators to physiotherapy/exercise programs or abdominoplasty, which have an intent to resolve the abdominal diastasis rectus. In consideration of the above, and the lack of recognised options to treat the underlying abdominal rectus diastasis in women whose symptoms are refractory to a first-line physiotherapy/exercise program, the applicant considered "no treatment" to be a more appropriate comparator. MSAC considered this to be appropriate.

MSAC noted that the resubmission identified three new case series studies (2 prospective; 1 retrospective) and a new publication providing 5-year follow-up data from the

Emanuelsson et al. (2014, 2016) trial; albeit with a low level of evidence. Abdominoplasty with repair of rectus diastasis has inferior safety compared with no treatment, but MSAC noted that it has similar safety when the procedure is used after weight loss or tumour abdominoplasty, both of which are currently accepted and funded on the MBS. MSAC noted that abdominoplasty with repair of rectus diastasis has superior effectiveness compared with no treatment, and that even though this is based on low-level evidence, the effect appears to be maintained to 5 years. In addition, MSAC noted that the link between rectus diastasis and back pain/pelvic pain/urinary incontinence, and the magnitude and durability of effect, remain uncertain; however, considered that the low-level evidence showed consistency in results. MSAC noted that it is unlikely that higher-level evidence will become available in the near future.

MSAC noted that in the pre-MSAC response, the applicant challenged the ESC advice that the included studies were at risk of bias, asserting that this is less relevant if the comparator is no treatment because most studies compared pre- and post-treatment outcomes.

MSAC noted that the economic evaluation is generally unchanged from the previous submission, apart from updated costs and a longer timeframe. MSAC considered that the model structure is still reasonable.

MSAC noted that the time horizon (5 years) in the previous model was considered conservative, as the condition does not lead to a reduction in survival. The outcomes were assumed to stay constant for the duration of the model beyond 12 months. MSAC noted that the time horizon has been extended to 20 years in the resubmission. This is appropriate for a chronic condition where the benefits of treatment accrue over a lifetime; however, there is considerable uncertainty regarding the clinical inputs and extrapolation of these over the longer time horizon.

MSAC noted that the cost of best supportive care increased from $311 to $2,491 in the resubmission. MSAC considered that as this cost is accrued pre-surgery it should be removed from the comparator arm of the economic model and noted that this results in an ICER of $30,187 to $9,634 per quality-adjusted life year (QALY) gained over 5 and 20 years, respectively. Overall, MSAC considered an ICER in this range to be acceptably cost-effective.

MSAC noted that the number of predicted services per annum is small, with modest additional costs to the MBS of $1.46–1.69 million over 5 years.

MSAC noted that the procedure is usually performed in private hospitals and that the out-of-pocket costs are significant and noted that there remains a question of whether MBS listing will provide equity of access to the procedure.

MSAC noted that patients with rectus diastasis may also present with hernia (midline and non-midline). Clinical advice sought by the Department recommended co-claiming restrictions with ventral hernia repair (MBS items 30651 and 30655; which have replaced items 30403 and 30405 as of 1 July 2021), noting that such midline hernia should be repaired as part of rectus divarication repair, but no restriction with other more common midline hernias that may coexist with rectus diastasis, such as umbilical hernia repair MBS item 30621, as umbilical repair is an additional task requiring extra time and complexity. Accordingly, MSAC noted that the Department supports the addition of co-claiming restrictions with MBS items 30651 and 30655 only. In addition, MSAC noted the pre-MSAC response advising that if a general surgeon is also required to

repair one of the concomitant hernias as part of the operation for repair of rectus diastasis, then the multiple operation rule will not apply.

MSAC noted that only open-approach abdominoplasty should be included in the item descriptor, because endo-laparoscopic procedures have a lower evidence base for the comparison of efficacy and safety and are more costly.

MSAC noted the pre-MSAC response proposing changes to the item descriptor (see Table 2). MSAC advised the following changes to the descriptor:

- Specify open procedure and not laparoscopic
- Include indication for post-12 months after the end of a pregnancy
- Include the limit of once per lifetime
- Including symptomatology (having at least moderate symptoms caused by rectus diastasis) and including urinary symptoms
- Explicitly include physiotherapy as part of failed conservative management
- Require ultrasound to confirm a minimum 3 cm size of separation.

MSAC considered that ultrasound is crucial to have some accountability in relation to sizing the separation and to prevent item leakage. MSAC noted it may be difficult to correlate the size of the separation with patient symptoms, but noted that rectus diastasis may progress and get larger over time, and also that the length of the diastasis may be important. MSAC considered the proposed separation distance of at least 3 cm to be reasonable.

MSAC noted advice from the Department that the MBS service descriptor available before the Lipectomy Review was at high risk of misuse for cosmetic purposes but that the Department is satisfied that the proposed item descriptor is substantially more robust and sufficiently restrictive to prevent this leakage.

MSAC advised that a review be conducted in 2 years to ensure that use of the item does not extend beyond the intended population or to purely cosmetic purposes. MSAC noted that an independent review of symptoms of rectus diastasis would be useful but would be difficult to implement.

4. Background

This applicant developed assessment report (ADAR) is the first resubmission of Application 1546. The purpose of Application 1546 was to reinstate MBS funding for abdominoplasty with repair of rectus diastasis in women who developed symptomatic rectus diastasis following pregnancy. In 2016, this patient group was removed from the MBS item 30177 after a review of abdominoplasty in the management of urinary incontinence due to concerns that the surgery was performed for largely cosmetic reasons and had no significant morbidity or mortality benefit. Radical abdominoplasty is currently reimbursed when required due to the surgical removal of large intra-abdominal or pelvic tumours (MBS item 30176) or due to massive weight loss (MBS item 30177).

At the November 2019 meeting, the MSAC did not support public funding of abdominoplasty with repair of rectus diastasis (aka rectus divarication; RD) following pregnancy. MSAC considered that the magnitude of benefit relative to best supportive care (i.e. physiotherapy and/or exercise) was uncertain and as a consequence the incremental cost-effectiveness was also uncertain (Public Summary Document [PSD], Application 1546, November 2019).

In December 2020, the Department sought MSAC Executive consideration of new evidence presented by the ASPS and a possible resubmission pathway for its MSAC Application 1546. The MSAC Executive noted that, as a result of the negative outcome, there has been significant media attention around the topic and a petition presented to the House of Representatives. Representatives of the ASPS have met with the Department to consider the new evidence and have proposed several possible revised item descriptors for the service. The ASPS also noted concerns with the comparator used in the original application, namely the inclusion of physiotherapy as a potential component of best supportive care, stating that it should not be included as it has no effect in the treatment of diastasis recti.

The MSAC Executive noted that, although there was a lot of discussion surrounding the definitions of the population and the comparator, it would be unlikely that a second PASC consideration could resolve these. The MSAC Executive considered that, to avoid delays in preparing for an MSAC reconsideration, a new assessment report could proceed straight to ESC consideration, as the new evidence would still need to be evaluated and incorporated into the economic modelling.

The MSAC Executive emphasised that the new evidence would need to demonstrate that MSAC could support any claim of clinically meaningful benefit. For instance, the evidence previously reviewed did not support any claim for an improvement in back pain, urological symptoms, mobility, exercise tolerance, or any other functional outcome. The MSAC Executive noted that the MBS cannot list services that are purely for cosmetic purposes. However, the MSAC Executive also noted that the consumer view of clinically meaningful benefits may perceive secondary cosmetic improvements as psychologically relevant.

The resubmission provided a detailed summary of the MSAC concerns for the previous submission (Application 1546 Department-Contracted Assessment Report; DCAR), and how they have been addressed in the resubmission (Application 1546.1). This was summarised by the commentary in Table 1.

Table 1 Key concerns raised in 2019 PSDF for Application 1546 and addressed in the reapplication

No.	Issue for MSAC	How addressed in reapplication	Assessment Group comments
1	Clinical effectiveness: Very low confidence in the conclusion that surgery is superior to physical therapy in terms of clinical effectiveness.	The reapplication states that the appropriate comparator is 'no treatment,' rather than physical therapy, because abdominoplasty would not be considered unless the RD was unresolved after attempting a physiotherapy/exercise program. The reapplication provides additional evidence to support the claim of superior clinical effectiveness compared with 'no treatment': (1) additional prospective cohort studies of surgical repair of rectus diastasis (n=2; k=170) (2) long-term outcomes from the Emanuelsson trial (3) a retrospective cohort study (n=94 patients) reporting an improvement in quality of life following surgical repair of rectus diastasis. The reapplication proposes wording of the MBS item descriptor to limit abdominoplasty to women whose symptoms are refractory to physical therapy.	*Not satisfactorily resolved. The ADAR has appropriately considered surgery as an additional option after failed conservative treatment rather than a direct comparator to conservative treatment. The ADAR has argued that based on this comparison, single arm studies with 'before and after' results are appropriate evidence. This is low level evidence at high risk of bias.* *The additional studies do demonstrate clinically and statistically significant improvements in quality of life and urinary incontinence; however, the lack of an external comparator, reliance on patient-reported outcomes and applicability concerns reduce confidence in the findings.* *The proposed MBS item descriptor does not limit abdominoplasty to women whose symptoms are refractory to physical therapy.*

No.	Issue for MSAC	How addressed in reapplication	Assessment Group comments
1.a	A number of issues with the two studies (Emanuelsson 2016; Taylor 2018) on which this submission was based.	The two studies remain key evidence in the reapplication and are not represented or analysed differently. They are supplemented with the new evidence noted above.	*The issues identified by MSAC hold for these two studies.*
1.b	It was noted that the Taylor study had outcomes of back pain-related disability and urinary incontinence. MSAC considered this problematic as it is unclear that rectus diastasis actually causes either of these symptoms, even though this seems to be a commonly held belief. MSAC noted there are many types of urinary incontinence, each requiring a specific diagnosis. Some of which (e.g. detrusor instability) are treated with medical therapy and would not be ameliorated by repair of the anterior abdominal wall. MSAC noted two papers (Bø, 2017; Sperstad, 2016) that both report on a study of 300 consecutive women with first pregnancy, followed until 12 months postpartum, which showed no difference in either symptom by the presence or absence of RD.	The reapplication (pp.30-32) includes a narrative review of the signs and symptoms of abdominal rectus diastasis. The narrative review claims, "The presence of abdominal rectus diastasis is reasonably considered causative of symptoms of pain local to the diastasis and functional impairment. In contrast, the association with symptoms such as low back pain and urinary incontinence is more complex and the literature on this matter is heterogeneous." According to the ADAR (pp.31-32), "The ASPS acknowledges that the presence of abdominal rectus diastasis will not result in persistent low back pain or urinary incontinence in <u>all</u> patients. Nonetheless, these symptoms are widely acknowledged as potential sequalae of the presence of abdominal rectus diastasis. On this basis the potential for reducing low back pain and urinary incontinence is considered relevant as part of the assessment of treatments for abdominal rectus diastasis."	*Not satisfactorily resolved.* *The ADAR refers to a systematic review by Benjamin (2019),which concluded "There was no significant association between the presence of DRAM and lumbo-pelvic pain or incontinence. There was a small association between the presence of DRAM and pelvic organ prolapse. DRAM width may be associated with HRQoL, abdominal muscle strength and severity of low back pain. Quality of studies was weak. There was variability in the methods used to assess DRAM."* *The association with HRQoL is based on the key trial Emanuelsson (2016).*
2	<u>Economic evaluation:</u> It was noted that the ICER is in the range typically considered to be acceptable at $40 000 per quality-adjusted life year, and there is a modest financial impact of $1.4 million per year. These are conditional on the procedure not being used in women who want it for cosmetic purposes (noting that this was the reason the item was removed from the MBS). However, since the clinical evidence is uncertain, the cost-effectiveness is also uncertain.	The Applicant claims that the additional clinical evidence provided reduces uncertainty in the assessment of cost-effectiveness. Also, updated inputs that better reflect the requested funding arrangement for abdominoplasty and the natural history of disease have been applied in the economic evaluation.	*Not resolved. The additional clinical evidence is at high risk of bias and does not reduce uncertainty in the clinical claim of superior clinical effectiveness compared with standard care. Regardless, the additional evidence is not used in the economic model.* *The structure of the economic model does not reflect the revised comparison presented in the ADAR.*

Source: Table constructed for the commentary, based on the PSD for Application 1546 and the ADAR, with commentary additions in italics [Table 14, pp27-28 of the commentary
ADAR = Applicant Developed Assessment Report; ASPS = Australian Society of Plastic Surgeons; DRAM = diastasis of the rectus abdominis muscle; HRQoL= health-related quality of life; ICER = incremental cost-effectiveness ratio; MBS = Medicare Benefits Schedule; MSAC = Medical Services Advisory Committee; PSD = Public Summary Document; RD = rectus diastasis

5. Prerequisites to implementation of any funding advice

This was unchanged from the previous submission; refer to the PSD Application 1546, November 2019.

6. Proposal for public funding

The MBS item descriptor proposed in the ADAR is summarised in Table 2. The applicant-proposed amendments to the item descriptor provided in the ADAR are marked up in red; and amendments to the item descriptor (with accompanying Explanatory Note) provided in the pre-ESC response and pre-MSAC response is marked up in blue and purple, respectively.

Table 2 Applicant-proposed MBS item descriptor: ADAR changes with the previous DCAR marked up in red; Pre-ESC response changes marked up in blue; Pre-MSAC response changes marked up in purple

Category 3017X – Category 3 – Therapeutic Procedures
Group T8 – surgical operations Subgroup 1 – general ~~Lipectomy,~~ Radical abdominoplasty ~~(Pitanguy type or similar)~~, with repair of rectus diastasis excision of skin and subcutaneous tissue, ~~repair of musculoaponeurotic layer~~ and transposition of umbilicus, not being a laparascopic procedure, not being a service associated with a service to which item 30165, 30403, 30405, 30168, 30171, 30172, 30176, 30177, 30179, 45530, 45564 or 45565 applies, and where it can be demonstrated, by measurement with Vernier calipers at a specialist consultation or with diagnostic ~~preprocedure~~ imaging, that the patient has an abdominal wall defect as a consequence of pregnancy and must: a) not be receiving this service (once per lifetime) within 12 months after the end of a pregnancy; b) have a diastasis of at least 3cm (measured by ~~appropriate~~ Vernier callipers or diagnostic imaging); and c) have documented ~~functional~~ symptoms (in the case notes) of pain or discomfort at the site of the diastasis in the abdominal wall during functional use and/or low~~er~~ back pain~~, combined with daily pain or discomfort at the site of the diastasis in the abdominal wall during functional use;~~ and d) have failed to respond to conservative treatment (non-surgical) (H) Multiple Operation Rule (Anaes.) (Assist.) See para TN.8.X of explanatory notes to this Category)
Fee: $1,025.60 Benefit: 75% = $769.20

Source: Compiled from ADAR Table 5 (p.39) and Pre-ESC response Table 1 (p5)

Proposed Explanatory Note Wording
In the context of eligibility for item XXXXX, acceptable examples of conservative non-surgical treatment include symptomatic management with pain medication, lower back braces, lifestyle changes, physiotherapy and/or exercise.

In the 1546 PSD, MSAC noted that the item was removed because of concerns of use in women who wanted the procedure for cosmetic reasons. The commentary stated that MSAC may wish to consider the following as they relate to this concern:

- Consider whether the excision of skin and subcutaneous tissue is required (the clinical evidence included in Section B relates to surgical repair of rectus diastasis, but not all procedures involved radical abdominoplasty, refer to Section B.4 Table 27 and Section C Table 45). MSAC may wish to consider whether the proposed descriptor should have no emphasis on the removal of skin and fat. Rather than retaining the phrase 'radical abdominoplasty (Pitanguy type or similar), with excision of skin and subcutaneous tissue,' the descriptor could focus solely on repair of the musculoaponeurotic layer
- Consider whether the use of Vernier calipers is appropriate. PASC advised that a requirement for pre-procedure imaging may help restrict use of the item for medical rather than cosmetic use. The use of Vernier calipers is justified based on a single study of 50 women which compared measurements made using calipers with those of ultrasound. It is claimed this will reduce MBS costs associated with ultrasound procedures (MBS item 55812, Fee $110.75)
- The proposed item descriptor stipulates that the service must not be received within 12 months after the end of a pregnancy. MSAC may wish to consider whether the exclusion period should be extended to 2 years [as per Swedish National Guidelines; Carlstedt et al. (2020)[1]]

[1] Carlstedt, A., Bringman, S., Egberth, M., Emanuelsson, P., Olsson, A., Petersson, U., Pålstedt, J., Sandblom, G., Sjödahl, R., & Stark, B. (2020). Management of Diastasis of the Rectus Abdominis Muscles: Recommendations for Swedish National Guidelines. Scandinavian Journal of Surgery, 1457496920961000.

- The proposed item descriptor does not stipulate that patient must have failed conservative treatment. This omission may result in surgery being used first-line or after an insufficient trial of conservative management
- The proposed fee is the same as existing items for the same procedure in different populations (MBS items 30176 and 30177). The Applicant has provided no information to justify the comparability of these procedures in terms of time and complexity. Given the key focus of this operation post-pregnancy is the repair of the musculoaponeurotic layer, there maybe differences in time and complexity compared to other populations
- MSAC may wish to consider whether the description of symptoms is sufficiently useful in the proposed MBS item. There is no stated duration, frequency or level of severity for functional impairments, abdominal or back pain.

In the pre-ESC response, the applicant proposed a further amendment to the item descriptor (with accompanying Explanatory Note) specifying that a patient must have failed conservative treatment (see Table 1 above).

7. Summary of public consultation feedback/consumer Issues

Consultation feedback on the resubmission was received from two individual specialists who perform the surgery and supported the service. One of the specialists declared they are a representative for the applicant. The feedback reiterated the benefits to patients in improved core strength and reduction of back pain following this surgery. A view was also expressed that having this service MBS-listed would constitute gendered fairness as a male that suffers a rectus divarication as a result of obesity is able to have it repaired as a ventral hernia. Access to wider employment opportunities for patients following this surgery was also raised. A letter from General Surgeons Australia (GSA) not provided in time for the consideration of MSAC Application 1546 also supported the service.

Consultation feedback was received from (41) individual consumers and (2) medical professionals for consideration of MSAC Application 1546. The National Association of Specialist Obstetricians & Gynaecologists was the only organisation to provide feedback at the time and showed its support for the application. One plastic surgeon, a representative for the applicant, also expressed support.

The consumers that provided feedback were all women who had either experienced positive outcomes from the surgery or who wanted to access the surgery through public funding. They described improvements in quality of life after the procedure and cited cost as a major barrier to accessing the service. Consumers considered some of the main benefits of the proposed medical service include;

- Improved mental health,
- Improvement in physical mobility in exercise and everyday activities,
- Reduction in lower back pain and abdominal sensitivity,
- Reduction or ceasing in the need for pharmacological pain relief.

There was significant media attention following the removal of abdominoplasty for post-partum women from the MBS and petitions by consumers have been presented to the House of Representatives to advocate for the re-listing of the item.

The applicant sought consumer and health practitioner input through a document survey and an online survey. The input was considered by MSAC as part of the application. The

applicant considered that the consumer input captured the experiences of women who had the procedure when it was subsidised, and practitioners who have performed the procedure as a subsidised intervention and as a private intervention. There were 1,419 responses including more than 1,000 responses from consumers (see table below).

Consistent with the consultation feedback for Application 1546, consumers reported improvements in quality of life and symptoms such as improvements in daily functioning and core strength, and reduction in back pain and incontinence.

Consultation input provided by the applicant

Respondent identified as	Number of responses[a]
Consumer/patient	1,174
ASPS Member (Specialist Plastic Surgeons)	21
General Practitioner	61
Specialist other than plastics and other medical professional	71
Physiotherapist or Allied Health	35
Nurse/Midwife	20
Caregiver	9
Other	29
Total respondents	**1,419**

Source: Applicant correspondence

[a] ASPS received responses in the form of both document surveys (n=31) and online survey (n=1,386). Respondents were able to select more than one identity in the online survey. Where a respondent ticked 'Patient/Consumer' as well as another identity, such as 'Other - Specialist', the applicant counted that response as a 'Specialist' rather than consumer.

8. Proposed intervention's place in clinical management

Description of proposed intervention

The medical service proposed by the applicant is the surgical repair of the abdominal wall defect by closing the distance between the rectus muscles. The repair would involve suturing the musculoaponeurotic layer of the abdominal wall and include the associated excision of redundant skin and fat and transposition of the umbilicus (radical abdominoplasty).

A radical abdominoplasty is an additional technique to remove excess skin and fat which may or may not be undertaken in surgical repair of diastasis rectus. A systematic review of treatment options for rectus diastasis excluded radical abdominoplasty (Mommers, 2017[2]). It presented a range of surgical techniques classified by the authors as plication techniques, modified hernia repair techniques and combined hernia and rectus diastasis techniques. There are a variety of options for the surgical repair of the rectus diastasis:

- can be conducted using an open (midline or transverse) or laparoscopic technique
- reinforcement of the linea alba can be undertaken using sutures alone (resorbable or non-resorbable, interrupted or continuous) or with mesh
- repair of the diastasis can be combined with abdominoplasty or not.

Description of medical condition(s)

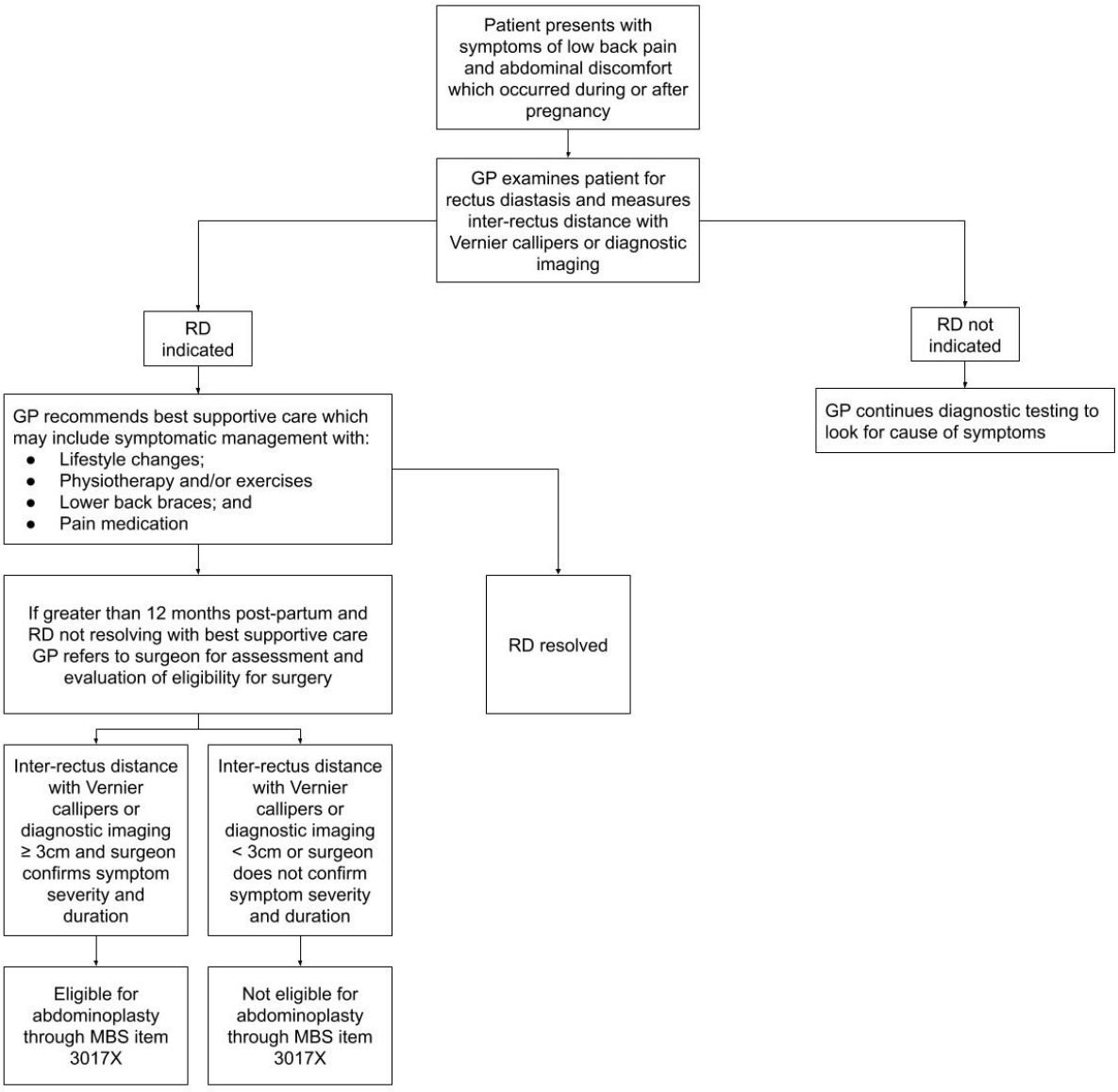
The ADAR stated that no changes to the population considered in the previous DCAR assessed by MSAC in November 2019 are proposed, that is postpartum women with

[2] Mommers, EH, Ponten, JE, et al. (2017). "The general surgeon's perspective of rectus diastasis. A systematic review of treatment options." Surgical endoscopy 31(12): 4934-4949.

abdominal rectus diastasis and unresolved symptoms at least 12 months after pregnancy would be eligible to have abdominoplasty funded through the MBS.

The resubmission provided an updated clinical management algorithm seeking to show the proposed place of abdominoplasty as a treatment option in women whose abdominal rectus diastasis has not resolved following conservative management with a physiotherapy/exercise program with or without adjunctive supportive care measures (Figure 1). The commentary considered the clinical management algorithm is appropriate to the population and comparators specified, noting that there are no MBS-funded treatment options for patients with pregnancy-acquired rectus diastasis.

Figure 1 Available treatment options for patients with postpartum rectus diastasis if funded through the MBS as proposed



Source: Figure ES1, p13 of the resubmission
Abbreviation: GP = general practitioner; MBS = Medicare benefits Schedule; RD=rectus diastasis

9. Comparator

The comparator outlined in the PICO Confirmation was best supportive care, which may include symptomatic management with pain medication, lower back braces, lifestyle changes,

physiotherapy and/or exercise (noting that patients have already failed to respond to conservative treatment including physiotherapy and/or exercise).

Due to the lack of recognised options to treat the underlying abdominal rectus diastasis in women whose symptoms are refractory to first-line physiotherapy/exercise program, the resubmission considers that 'no treatment' is a more appropriate comparator. The commentary considered this change to be appropriate; however, it would be clearer to describe the comparator as 'ongoing conservative treatment' and describe the intervention as 'conservative treatment plus abdominoplasty.' The commentary stated that this change is nor reflected consistently in the ADAR.

10. Comparative safety

A summary of the evidence used in the resubmission is provided in Table 3.

The applicant stated that the three additional studies provide pre-post data and therefore are interrupted time series ('before and after') without a parallel control group (National Health and Medical Research Council (NHMRC) Level III-3). The commentary considered that as the additional studies do not account for trend (changes) over time and perform simple statistical analysis of pre versus post intervention outcomes, they are more appropriately classified as non-comparative case series (NHMRC Level IV). The commentary noted that case series are at high risk of bias due to the limitations of the study design regardless of the methodological quality of the studies themselves.

The commentary considered that of the three additional studies presented in the ADAR, Olsson (2019) is the only prospective study and the most applicable due to patients having failed conservative therapy.

Table 3 Key features of the included evidence

Study ID *Risk of bias*	Design/ duration	Patient population	Intervention	Key outcomes	Results used in economic model
Emanuelsson trial[3] *High*	OL RCT Follow-up: 12 months for surgical groups (mesh and Quill) and 3 months for exercise group Long-term follow-up median 5-years for surgical groups.	Predominately postpartum women (98%) with an of RD ≥ 3 cm and experienced abdominal wall discomfort N=86	1. Radical abdominoplasty with complete plication of the rectus with retromuscular polypropylene 2. Radical abdominoplasty with double-layer plication of the rectus with Quill suture. 3. Thrice weekly specialised exercise program to strengthen the rectus, oblique and transverse abdominal muscles.	Presurgical and postsurgical measures for: pain (VPHQ); HRQoL (SF-36); self-rated changes in abdominal strength (VAS); objective improvement in abdominal strength (Biodex System- 4), AEs and reoccurrence	Yes

[3] Emanuelsson, P, Gunnarsson, U, et al. (2016). "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." Surgery 160(5): 1367-1375.
Emanuelsson, P, Gunnarsson, U, et al. (2014). "Early complications, pain, and quality of life after reconstructive surgery for abdominal rectus muscle diastasis: a 3-month follow-up." Journal of plastic, reconstructive & aesthetic surgery 67(8): 1082-1088.
Swedenhammar, E, Strigard, K, et al. (2020). "Long-term follow-up after surgical repair of abdominal rectus diastasis: a prospective randomized study." Scandinavian journal of surgery : SJS : official organ for the Finnish Surgical Society and the Scandinavian Surgical Society: 1457496920913677.

Study ID *Risk of bias*	Design/ duration	Patient population	Intervention	Key outcomes	Results used in economic model
Taylor (2018) study[4] (Australian cohort) *High to serious*	Prospective case series Follow-up: 6 months	All postpartum women who underwent abdominoplasty in Australia between 2014 and 2016 N=214	Abdominoplasty with various methods	Presurgical and postsurgical measures: UI (ICIQ); and back pain (ODI)	Not used
Olsson (2019) study[5] *High*	Prospective case series Follow-up: 12 months	Postpartum women with an RD of ≥ 3 cm and trunk instability symptoms persisting after more than 3 months of trunk training program and more than 1 year from last delivery N=60	Suture repair of the diastasis with double-layer plication of the rectus with Quill suture using one of: A. midline incision B. low transverse incision, including limited resection of excessive skin and a floating umbilicus; C. abdominoplasty, including resection of excessive skin and umbilical transposition	Presurgical and postsurgical measures: abdominal trunk function (ATFP); HRQoL (SF-36); UI (IIQ-7); UDI-6; and post-operative complication and recurrence rates	Not used
Carrara (2020) study[6] *High*	Prospective case series Follow-up: up to 24 months	Predominately postpartum women (93%) with presence of at least one primary midline defect with a diameter ≥ 10 mm associated with RD ≥ 3 cm and more than 1 year from last delivery N=110	Endo-laparoscopic reconstruction of abdominal wall with linear staplers	Presurgical and postsurgical measures: HRQoL (EuraHSQoL); UI (ISI score); back pain (ODI); and post-operative complication and recurrence rates	Not used
Fiori (2020) study[7] *High*	Retrospective case series retrospective Follow-up: up to 24 months	Predominately postpartum women (98%) with an of RD ≥ 5 cm associated or not with primary umbilical or midline hernia N=94	Open surgery (laparoabdominoplasty or laparominiabdominoplasty), or Totally endoscopic sublay anterior repair	Presurgical and postsurgical measures: HRQoL (EuraHSQoL); and post-operative complication	Not used

Source: Compiled for the commentary, based on ADAR Table 9 (pp.46-47) [Table 25, pp45-46 of the commentary]
AE = adverse events; ATFP = Abdominal Trunk Function Protocol; HRQoL = health-related quality of life; ICIQ = International Consultation on Incontinence Questionnaire; IIQ-7 = Incontinence Impact Questionnaire; ISI = Incontinence Severity Index; ODI = Oswestry Disability Index; OL = open label; RCT = randomised control trial; RD = rectus diastasis; SF-36 = 36-item Short Form health survey; VHPQ = Ventral Hernia Pain Questionnaire; VAS = visual analogue scale; UI = urinary incontinence.

The resubmission did not present a comparison of abdominoplasty safety versus physiotherapy on the basis that there is insufficient data reported to support a meaningful comparison of safety and that patients considered for abdominoplasty would have unresolved abdominal rectus diastasis following conservative management, which may include a physiotherapy program.

[4] Taylor, DA, Merten, SL, et al. (2018). "Abdominoplasty improves low back pain and urinary incontinence." Plastic and reconstructive surgery 141(3): 637-645.
[5] Olsson, A, Kiwanuka, O, et al. (2019). "Cohort study of the effect of surgical repair of symptomatic diastasis recti abdominis on abdominal trunk function and quality of life." BJS Open 3(6): 750-758.
[6] Carrara, A, Catarci, M, et al. (2020). "Prospective observational study of abdominal wall reconstruction with THT technique in primary midline defects with diastasis recti: clinical and functional outcomes in 110 consecutive patients." Surgical Endoscopy.
[7] Fiori, F, Ferrara, F, et al. (2020). "Surgical treatment of diastasis recti: the importance of an overall view of the problem." Hernia: 1-12.

The commentary considered this was appropriate and in agreement with the revised PICO. The appropriate consideration for safety is the additional risk of surgery rather than a comparison with conservative treatment.

The commentary also noted that adverse events were inconsistently reported and the interventions varied across and within studies.

The resubmission's additional evidence reports a much lower rate of wound infections associated with surgery (3-4%) compared with the rate of 25% reported in the Emanuelsson trial (18% for infection requiring antibiotics.) Reoperation rates of 9% in the Emanuelsson trial for haematoma and 7% in the Olsson study for seroma were reported. No recurrences were reported in the additional studies (Table 4).

Table 4 Summary of safety outcomes reported in the included evidence

Adverse event	DCAR	ADAR resubmission	
	Emanuelsson trial N = 57	Olsson (2019) N = 60	Carrara (2020) N=110
Any wound infection	14 / 57 (25%)	2 / 60 (3%)	4 / 100 (4%)
Any seroma	9 / 57 (16%)	4 / 60 (7%)	1 (0.9%)
Haematoma	2 / 57 (4%)	5 / 60 (8%)	5 (5%)
Recurrence rectus diastasis	1/57 (2%) at 1-year 0/52 (0%) at 5-years	0/60 (0%) at 1 year	0/110 (0%) at 2 years

Source: Table ES.3, p16 of the ADAR resubmission

11. Comparative effectiveness

Health related quality of life

The mean change from baseline in SF-36 scores at 12 months' follow-up is presented in Table 5 for the two studies that reported this outcome. A positive mean difference relates to an improvement in health-related quality of life (HRQoL). The baseline and follow-up scores are compared with Australian normative values.

Patients experienced statistically significant improvements across the domains of the SF-36 at 12 months' follow-up. These changes were above the proposed clinically important threshold of eight points for the following domains in both studies: Role – physical, Bodily pain, Vitality and Social functioning.

The commentary considered that although there are clinically relevant differences from baseline to follow-up in the two studies, these should be interpreted with caution as there is no external comparator, and they are patient-reported outcomes.

Table 5 Comparison of SF-36 scores reported in Olsson 2019 study with Australian normative values

SF-36 domains	Emanuelsson			Olsson (2019)			Australian normative value[a]
	Baseline Mean (SD)	12-month follow-up Mean (SD)	Mean change from baseline (95% CI)	Baseline Mean (SD)	12-month follow-up Mean (SD)	Mean change from baseline (95% CI)	Mean (SD)
Physical Function	83.30 (17.06)	93.57 (14.23)	**10.38 (6.64;14.11)** *	70.5 (19.2)	93.7 (9.5)	**23.2** ***(17.7;28.7)*** *	81.8 (24.1)
Role – Physical	69.09 (38.18)	90.63 (26.78)	**21.80 (12.29;31.32)** *	49.2 (39.9)	90.7 (23.4)	**41.5** ***(29.7;53.4)*** *	80.7 (27.1)
Bodily Pain	66.50 (23.84)	82.09 (22.26)	**15.76 (10.34;21.18)** *	49.5 (24.7)	87.6 (17.8)	**38.1** ***(30.3;45.9)*** *	73.1 (22.2)
General Health	71.50 (20.92)	80.70 (21.23)	**9.58 (4.86;14.29)** *	66.2 (19.8)	78.2 (18.9)	**12.0** ***(5.0;19.0)*** *	69.6 (22.9)
Vitality	50.36 (22.92)	66.25 (21.43)	**15.90 (9.31;22.49)** *	38.9 (23.6)	64.9 (22.7)	**26.0** ***(17.6;34.4)*** *	57.2 (21.8)
Social Functioning	71.21 (30.24)	88.39 (29.60)	**17.26 (8.69;25.82)** *	71.9 (25.8)	88.6 (20.0)	**16.7** ***(8.35;25.0)*** *	82.9 (24.2)
Role– Emotional	73.81 (36.36)	86.90 (20.35)	**13.18 (3.43;22.94)** *	59.3 (42.5)	83.0 (32.6)	**23.7** ***(10.0;37.4)*** *	88.5 (20.6)
Mental Health	71.29 (18.34)	77.07 (8.73)	**5.74 (0.35;11.12)**	65.0 (17.6)	77.5 (16.2)	**12.5** ***(6.4;18.6)*** *	77.4 (18.3)
PCS	47.88 (11.71)	55.12 (12.88)	**7.31 (4.49;10.13)**	NR	NR	NR	NR
MCS	42.06 (13.96)	47.08 (0.122)	**5.44 (1.13;9.76)**	NR	NR	NR	NR

Source: Adapted from ADAR Table 19 (p.67) and DCAR Table Att.F83 (p.117). Australian normative value: (Marin 2009); Olsson trial: Table S1 (p. 8) of Supplement to (Olsson et al. 2019) [Table 4, pxv of the commentary]

CI = confidence interval; MCS = mental components summary score; NR = not reported; PCS = physical components summary score; SD = standard deviation; SF-36 = 36-item Short Form health survey

Bold = statistically significant at P-value<0.05; * clinically meaningful change based on MCID threshold of 8

[a] *Note these Australian normative values are population norms rather than normative values specific to women with a similar age range*

Abdominal wall muscle strength

The Disability Rating Index (DRI) is a measure of overall physical disability and is not specific to abdominal wall muscle strength. It was used to measure patient-reported abdominal wall muscle strength in the Olsson (2019) study (Table 6).

Table 6 Disability Rating Index results at baseline and 1-year post-surgery reported in Olsson (2019) study

	At baseline (N = 60)	At 1 year post surgery (N = ~~60~~ *56*)	P-value
Specific DRI (0–100 points), median (range)			
Dressing	1 (0·0–7·0)	0 (0·0–1·0)	0·006
Outdoor walks	4 (0·0–9·5)	0 (0·0–4·4)	< 0·001
Climbing stairs	3 (0·0–9·4)	0 (0·0–4·4)	< 0·001
Sitting for a longer period	28 (0·0–9·6)	0 (0·0–5·2)	< 0·001
Standing bent over a sink	41 (0·0–10·0)	0 (0·0–5·3)	< 0·001
Carrying a bag	29 (0·0–8·3)	1 (0·0–4·9)	< 0·001
Making the bed	13 (0·0–8·4)	0 (0·0–4·5)	< 0·001
Running	49 (0·0–10·0)	1 (0·0–9·6)	< 0·001
Light work	21 (0·0–10·0)	0 (0·0–5·0)	< 0·001
Heavy work	64 (0·0–10·0)	5 (0·0–9·8)	< 0·001
Lifting heavy objects	63 (0·1–10·0)	9 (0·0–9·8)	< 0·001
Exercise/sports	54 (0·1–10·0)	5 (0·0–9·4)	< 0·001
Total DRI score (0–120 points*), mean (SD) (as reported in Olsson (2019))	386 (247)	82 (118)	< 0·001
Total DRI score as calculated in commentary (0-100 scale)	*32.2*	*6.8*	

Source: ADAR Table 22 (p.71) with commentary additions in italics [Table 5, pxvi of the commentary]
DRI = Disability Rating Index; SD = standard deviation
* as reported, should read 0-1,200 points

Statistically significant changes in DRI were reported and these are greater than proposed minimal clinically important difference (MCID) values; however, the commentary considered that the findings should be considered cautiously as there is no external comparator and it is a patient-reported outcome.

Physiological tests by a physiotherapist were also conducted in the Olsson (2019) study. A majority of patients (38 of 50, 76%) had significantly better performance and stamina at follow-up than before surgery based on the physiological tests. The commentary stated this was the only non-patient reported outcome reported in the ADAR, although may still be at risk of bias as the physiotherapist was not blinded and the study was non-comparative.

Back pain

Change in back pain measured with the Oswestry Disability Index (ODI) is presented in Table 7. The ODI ranges from 0 to 100% with a change of 9.5 considered clinically significant. The ADAR proposed that a post-operative reduction in baseline ODI of 35% is a suitable MCID for ODI.

Table 7 Change in Oswestry Disability Index score for back pain from baseline

Study ID	N	Mean (SD) at baseline	Mean (SD) at 4-6-week follow-up	Mean (SD) at 6-month follow-up	Mean Difference (6-month to baseline) (95% CI)	Reduction in baseline ODI (%)
Taylor (2018) study (Australian cohort)	214	10.9 (7.31)	3.97 (5.65)	1.58 (3.49)	**-9.32 (-10.40; -8.24)**	85.5%
Carrara (2020)	~~110~~ *75*	11.5 (4.4)	4.3 (5.4)	2.6 (3.1)	**-8.9 (-9.91; -7.89) P <0.001[a]**	77.4%

Source: Modified from Table 23 (p.72) of ADAR, with commentary amendment in italics. [Table 6, pxvii of the commentary]
CI = confidence interval; ODI = Oswestry Disability Index; SD = standard deviation
Bold = statistically significant change from baseline (P < 0.05)
a Calculated by Applicant during the preparation of the ADAR

In the two studies reporting this outcome (Carrara, 2020; Taylor, 2018), there was a statistically significant change at 6 months compared with baseline. However, in both studies the baseline value was very low (<20%, indicating minimal disability) and the change did not reach clinical significance.

The commentary considered that the ODI scores in the two studies also raise applicability concerns as these patients had mild back pain for which no treatment is indicated and therefore may not be eligible for the proposed MBS item, although no threshold is explicitly specified.

An alternative analysis of the ODI was presented in Taylor (2018) in which the number of patients in each category of disability at baseline and at 6 months post-surgery is reported (Table 8).

Table 8 Oswestry Disability Index categories at baseline and 6-month follow-up reported in Taylor (2018) study

Oswestry Disability Index scoring categories	Disability	No. of patients Baseline	No. of patients 6-month follow-up
0-20%	Mild	105	206
21-40%	Moderate	89	7
41-60%	Severe	17	0
61-80%	Crippled	3	1
81-100%	-	0	0

Source: Taylor (2018) Table 7. Note that the Table is incorrectly titled "Incontinence scores" in the publication. [Table 7, pxvii of the commentary]

The commentary considered that patients with moderate to severe back pain demonstrated a high response rate at 6 months post-surgery. These patients are more likely to meet the intent of the proposed population; however, the results should be interpreted with caution as there was no external comparator and the outcome is patient reported.

Urinary incontinence
Three studies reported urinary incontinence symptoms (Carrara, 2020; Olsson, 2019; Taylor, 2018). The Olsson (2019) study did not report mean difference and is excluded from Table 9 but discussed in the body of the report. The tools used to assess urinary incontinence differed across the studies.

Table 9 Assessment of reduction in urinary incontinence symptoms

	Study ID	Instrument used	Mean (SD) at baseline	Mean (SD) at follow-up	Mean Difference (95% CI)	*MCID*
Presented in DCAR						
At 6 weeks postsurgery	Taylor (2018)	ICQI-UI-SF	6.22 (5.36)	1.63 (2.87)	**-4.59 (-5.40; -3.78)**	*5*
At 6 months postsurgery			6.22 (5.36)	1.60 (2.92)	**-4.62 (-5.43; -3.81)**	*5*
Additional evidence in ADAR						
At 1 month postsurgery	Carrara (2020)	ISI	3.6 (3.0)	0.9 (1.5)	**-2.7 (-3.33; -2.07) P <0.0001**	*Change in severity*
At 6 months postsurgery			3.6 (3.0)	0.7 (1.5)	**-2.7 (-3.53; -2.27) P <0.0001**	*Change in severity*

Source: ADAR Table 25 (p.74) with commentary additions in italics [Table 8, pxviii of the commentary]

CI = confidence interval; ICQI-UI-SF = International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form; ISI = Incontinence Severity Index; MCID = minimal clinically important difference; SD = standard deviation
Bold = statistically significant change from baseline (P < 0.05)

The ICQU-UI-SF has a maximum score of 21 with a value of ≥6 representing symptomatic urinary incontinence. The ISI has a range of 0-12 where scores of 1-2 are classified as 'slight,' 3-6 as 'moderate,' 8-9 as 'severe' and 12 as 'very severe' (Barber, 2009)[8].

The mean score at baseline in the Taylor (2018) study was 6.22, which is just above the value of ≥6 representing symptomatic urinary incontinence (Skorupska, 2021[9]). In an alternative analysis, the study used a cut point of ≥5 to specify 'urinary incontinence of significant concern.' Of the 214 included patients, 59 had no incontinence preoperatively (presumably a value of 0). Of the 166 who did report incontinence, 66 scored over five on the ICQI-UI-SF preoperatively. At 6 months' follow-up, four patients scored over five.

The commentary stated that of the total number of patients in the Taylor (2018) study, 31% met the study-defined threshold for urinary incontinence. Of these patients, there was a high response rate with only four patients (1.9% of the total study population) meeting this threshold at 6 months' follow-up. This suggests that although the mean change in ICQU-UI-SF score did not reach clinical significance, for those patients with urinary incontinence there were clinically significant changes observed.

The commentary noted in the Carrara (2020) study, baseline scores using the incontinence severity (ISI) appear to reflect a higher burden of urinary incontinence than the other studies, with the mean score of 3.6 corresponding to 'moderate' urinary incontinence. The mean change does span a change in category from 'moderate' to 'slight/none' and therefore likely reflects both a statistically and clinically significant effect. No data were reported to estimate patient response rates or number of patients who had a clinically significant response. This

[8] Barber, M. D., Spino, C., Janz, N. K., Brubaker, L., Nygaard, I., Nager, C. W., Wheeler, T. L., & Network, P. F. D. (2009). The minimum important differences for the urinary scales of the Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire. American journal of obstetrics and gynecology, 200(5), 580. e581-580. e587.

[9] Skorupska, K., Grzybowska, M. E., Kubik-Komar, A., Rechberger, T., & Miotla, P. (2021). Identification of the Urogenital Distress Inventory-6 and the Incontinence Impact Questionnaire-7 cutoff scores in urinary incontinent women. Health and quality of life outcomes, 19(1), 1-6.

study is the least applicable as the procedure was endo-laparoscopic reconstruction using staplers.

Clinical claim
On the basis of the benefits and harms reported in the evidence base, the ADAR proposes that, relative to conservative treatment alone, abdominoplasty following failed conservative treatment has inferior safety and superior effectiveness.

The commentary considered that the clinical claim of superior effectiveness is reasonable; however, the magnitude of the benefit remains uncertain due to the same factors outlined in the previous DCAR:

- All studies have high to serious risk of bias and the outcomes reported in the ADAR are on the basis of a pre and post research design without a valid external control group
- The outcomes are almost exclusively patient-reported. While these are important for measuring the patient's experience of the treatment, they would ideally be supplemented with some objectively measured outcomes
- There is variability across the included studies with respect to the population and the intervention. Therefore, there are applicability concerns, which resulted in downgrading of GRADE outcomes. In particular:
    - Back pain was not an inclusion criteria in any study but is for the proposed MBS item. In the studies that reported baseline rates (Carrara, 2020; Taylor, 2018), there was a low burden of disability due to back pain despite high numbers of patients reporting back pain
    - There were a high number of patients with ventral hernias, particularly in the studies presented for the first time in the ADAR (Carrara, 2020; Olsson, 2019). There are existing MBS items for the repair of ventral hernias (MBS items 30403 and 30405) and umbilical or linea alba hernias (MBS item 30621). The PICO Confirmation does not discuss the applicability of abdominoplasty for patients with hernia or the eligibility of these patients for repair within existing MBS item numbers.
    - The intervention varied across studies and was rarely a radical abdominoplasty as described in the proposed MBS item descriptor.

As a surgical intervention compared to non-surgical care, the claim of inferior safety is appropriate. The magnitude of the surgical harms was variable across studies and may reflect the variability in the procedure; however, rates of complications in the Emanuelsson (2014) trial are high.

Overall, the commentary considered that the clinical claim of superior effectiveness and inferior safety is supported by the evidence base, albeit with a high level of uncertainty.

Translation issues
The translation issues are summarised in Table 10.

Table 10 Translation issues

Type	Issue	DCAR Comments	*Commentary*
Applicability	Generalisability of the evidence • Comparability of trial population vs MBS population - Baseline characteristics - Type of treatment patients received	In general, the population in the trial was comparable to the Australian population. The approach to the repair of the rectus abdominus may vary from Australian techniques.	*There are concerns regarding both the baseline characteristics of the patients and the treatment received.*
Extrapolation	Time horizon of the model	The time horizon in the model was considered conservative as the condition does not lead to a reduction in survival. The outcomes were assumed to stay constant for the duration of the model beyond 12 months.	*The time horizon has been extended in the ADAR. This is appropriate from the perspective of the condition being a chronic condition with benefits to treatment accruing over a lifetime; however, there is considerable uncertainty regarding the clinical inputs and extrapolation of these over the longer time horizon.*
Transformation	Utilities applied in the stepped economic evaluation Costing of different health states	The utilities were calculated directly from the trial utilities. Costs were based on local costs.	*These are unchanged in the ADAR.*

Source: Table 9, pxiii of the commentary
MBS = Medicare Benefits Schedule

12. Economic evaluation

The economic evaluation is summarised in Table 11.

Table 11 Summary of the economic evaluation

Perspective	Australian Health System
Comparator	Best supportive care *The ADAR argues that no treatment is the ideal comparator, not 'best supportive care,' as conservative treatment is assumed to have been trialled prior to offering surgery (ADAR p. 11).*
Type of economic evaluation	Cost-utility analysis
Sources of evidence	Emanuelsson trial (Emanuelsson et al. 2014, 2016; Swedenhammar et al. 2020)
Time horizon	20 years *Changed from 5 years in the DCAR.*
Outcomes	QALYs
Methods used to generate results	Cohort expected value analysis, Markov model
Health states	Abdominoplasty arm: State 1: Alive without recurrent rectus diastasis (i.e., successful surgery) State2: Alive with recurrent rectus diastasis (i.e., surgery failed ➔ patient receives best supportive care) State 3: Dead Best supportive care arm: State 1: Alive State 2: Dead
Cycle length	3 months, with half cycle correction
Discount rate	5% per annum (costs and outcomes)
Software packages used	Treeage Healthcare Pro

Source: Table 10, pxxi of the commentary

The commentary stated that the structure of the model is unchanged from the previous DCAR. The main changes relate to updated costs and to a longer time horizon of 20 years for the base case analysis.

The commentary considered that if conservative management is to be applied before offering surgery to postpartum women then the 'best supportive care' arm should more appropriately be labelled 'no treatment,' as physiotherapy-based exercise programs precede the decision to offer surgical management as an option. The model also assumes that patients with a surgical repair and no recurrence incur no ongoing conservative management costs.

The commentary considered that if both intervention and comparator groups undergo exercise-based programs prior to offering surgery, then the cost of this should be applied to both groups (in which case the marginal cost for this item would be $0), or to neither group (in which case the marginal cost for this item would also be $0).

The commentary also considered that if the costs of 'best supportive care' were removed from the model, the incremental cost and therefore the ICER would increase, relative to that presented in the ADAR.

The results of a stepped analysis of the base case economic evaluation are given in Table 12.

Table 12 Results of updated cost-utility analysis (NB: no recalculation from the ADAR values)

Step and component	Abdominoplasty	Best supportive care	Increment
Base case in DCAR			
Cost	$12 195	$311	$11 884
LYs	4.45	4.45	0
QALYs	2.95	2.66	0.30
Incremental cost per QALY gained			**$39 942**
Base case in ADAR			
5-year time horizon			
Cost	$9056	$2490	$6565
LYs	4.45	4.45	0
QALYs	2.95	2.66	0.30
Incremental cost per QALY gained			**$22 067**
20-year time horizon			
Cost	$9056	$2490	$6565
LYs	12.69	12.69	0
QALYs	8.55	7.60	0.94
Incremental cost per QALY gained			**$6 951**

Source: Base Case_ADAR.trex, ADAR Table 27.
ADAR = Applicant Developed Assessment Report; LY = life year; QALY = quality-adjusted life year

The commentary stated the modelled results were most sensitive to the time horizon.

13. Financial/budgetary impacts

The commentary noted that the MSAC did not, in the PSD, outline substantial issues with the financial estimates in the DCAR. However, the resubmission outlines that not all clinical criteria used to determine patient eligibility for MBS-funded abdominoplasty were included

in the previous DCAR, nor was the circumstances of use of MBS-funded abdominoplasty in broader clinical practice properly considered. Together, these factors are considered to have resulted in an overestimate of the number of patients eligible for treatment in the previous DCAR, which has flow-on consequences for the estimated financial implications.

The commentary considered that the ADAR's estimate of the number of services per year (567 in 2022 increasing to 656 in 2026) is unreasonable as it is lower than the historic uptake of abdominoplasty in postpartum women, which ranged from 967 to 1185 between 2010 and 2015. Therefore, the commentary did not present these in Table 12.

The commentary considered that the estimate from the previous DCAR which was based on this historic data was the more appropriate measure.

The financial implications to the MBS resulting from the proposed listing of abdominoplasty with surgical repair of rectus diastasis following pregnancy are summarised in Table 13.

Table 13 Total costs to the MBS associated with the proposed listing for abdominoplasty

-	2020	2021	2022	2023	2024	2025	2026
Abdominoplasty (DCAR)							
Number of services	1139	1161	1183	1203	1221	1238	1369
Sub-total cost	$867 978	$885 312	$901 605	$916 749	$930 694	$943 416	$1 043 841
Co-administered services (ADAR)							
Number of services	6376	6503	6623	6734	6837	6930	7668
Sub-total cost	$408 969	$417 136	$424 814	$431 949	$438 519	$444 514	$491 831
Total services	7514	7665	7806	7937	8057	8168	9037
Total cost	**$1 276 948**	**$1 302 448**	**$1 326 419**	**$1 348 698**	**$1 369 214**	**$1 387 929**	**$1 535 672**

Source: ADAR Table 29 and ADAR spreadsheet, updated to reflect commentary.

The commentary considered that the estimated potential net cost/year to the MBS is likely to be greater than estimated in the resubmission but similar to that estimated previously in the DCAR.

14. Key issues from ESC for MSAC

ESC key issue	ESC advice to MSAC
Efficacy of post-partum abdominoplasty	Abdominoplasty is superior to "no treatment" in terms of clinical efficacy. The new evidence presented in this resubmission reported improvements in all efficacy endpoints after abdominoplasty including improved health-related quality of life, abdominal strength, reduced back pain and urinary incontinence. While the clinical claim of superior effectiveness is reasonable, the magnitude of the benefit remains uncertain, as the studies all have risk of bias in design with no control group. However, a control group is difficult to achieve for this condition.
Safety of post-partum abdominoplasty	The safety profile for abdominoplasty is considered acceptable in consideration of the clinical benefit provided, and no worse than the safety of MBS-reimbursed abdominoplasty after significant weight loss or removal of an intra-abdominal or pelvic tumour.

MBS item descriptor	MSAC may want to consider a separate, new, item descriptor (3017X) if this procedure was recommended for funding.
Economic evaluation	The economic evaluation is generally unchanged from the previous submission, apart from updated costs and a longer timeframe. The model structure is still considered to be reasonable. If the clinical data can be considered reliable, the intervention appears to be cost-effective.
Cost implications and possible offsets	The number of predicted services per year is small, so there will be modest additional costs to the MBS.
Uptake	The revised estimates provided may be lower than actual uptake; the number of procedures in the previous submission may be more appropriate.

ESC Discussion
ESC noted that this is a resubmission and that the purpose is to reinstate Medicare Benefits Schedule (MBS) funding of abdominoplasty to treat rectus diastasis following pregnancy. ESC noted that this application was not supported by the MSAC in 2019 because of uncertainty on the magnitude of benefit as well as uncertainty regarding the incremental cost-effectiveness ratio (ICER).

ESC noted that there has been significant media attention and a petition to the House of Representatives because of the perceived unfairness in access to MBS rebates for post-partum women seeking public funding for abdominoplasty to treat rectus diastasis compared to those can access rebates for abdominoplasty following massive weight loss. ESC also noted that the applicant has collected a large volume of consultation survey data, including >1,000 responses from consumers, which it will submit to the July MSAC meeting for consideration.

A true abdominal hernia is characterized by having a fascial defect with protrusion of the abdominal viscera or omentum. ESC noted that divarication recti is not a true hernia as it is not associated with a fascial defect in the abdominal wall; it is not associated with bowel obstruction or strangulation. However, it is possible for a midline hernia (in the linea alba) to evolve following divarication of the recti. ESC noted that a midline open approach abdominoplasty (described by Pitanguy) to repair divarication would concomitantly repair a midline hernia if present.

ESC noted that the comparator proposed in the PICO confirmation was best supportive care, which may include symptomatic management with pain medication, lower back braces, lifestyle changes, physiotherapy and/or exercise. Physiotherapy and/or exercise are acknowledged by the applicant as representing the preferred first-line treatment option for post-partum women with abdominal rectus diastasis. However, non-physiotherapy/exercise program interventions such as pain medicines, lower back braces and lifestyle changes would be considered as part of the overall management of any patient with abdominal rectus diastasis and not as direct alternatives/comparators to physiotherapy/exercise programs or abdominoplasty, which have an intent to resolve the abdominal diastasis rectus. In consideration of the above, and the lack of recognised options to treat the underlying abdominal rectus diastasis in women whose symptoms are refractory to first-line physiotherapy/exercise program, the applicant considered “no treatment” to be a more appropriate comparator. ESC considered that this may be reasonable.

ESC noted that the previous submission included two studies: one randomised controlled trial [RCT] – the Emanuelsson (2014) trial; and one prospective case series– Taylor (2018). This resubmission included three additional studies: two prospective case series (Olsson 2019;

Carrara 2020) a retrospective case series (Fiori 2020); and the long-term follow-up of the surgical group from the Emanuelsson (2014) trial. ESC noted that of the three additional studies, Olsson (2019) study was the most applicable due to patient having were required to have failed conservative therapy.

Regarding surgical approaches, ESC noted that the two studies in the previous submission used open approach abdominoplasty, whereas in the three additional studies, one used open approach abdominoplasty, one used endo-laparoscopic midline reconstruction, and one used mixed open and endoscopic techniques. The proposed item descriptor refers to 'radical abdominoplasty (Pitanguy type or similar)", which ESC considered does not include a laparascopic approach, or mixed approach. ESC also noted that the procedure may include the removal of excess skin, but that this is not always necessary depending on the patient build.

In terms of safety, the additional two prospective case series reported lower rates of infection and seroma than what was reported in the Emanuelsson (2014) trial. Long-term follow-up (5 years) of the Emanuelsson (2014) trial did not identify any additional patients experiencing recurrence to the one patient previously reported, and no patients in the additional two studies were reported as experiencing recurrence. ESC also noted that the magnitude of the surgical harms was variable across studies and may reflect the variability in the procedure; however, rates of complications in the Emanuelsson (2014) trial are high. Given the invasive nature of the procedure and requirement for general anaesthesia, the safety of abdominoplasty is considered to be inferior to "no treatment".

The prospective case series presented in this resubmission reported improvements in all efficacy endpoints after abdominoplasty:

- Health-related quality of life (HRQoL): statistically and clinically significant improvements in all domains of the 36-item Short Form health survey (SF-36) instrument reasonably associated with morbidity resulting from unresolved abdominal rectus diastasis (Olsson 2019) and the Emanuelsson (2014) trial from the previous submission
- Abdominal strength: statistically and clinically significant improvements in self-reported abilities to perform daily activities in 98% of patients after receiving abdominoplasty (Olsson 2019)
- Back pain: statistically significant reductions in back pain assessed using the Oswestry Disability Index (ODI) at 6 months compared with baseline in Carrara (2020) and Taylor (2018) from the previous submission. However, the baseline value was very low (<20%, indicating minimal disability) and the change did not reach clinical significance
- Urinary incontinence: statistically significant reductions in urinary incontinence symptoms were reported postsurgery across all studies: the 6-item short form of Urinary Distress Inventory (UDI-6) and the Incontinence Impact Questionnaire (IIQ-7) in Olsson (2019); the Incontinence Symptom Index (ISI) in Carrara (2020) and International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form (ICQI-UI-SF) in Taylor (2018) from the previous submission. ESC noted the consistency in results using different instruments may support a conclusion that the reduction in urinary incontinence symptoms is reasonably attributable to surgical repair of the abdominal wall and not reporting errors of any given instrument or erroneous results from any given study.

ESC noted that, in the absence of an alternative treatment option for women at least 12 months post-partum with unresolved symptomatic abdominal rectus diastasis, abdominoplasty is superior to 'no treatment' in terms of clinical efficacy.

ESC considered that the clinical claim of superior effectiveness is reasonable; however, the magnitude of the benefit remains uncertain due to the same factors outlined in the previous submission:

- All studies have high to serious risk of bias, and the outcomes reported in the resubmission are based on a pre- and post-research design without a valid external control group
- The outcomes are almost exclusively patient-reported. While these are important for measuring the patient's experience of the treatment, they would ideally be supplemented with some objectively measured outcomes
- There is variability across the included studies with respect to the population (e.g. high proportion of patients with concurrent rectus diastasis and hernias) and the intervention.

ESC also considered that the safety profile for abdominoplasty may be acceptable in consideration of the clinical benefit provided and no worse than the safety of MBS-funded abdominoplasty after significant weight loss or removal of an intra-abdominal or pelvic tumour.

ESC noted that in the pre-ESC response, the applicant considered that the commentary overstated the risk of bias and that there is no evidence of systematic bias in the results presented in the resubmission.

ESC considered it to be appropriate to have a separate and alternative item descriptor to 30117X if the application is recommended for funding. ESC noted that the eligibility of the service is dependent on the rectus diastasis threshold ≥ 3cm and also that the patient is symptomatic (i.e. have lower back pain and abdominal discomfort during functional use). ESC also noted that the proposed MBS item descriptor does not include a criterion that a patient must have previously attempted conservative management. This additional condition could be written into the descriptor, which the applicant agreed to in the pre-ESC response. ESC considered that the duration of failure to conservative management should be specified, noting the related MBS item 30177 specifies a duration of 3 months for failed conventional (or non-surgical) treatment.

ESC noted that clarity is needed on which procedure is being approved. The descriptor only describes the open procedure. ESC noted that, if the item is broadened to include other procedures, then it could lead to misuse.

ESC noted that the fee increase requested by the applicant from $985.70 to $1016.45 is in line with items 30176 and 30172. ESC also noted that the use of callipers might reduce the cost of imaging.

ESC noted that there was very little difference between this item and the previous submission in terms of the economic analysis. The model is unchanged, but there was an increase in the timeframe, and the costs were updated. The utilities remained unchanged. However, ESC noted that the updated comparator is not reflected in the model.

ESC noted that the time horizon has been extended in this resubmission. This is appropriate from the perspective of the condition being a chronic condition with benefits to treatment accruing over a lifetime; however, there is considerable uncertainty regarding the clinical inputs and extrapolation of these over the longer time horizon.

ESC noted that the updated costs of surgery and adverse events were reasonable. The cost of best supportive care increased from $311 to $2,491, but ESC noted that this cost should now be considered pre-surgery, not the comparator. Overall, ESC considered that the true ICER would be in between the $39,942 reported in the previous submission and the $6,951 reported in the resubmission.

ESC noted that the previous submission estimated the number of services to be 1,183–1,369 per year, making the budget impact $1.46–1.69 million per year. The new submission made some changes that resulted in a reduction in number of surgeries to 567 to 656 over the 5 years and cost of $635,937 to $736,261, which is approximately half that of previous submission. However, ESC noted that the commentary suggested that the rate of surgery is uncertain and more likely to be closer to the previous submission. Updated estimates in the commentary indicate 1.28 to 1.54 million over 5 years (see Table 12).

ESC noted there is minimal bulk billing for this procedure and that substantial out-of-pocket costs will remain. ESC also noted the consumer issues related to the potential ongoing costs resulting from a loss of work and the extra help needed. There is also an accessibility issue when considering access to physiotherapy in rural and regional areas.

ESC noted that studies cited by the applicant include a high proportion of patients with hernias, and that there are existing MBS items for the repair of ventral hernias (MBS items 30403 and 30405) and umbilical or linea alba hernias (MBS item 30621) and questioned whether there should be additional co-claiming blocks with items 30403, 30405 and 30621 in the proposed item descriptor. ESC noted the pre-ESC response advising that hernias that are present in patients with postpartum abdominal rectus diastasis would be repaired at the same time as the abdominoplasty procedure. ESC considered that surgical repair of rectus diastasis would repair the midline hernia and that a co-claiming block may need to apply. However, ESC noted that for repair of non-midline hernias such as inguinal and femoral hernias, then the multiple operation rule would apply. ESC asked the Department to seek clinical advice to amend the descriptor as required.

ESC discussed whether the procedure could be performed in the public hospital system, and claimed on the MBS if a private patient. ESC noted this may occur, but likely only in small numbers of patients.

ESC recalled that at the previous MSAC meeting, it was stated that there is no physiological basis for rectus diastasis causing pain. However, ESC noted that intra-abdominal pressure reduces disc loads, as well as intradiscal pressure especially at large flexion angles (Liu et al. 2019[10]). ESC discussed that in the absence of a rectus diastasis, the abdominal wall enables an increase in intra-abdominal pressure, and thus considered that a person with rectus diastasis may not be able to generate the adequate intra-abdominal pressure needed to support their back.

[10] Liu T, Khalaf K, Adeeb S, El-Rich M. Numerical Investigation of Intra-abdominal Pressure Effects on Spinal Loads and Load-Sharing in Forward Flexion. Front Bioeng Biotechnol. 2019 Dec 17;7:428. doi: 10.3389/fbioe.2019.00428. PMID: 31921829; PMCID: PMC6928040.

15. Other significant factors

Nil.

16. Applicant comments on MSAC's Public Summary Document

ASPS notes the deliberations of MSAC and is pleased that women who have symptoms related to rectus diastasis following pregnancy can once again access appropriate services.

17. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website: visit the MSAC website