

# Medical Services Advisory Committee (MSAC) Public Summary Document

## ***Application No. 1685 Ventral Rectopexy for the treatment of rectal prolapse and intussusception***

**Applicant:** Colorectal Surgical Society of Australia and New Zealand (CSSANZ)

**Date of MSAC consideration:** MSAC 86<sup>th</sup> Meeting, 24-25 November 2022  
MSAC Executive Meeting, 30 January 2023

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, [visit the MSAC website](#)

### **1. Purpose of application**

An application requesting Medicare Benefits Schedule (MBS) listing of minimally invasive ventral rectopexy (MIVR) for treatment of rectal prolapse and high-grade rectal intussusception (or 'rectoanal intussusception') was received from the Colorectal Surgical Society of Australia and New Zealand by the Department of Health and Aged Care.

### **2. MSAC's advice to the Minister**

#### ***November 2022 MSAC consideration***

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness, cost-effectiveness and total cost, MSAC supported the creation of a new Medicare Benefits Schedule (MBS) item for the listing of minimally invasive ventral rectopexy (MIVR) for the treatment of external rectal prolapse and symptomatic rectoanal intussusception. For the external rectal prolapse population (population A), MSAC considered ventral rectopexy to be superior in clinical effectiveness and non-inferior in safety compared to other surgical techniques. For the symptomatic rectoanal intussusception population (population B), MSAC considered MIVR inferior in safety compared to conservative management but superior in effectiveness. Based on the recurrence rates associated with the procedures and the economic analysis provided, MSAC considered the incremental cost of MIVR and recurrence to be less than the comparators. The financial impact to the MBS was considered to be modest. Given the concomitant use of a surgical mesh in MIVR, MSAC considered patients undergoing the procedure could be captured in an appropriate registry.

#### ***January 2023 MSAC Executive consideration***

The MSAC Executive noted the department sought further advice on MSAC Application 1685 as well as providing further updates and information requested by MSAC during its November 2022 consideration.

The MSAC Executive agreed the MBS item should remain neutral on the type of mesh to be used in MIVR and supported the MSAC recommendation that the choice of mesh should be left to the

clinician and their patients. The MSAC Executive also agreed with the suggestion to explore expanding the Australasian Pelvic Floor Procedure Registry (APFPR) to include MIVR procedures to support data collection for these items.

The MSAC Executive agreed with amendments to the MBS item and confirmed no age limit should apply to the service. In addition, for the purposes of the MBS item, the proposed item descriptor was amended to replace the term “rectoanal intussusception” with “high grade rectal intussusception” followed by a plain language description, which must be confirmed by diagnostic imaging and not by other procedures such as examination under sedation. In addition, the fee was updated to reflect the current fee for sacral colpopexy (MBS item 35597) following indexation changes updated on 1 July 2023. The updated item is shown below in Table 1.

**Table 1 (addendum) MSAC Executive supported item descriptor**

Category 3 – T8 Subgroup 2 (Colorectal)
<p>MBS item 32118</p> <p>VENTRAL RECTOPEXY. Treatment of external rectal prolapse or symptomatic high grade rectal intussusception (the rectum descends to the level of or into the anal canal, confirmed by diagnostic imaging) by minimally invasive surgery involving ventral dissection of the extra-peritoneal rectum and suspension of the rectum from the sacral promontory by means of a prosthesis and including suspension of the vagina and any associated repair where performed, other than a service associated with a service to which item 35595, 35597 or 30390 applies (H)</p> <p>Multiple Operation Rule (Anaes.) (Assist.)</p> <p><u>Explanatory note:</u></p> <p>Surgeons performing minimally invasive ventral rectopexy procedures should be colorectal surgeons or general surgeons with a sub-specialist interest in colorectal surgery, with experience in the procedure.</p>
Fee: \$1,613.45 Benefit: 75% = \$1,210.10

## Consumer summary

This is an application from the Colorectal Surgical Society of Australia and New Zealand requesting Medicare Benefits Schedule (MBS) listing of a surgical procedure called ventral rectopexy to treat two conditions that can affect a person's rectum. The rectum is the last 20cm or so of the large bowel (intestine). It is the temporary storage area for bowel motion (faeces). Rectal prolapse is a condition where the rectum becomes stretched out and can come out of the anus. This causes problems with the way the rectum and muscles of the anus usually work together to contain and then empty faeces; it can be difficult or painful to empty the bowels, and it can be harder to control the bowels (faecal incontinence).

In the early stages of prolapse, the stretched rectum can cause significant problems, a portion of the inside lining of the bowel may slip out during a bowel motion, but it will go back inside on its own. This is called "symptomatic rectoanal intussusception" and can lead to constipation and difficulty passing faeces. When a prolapse gets worse, the end of the rectum comes right out through the anus. This causes incontinence, bleeding and ulceration of the exposed lining of the rectum (mucosa).

Ventral rectopexy is a surgical procedure proposed to treat rectal prolapse. The surgeon sews a mesh to the rectum and then anchors the top of the mesh to a part of the spine. This stops the rectum from sliding down. In women, the mesh is also attached to the vagina to provide support and prevent possible future prolapse of the uterus. The mesh can be synthetic (made of polymer) or biologic (called a graft and made from tissues from humans, cows or pigs). This surgery can be performed as a minimally invasive surgery, which is where doctors use a variety of techniques to operate without opening the body up as much as with open surgery. In general, minimally invasive surgery is thought to be associated with less pain, a shorter hospital stay and fewer complications.

In a different type of rectopexy procedure, called abdominal rectopexy, some nerves may be accidentally damaged, and this can lead to constipation after surgery. It is likely that ventral rectopexy causes less nerve damage and therefore constipation is less of a problem. These types of surgery may result in reduced faecal incontinence and constipation, improved sexual function and quality of life.

MSAC noted that the clinical evidence for ventral rectopexy was limited because the studies had small patient numbers and long-term outcomes were not known. The evidence did show that ventral rectopexy was better than other management options in terms of the risk of prolapse happening again (recurrence). MSAC considered that it was not likely that there would be any better evidence in the future. This is because surgeons now prefer ventral rectopexy, and therefore would not want to run studies comparing it with older techniques. MSAC also noted that ventral rectopexy is just as safe as other similar surgical procedures.

MSAC noted that the costs of ventral rectopexy to the MBS were uncertain but not likely to be high.

MSAC recommended that the Australian Government establish a register to record all ventral rectopexy procedures. Whilst there is good evidence that using mesh for this procedure is safe, a register will allow the government to monitor for complications with the mesh over time, as well as track other long-term outcomes. MSAC recommended that patients help design the registry to make sure it captures data about what is relevant and important to them, in a respectful way (called a co-design process).

### **MSAC's advice to the Commonwealth Minister for Health and Aged Care**

MSAC supported MBS listing of ventral rectopexy for the treatment of rectal prolapse. MSAC considered that ventral rectopexy was effective, safe and likely good value for money. MSAC advised that the Australian Government should set up a registry to track the outcomes of patients undergoing this procedure.

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

#### *November 2022 MSAC consideration*

MSAC noted that this application from the Colorectal Surgical Society of Australia and New Zealand was requesting MBS listing for MIVR for the treatment of external rectal prolapse and symptomatic rectoanal intussusception. MSAC has not previously considered MIVR for the treatment of these conditions.

MSAC noted that MIVR was previously being reimbursed under several co-claimed MBS item numbers. The Colorectal Subcommittee of the MBS Taskforce recommended a new item be created to differentiate MIVR from other abdominal rectal prolapse repairs and to allow for a suitable fee. In July 2022, the Australian Government amended MBS item 32117 (abdominal rectopexy) to exclude ventral mesh rectopexy and introduced a new temporary item for MIVR (MBS item 32118).

MSAC noted that the wording of the item descriptor (Table 1) has evolved throughout the application process. MSAC considered that a diagnostic imaging or diagnostic procedure (e.g. examination under sedation) is needed to confirm rectoanal intussusception and differentiate it from haemorrhoids. MSAC considered the type of imaging modality or diagnostic procedure should not be specified in the item descriptor to allow for clinician discretion. For external rectal prolapse, confirmation by diagnostic imaging or procedure is not required. MSAC considered a lifetime restriction on MIVR was not required given the nature of the procedure and challenges for multiple procedures. Because of the potential for erosion with synthetic mesh, MSAC suggested a practice note could be included to encourage use of a biologic graft, but that the choice of mesh should be left to the clinician's discretion. However, this advice was reconsidered by the MSAC Executive in January 2023 – see section below.

MSAC noted that the MBS descriptor should specify minimally invasive surgery and exclude pelvic floor repair and vaginal prolapse repair. If these procedures are required, they should be performed by a urogynaecological surgeon alongside MBS items 35595 and 35597.

MSAC noted that the fee for the temporary item is \$1,328, and the new item will have an increased fee of \$1,557.40 (equivalent to the fee for sacral colpopexy item 35597). MSAC considered this to be appropriate as this reflected the complexity of the MIVR procedure. MSAC considered that MIVR should be performed by colorectal surgeons or general surgeons with a sub-specialist interest in colorectal surgery, with expertise in the procedure.

MSAC noted that for patients with external rectal prolapse (population A), the comparators were abdominal rectopexy (alone or as part of a resection rectopexy), resection rectopexy, and perineal repair using a Delorme's procedure. For patients with symptomatic rectoanal intussusception (population B), the comparators were continued conservative management, abdominal rectopexy, and intra-anal Delorme's procedure. MSAC considered these comparators to be appropriate. MSAC noted the clinical management algorithms for both patient groups. MSAC noted that, in both cases, MIVR is proposed as an additional option available to surgeons, along with the comparator procedures.

MSAC noted that the evidence base for MIVR is limited by small patient numbers and short follow-up times, and the studies have some risk of bias. However, MSAC acknowledged that MIVR is now the preferred technique for a majority of surgeons, meaning that further comparative clinical studies are unlikely and the evidence base will not improve with time. MSAC noted the pre-MSAC response stated that overseas studies had failed to recruit adequate patients.

MSAC noted that evidence from 15 studies showed that, for patients with external rectal prolapse, MIVR had non-inferior safety versus the comparator procedures. For patients with symptomatic rectoanal intussusception, evidence from 12 studies showed that MIVR had inferior safety compared with conservative management. However, MSAC considered that all surgical procedures will have a higher risk profile compared to conservative management, so considered that this safety profile was acceptable.

Regarding clinical effectiveness, MSAC noted that data from 12 studies on patients with external rectal prolapse showed that MIVR was non-inferior to other surgical options in terms of symptom improvement and quality of life. Overall, recurrence rates were lower with MIVR compared with all comparator procedures pooled together (RR 0.58, 95% CI: 0.38–0.88), therefore suggesting that MIVR has superior clinical effectiveness based on recurrence rates. For patients with symptomatic rectoanal intussusception, evidence from 12 studies suggested that MIVR has superior clinical effectiveness compared with conservative management. No comparative evidence was found for symptomatic rectoanal intussusception compared to abdominal rectopexy or intra-anal Delorme's procedure.

For the economic evaluation, MSAC noted that the Department-contracted assessment report (DCAR) presented a model that was described as a cost-consequence analysis. MSAC noted however that the model only compared the incremental costs associated with MIVR plus recurrence against the cost of other procedures plus recurrence and did not include any outcomes. As such, MSAC considered that the model represented a partial economic analysis and is more appropriately labelled as a cost-comparison and noted that this meant that no cost effectiveness claims can be made.

MSAC noted that the recurrence rate was the only outcome for which there was a statistically significant difference between MIVR and the (pooled) comparators and so this formed the basis of the model structure. MSAC noted that the cost comparison presented in the DCAR (as opposed to a cost-utility or cost-effectiveness analysis as outlined in the PICO) was chosen because no utility values were identified that correlated with the health states in the model. MSAC noted that some quality-of-life estimates were reported in the literature, but these were heterogenous in terms of how they were recorded, the types of participants included and procedures evaluated. The only utility values that were identified in the literature did not correspond to the states in the model and could not be used. Overall, MSAC considered that while a full economic analysis that took health outcomes into account would have been more appropriate, on the basis of the evidence available, that the cost-comparison analysis in the DCAR was sufficient for decision-making purposes.

Populations A and B were not differentiated in the cost comparison due to insufficient data, and the model was based on the pooled recurrence rates, with MSAC recalling the concerns around the small study sizes, short follow-up and heterogeneity across the studies. MSAC noted that although the MBS fee for MIVR was higher than the comparator procedures, the cost comparison reported that overall, MIVR was cost saving compared to the other procedures and this was due to the lower rate of recurrence and associated hospital costs. The results of the cost comparison indicated that MIVR was associated with a cost per procedure over a lifetime of \$22,553 for MIVR, \$23,826 for abdominal rectopexy and \$23,060 for Delorme's procedure, based on the costs included. MSAC noted that the incremental costs were relatively robust to variations in the assumptions around recurrence rates.

MSAC noted that the DCAR model did not include costs for the prosthesis however, an additional analysis was provided by the assessment group for consideration by the MSAC Executive.

MSAC noted that, although MIVR appeared cost saving in the cost comparison presented in the DCAR, it was associated with an overall increase in cost to the MBS (calculated in the DCAR as

\$83,251 in Year 1 to \$129,414 by Year 6). MSAC noted that this was due to the total number of patients claiming for the new, unique, MIVR item and that this would likely be larger than the number of patients who had co-claimed item numbers previously (noting there was uncertainty associated with estimating current MIVR usage using these estimates without a separate item). MSAC also considered that if MIVR was used more than Delorme's procedure in the future, then this would also result in a slightly higher overall cost to the MBS. MSAC noted that the financial impact was most sensitive to the replacement rate between MIVR and Delorme's procedure (assumed to be 15%) and increasing costs of Delorme's procedure due to inflation. MSAC noted that, while the financial impact of the new MIVR item is uncertain, it is likely to be modest over the next six years.

MSAC advised that the new item be reviewed after two years so that its actual costs can be analysed and compared with current co-claiming patterns for items 32117 (abdominal rectopexy), 35595 (pelvic floor repair), 35597 (sacral colpopexy with mesh) and 32024 (high restorative anterior resection of the rectum).

MSAC recommended that the Australian Government establish a register to record outcomes and mesh complications following MIVR. A registry will allow analysis of whether the type of mesh used results in any different outcomes for patients. MSAC recommended that the registry be co-designed with patients and careful attention be paid to respectful language that accurately describes rectal prolapse as an important medical problem that can be treated, as there can be stigma attached to this condition. MSAC noted that the Royal Australasian College of Surgeons already has a hernia registry and there is a vaginal pelvic floor procedures registry, and one of these could possibly either be expanded to include, or be used as a template, for the rectal prolapse registry.

### **January 2023 MSAC Executive consideration**

The MSAC Executive noted the department sought further advice on MSAC Application 1685 as well as providing further updates and information requested by MSAC during its November 2022 consideration.

The assessment group provided an additional analysis for MSAC Executive consideration which included the cost of mesh (but not the tacker), and this results in a very modest impact on the incremental costs/savings associated with performing a MIVR compared with comparator procedures (Table 2). When including the cost of a biologic graft (\$722 as currently listed benefit on the Prosthesis List), the incremental cost saving of MIVR increases marginally to \$1,328 from \$1,273, compared to abdominal rectopexy. However, MIVR incurs an incremental cost burden of \$290 when compared to Delorme's procedure, which does not use the mesh (it had previously incurred an incremental cost saving of \$507). This change in the direction of the cost comparison analysis was not considered by MSAC. The impact to the incremental cost is likely to be even less for synthetic mesh (\$72, current benefit Prosthesis List). The change in the incremental cost does not affect the impact to the MBS budget.

**Table 2 (addendum): partial cost-consequence analysis (including mesh costs)**

Strategy	Base case		With mesh cost	
	Cost	Incremental Cost	Cost	Incremental Cost
Ventral rectopexy	\$22,553	-	\$23,350	-
Abdominal rectopexy	\$23,826	-\$1,273	\$24,678	-\$1,328
Delorme's procedure	\$23,060	-\$507	\$23,060	\$290

The MSAC Executive noted the tacking device (Protack) would be removed from the Prostheses list (PL) on 1 July 2023 and no similar device (endoscopic tacker device) is listed. The MSAC Executive considered that as a result of changes to the PL, patients may be faced with an additional out-of-pocket expense unless the cost can be covered by hospital or health insurer.

The MSAC Executive reconsidered the MSAC recommendation to include a practice note to encourage use of biologic graft and potential promotion of the use of biological mesh over synthetic mesh. The MSAC Executive noted there was no distinctive difference suggested in the evidence evaluated in the DCAR or international guidelines<sup>123</sup> to support a preference for which mesh to use. The MSAC Executive considered that there may be circumstances where biological mesh may be preferable for some patients as noted by MSAC but agreed the MBS should remain neutral on the type of mesh to be used in MIVR. The MSAC Executive supported the MSAC recommendation that the choice of mesh should be left to the clinician and their patients.

The MSAC Executive recalled MSAC recommending that a registry be established to accurately document MIVR procedures performed. The MSAC Executive noted from department advice that the Australasian Pelvic Floor Procedure Registry (APFPR) is an existing national clinical quality registry (CQR) that monitors outcomes of pelvic floor procedures involving mesh devices. The MSAC Executive noted that the APFPR is funded by the department and maintained by Monash University. The MSAC Executive agreed with the suggestion to explore expanding the APFPR to include MIVR procedures to support data collection for these items. The MSAC Executive noted that the registry could capture complications with the procedure and mesh type used to alert any safety issues.

The MSAC Executive confirmed no age limit should apply to the service. The MSAC Executive agreed with the department proposal to simplify the item descriptor, and supported co-claiming restrictions on item 35595, 35597 and 30390. Following further consideration, the proposed item descriptor was amended to replace the term “rectoanal intussusception” with “high grade rectal intussusception” followed by a plain language description, which must be confirmed by diagnostic imaging and not by other procedures such as examination under sedation. In addition, the fee was updated to reflect the current fee for sacral colpopexy (MBS item 35597) following indexation changes updated on 1 July 2023. The updated item is shown in Table 1.

## 4. Background

MSAC has not previously considered ventral rectopexy for treatment of rectal prolapse or rectal intussusception.

Multiple procedures have been described for the correction of rectal prolapse and rectal intussusception, with the aim to correct the morphologic alteration and treat the symptoms. Most procedures combine rectal mobilisation and fixation of the rectum (rectopexy), and some add

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1 Mercer-Jones MA, Brown SR, Knowles CH, Williams AB. Position statement by the Pelvic Floor Society on behalf of the Association of Coloproctology of Great Britain and Ireland on the use of mesh in ventral mesh rectopexy. *Colorectal Dis.* 2020 Oct;22(10):1429-1435. doi: 10.1111/codi.13893. PMID: 28926174; PMCID: PMC7702115.

2 Bordeianou L, Paquette I, Johnson E, Holubar S, Gaertner W, Feingold D, Steele S. Clinical Practice Guidelines for the Treatment of Rectal Prolapse. *DISEASES OF THE COLON & RECTUM VOLUME 60: 11* (2017). DOI: 10.1097

3 Mercer-Jones, M.A., D'Hoore, A., Dixon, A.R., Lehur, P., Lindsey, I., Mellgren, A. and Stevenson, A.R.L. Consensus on ventral rectopexy: report of a panel of experts. *Colorectal Dis.* 16: 82-88. 2014. <https://doi.org/10.1111/codi.12415>

resection or plication of redundant bowel<sup>4</sup>. The choice of the procedure is usually dictated by the patient's overall medical condition and surgeon's preference and experience.

Ventral rectopexy is an autonomic nerve-sparing rectopexy technique. The dissection is strictly ventral in the rectovaginal or rectovesical space down to the pelvic floor without lateral or dorsal mobilization of the rectum. The rectum is attached to the sacrum by a prosthesis (synthetic mesh or biological graft) which is sutured to the anterior side of the rectum. Minimally invasive approaches, which are of interest to this assessment, include laparoscopic ventral rectopexy and robot-assisted ventral rectopexy.

Other procedures used for treating rectal prolapse or rectal intussusception include abdominal rectopexy procedures include suture rectopexy, posterior mesh rectopexy and anterior sling rectopexy, either by open or laparoscopic approach. The main disadvantage of abdominal rectopexy is high rates of postoperative constipation due to denervation during posterolateral rectal mobilisation. One method to avoid this complication is to combine abdominal rectopexy with sigmoid resection to remove the affected portion of the colon in a high anterior resection; this procedure is known as resection rectopexy. While effective at controlling rectal prolapse without constipation, it is more complex and carries a higher risk due to the possibility of an anastomotic leak.

Perineal approaches include mucosal sleeve resection (Delorme's procedure), anal encirclement (Thiersch procedure) and perineal proctosigmoidectomy (Altemeier's procedure, not frequently performed in Australia).

Delorme's procedure can also be performed from within the anal canal (the intra-anal approach) rather than via the perineum. This technique is used for treatment of rectoanal intussusception.

Abdominal rectopexy, resection rectopexy and Delorme's procedure (perineal approach for rectal prolapse and intra-anal approach for rectal intussusception) are considered comparator procedures for the purpose of this assessment.

Ventral rectopexy is currently performed in Australia and has been reimbursed under MBS item 32117<sup>5</sup> (RECTAL PROLAPSE, abdominal rectopexy of) as an item did not exist specifically for ventral rectopexy. However, the applicant has stated that item 32117 does not reflect the increased technical difficulty of ventral rectopexy; therefore, the item was often co-claimed with items for pelvic floor repair or colposacrosuspension (MBS items 35595 or 35597) as rectal prolapse is nine times more prevalent in women than in men<sup>6</sup>. The Colorectal Subcommittee of the MBS Taskforce recommended a new item be created for ventral rectopexy in order to differentiate the procedure from other abdominal rectal prolapse repairs and to allow for a fee that reflected the complexity of the procedure.

The Australian Government introduced a new temporary item for ventral rectopexy on 6 July 2022 (MBS item 32118), to ensure that patients can continue to access affordable ventral rectopexy procedures previously accessed under MBS item 32117<sup>5</sup>.

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<sup>4</sup> Shaikh, I. H. S. (2015). Surgical Approaches for Rectal Prolapse and their Comparative Study. *World*, 8(3), 90-95.

<sup>5</sup> Item 32117 was modified to exclude ventral mesh rectopexy on 1 July 2022.

<sup>6</sup> Wijffels, N. A., Collinson, R., Cunningham, C., & Lindsey, I. (2010). What is the natural history of internal rectal prolapse?. *Colorectal Disease*, 12(8), 822-830.



## 5. Prerequisites to implementation of any funding advice

Ventral rectopexy requires the use of a prosthetic mesh or biological graft to hold the bowel in position. There is one specifically marketed biologic graft for ventral rectopexy, BioDesign Rectopexy Graft (BRG) (Endotherapeutics). Another biologic graft commonly used for ventral rectopexy is Permacol Biological Implant (Medtronic). Commonly used synthetic meshes include Ti-mesh (Medical Specialities), a titanized polypropelene mesh and Prolene Mesh (Johnson & Johnson), an uncoated polypropelene mesh.

Additionally, a laparoscopic tacking device is used to secure the prostheses to the sacral promontory, such as ProTack by Medtronic, currently listed on the Prosthesis List. This tacking device has been described by the applicant as single use.

No further additions to the Prosthesis List are required for the funding advice for this MSAC application; however, it is possible that other brands of mesh or graft are listed over time.

As the procedure is already being used in clinical practice, and there is good knowledge and experience of the methodology amongst practicing colorectal surgeons, there are no proposed or suggested other prerequisites for implementation of any funding advice.

## 6. Proposal for public funding

The applicant is proposing the intervention to be publicly funded through the MBS. The proposed new MBS item descriptor (as considered by PASC) is presented in Table 3.

**Table 3 Proposed item descriptor for ventral rectopexy**

Category 3 – T8 Subgroup 2 (Colorectal)
<p>MBS item XXXXX</p> <p>VENTRAL RECTOPEXY. Treatment of external rectal prolapse (grade V, Oxford Rectal Prolapse Scale) or symptomatic high-grade (grade III or IV, Oxford Rectal Prolapse Scale) internal rectal prolapse by minimally invasive surgery including where relevant<sup>7</sup> dissection of the rectovaginal septum to the pelvic floor, fixation, associated pelvic floor repair incorporating the fixation of the uterosacral and cardinal ligaments to rectovaginal and pubocervical fascia for symptomatic upper vaginal vault prolapse.</p> <p>(Note: Items 35595 and 35597 not to be co-claimed by the same surgeon claiming XXXXX. A second surgeon may claim 35597 if the patient requires synchronous repair of symptomatic upper vaginal vault prolapse involving fixation of separate prosthesis secured to vault, anterior and posterior compartment and to sacrum for correction of symptomatic upper vaginal vault prolapse.)</p> <p>Multiple Operation Rule (Anaes.) (Assist.)</p>
Fee: \$1,557.40 Benefit: 75% = \$1,168.05 <sup>8</sup>

The proposed intervention is referring to minimally invasive ventral rectopexy, performed either laparoscopically or using a master-slave robotic platform. The technique involves the use of a

<sup>7</sup> The applicant requested a minor change to the item descriptor to replace “involving and including” with “including where relevant” to ensure the procedure is not restricted to women only.

<sup>8</sup> The fee for ventral rectopexy is proposed to be the same as for sacral colpopexy item 35597, which increased on 1 July 2022 from \$1,532.85 to \$1,557.40. The proposed fee has been updated to reflect this.

prosthesis, either synthetic mesh or biological graft, to anchor the rectum to the sacral promontory.

Ventral rectopexy is performed as an in-hospital procedure under general anaesthetic, usually with a 1-to-2-night stay, although for selected patients it can be performed as a day-case procedure. The proposed service is performed by colorectal surgeons (or general surgeons with a sub-specialist interest in colorectal surgery) with adequate training and expertise in pelvic floor surgery and ventral rectopexy.

The proposed fee for ventral rectopexy is the same as for sacral colpopexy. The applicant has advised that these procedures are of equivalent complexity. Although the fee proposed for ventral rectopexy is higher than for abdominal rectopexy (currently \$1,557.40 versus \$1,328.00), the applicant has advised that abdominal rectopexy was often co-claimed with an item for anterior resection (currently \$1,442.60) to perform a resection rectopexy. The total cost for the combined procedure is \$2,106.60.

Further, the applicant has stipulated in the item descriptor that the proposed item should not be co-claimed with items 35595 and 35597 (which are often co-claimed with item 32117), except in specific circumstances (see in Table 3).

. Therefore, there is expected to be a cost saving to the MBS when ventral rectopexy is performed using the new item number compared to using items 32117 + 35595 (total fee \$1,658.15) or 32117 + 35597 (total fee \$2,221.40).

The applicant has acknowledged that where ventral rectopexy replaces Delorme's procedure (previously provided under MBS item 32111 and currently provided under MBS item 32233; \$678.40) there may be increased costs to the MBS; however, the applicant claimed that the lower recurrence rate and therefore lower reoperation rate associated with ventral rectopexy will offset this cost difference.

## 7. Population

Rectal prolapse can generally be divided into two categories: external rectal prolapse and internal rectal prolapse, also termed rectal intussusception. It is believed that the two conditions represent a continuum of disease. The Oxford Rectal Prolapse Grade, a radiological grading system, is used to categorise the extent of the prolapse.

One PICO set was defined in the PICO confirmation.

The proposed populations for this application are:

- patients with full-thickness rectal prolapse (Grade V Oxford Rectal Prolapse Scale; population A)
- patients with rectoanal intussusception (Grade III and IV Oxford Rectal Prolapse Scale) with severe symptoms who have failed to improve with conservative management (population B).

While the two populations represent different stages of the disease and may have different pre-operative treatment strategies, the applicant has indicated that they should be considered as a single population for the purposes of funding decision-making, and both populations should be included under the same MBS item number.

The ventral rectopexy procedure is proposed to be used as an additional treatment option to abdominal rectopexy, resection rectopexy and Delorme's procedure in patients with a confirmed full-thickness rectal prolapse (grade V, population A), and as an alternative to continued

conservative management and abdominal rectopexy in patients with a confirmed diagnosis of high-grade (grade III-IV) rectal intussusception (population B).

The assessment report addresses the requirements of the confirmed PICO.

## 8. Comparator

For patients with rectal prolapse (population A), the comparators to ventral rectopexy are:

- abdominal rectopexy (other than by minimally invasive ventral rectopexy), whether alone or as part of a resection rectopexy
- resection rectopexy
- perineal repair using a Delorme's procedure.

For patients with rectoanal intussusception (population B), the comparators are:

- continued conservative management
- abdominal rectopexy
- intra-anal Delorme's procedure.

The surgical approach for Delorme's procedure can be either via the perineum (for external rectal prolapse, population A) or performed within the anal canal (for high grade rectal intussusception, population B).

Ventral rectopexy is currently performed in Australia and has been reimbursed under MBS item 32117 (RECTAL PROLAPSE, abdominal rectopexy of) (sometimes in conjunction with item 35595 for pelvic floor repair or item 35597 for colposacrosuspension) as an item did not previously exist specifically for ventral rectopexy. Item 32117 has been listed on the MBS since at least December 1991.

## 9. Summary of public consultation input

Consultation feedback was received from three organisations:

- Australian Association of Stomal Therapy Nurses (AASTN).
- Private Health Australia (PHA)
- Urogynaecological Society of Australasia (UGSA).

PHA and UGSA were generally supportive of the application, and AASTN was very supportive. Both UGSA and PHA noted that the fee was appropriate as VR is similar in complexity to sacral colpopexy.

### Benefits

All consultation responses considered that published data suggest that patients receiving this treatment have less morbidity and recurrence, and appear to have a faster recovery, including potentially faster discharge from hospital care.

### Disadvantages

PHA stated that the use of non-absorbable mesh and sutures for this technique would appear to have a much higher incidence of complications, especially erosion, and that these complications would require a more complex and potentially dangerous surgery to correct any issues. PHA

noted that more detail on the increased number of consumables would be useful, because the ventral technique comes with increased surgical costs from increased use of disposables, especially if a robotic platform is used. However, the faster recovery rate could offset the additional cost.

PHA did not agree with the proposed MBS descriptor, stating that there is insufficient evidence to add 'robotic' to the descriptor, as the use of a robotic assisted platform does not appear to have any discernible advantage in patient outcomes and results in a much more expensive procedure.

UGSA did not agree with the proposed MBS descriptor, stating that the proposed wording implies that pelvic floor repair is an intrinsic part of VR. UGSA note that, at times, separate rectal and vaginal procedures may be required but pelvic floor repair using uterosacral and cardinal ligaments is not an essential aspect of correction of rectal prolapse or rectoanal intussusception. UGSA also noted that in the case of recurrent vaginal prolapse, subsequent performance of a more effective sacrocolpopexy may be complicated by the full-length posterior wall mesh.

PASC noted that the literature does not support the concerns around the mesh complications associated with ventral rectopexy in ways that have been seen in other pelvic operations, particularly on the bladder. It was acknowledged that these complications do exist but at very low levels, approximately 1% as documented in the literature (Mercer-Jones et al., 2020).

The applicant noted that synthetic mesh may have a potentially higher incidence of complications and erosion in other operative settings. However, in the context of ventral rectopexy, synthetic mesh has lower cost compared to biological graft and low risk of erosion or complications when used by experienced surgeons.

## **10. Characteristics of the evidence base**

A total of 29 studies (published across 33 papers) met the inclusion criteria for assessing the safety and effectiveness of minimally invasive ventral rectopexy compared to comparator procedures, grouped under broader terms of abdominal rectopexy, resection rectopexy, and Delorme's procedure for Population A (patients with full-thickness rectal prolapse).

For Population B (patients with rectoanal intussusception), one randomised controlled trial (RCT) comparing laparoscopic ventral mesh rectopexy with continued conservative management was identified. It was at high risk of bias and suffered from significant under-recruitment. The remainder of the identified evidence consisted of before-after comparisons of patients who underwent minimally invasive ventral rectopexy after failing conservative management. Some of the studies included patients with mixed indications for ventral rectopexy (patients with various grades of Oxford Rectal Prolapse Scale, with or without recto- and enterocele), raising concerns over the indirectness of evidence. No comparative evidence was found for the comparators of abdominal rectopexy or intra-anal Delorme's procedure.

A summary of the key features of the studies on comparative safety and effectiveness of minimally invasive ventral rectopexy is provided in Table 4.

**Table 4 Key features of the included evidence**

References	N	Design/duration	Risk of bias	Patient population	Outcome(s)	Use in modelled evaluation
<b>Population A, minimally invasive ventral rectopexy vs abdominal rectopexy</b>						
Lundby et al. (2016) Hidaka et al. (2019)	75	DB RCT 6 years	<i>Some concern</i>	Patients with primary full-thickness rectal prolapse	Safety Functional outcomes Recurrence	Yes
Cavallaro et al. (2021)	180	Prospective cohort study, MC 3 months	<i>Serious</i>	Consecutive patients undergoing repair for ERP	Perioperative parameters Safety Functional outcomes	Yes
Gleditsch et al. (2018)	93	Retrospective cohort study Mdn 6.8 years	<i>Serious</i>	All patients undergoing surgery for ERP 1998-2017	Safety Recurrence	Yes
Heemskerk et al. (2007)	33	Cohort study NR	<i>Serious</i>	Patients with full-thickness rectal prolapse	Perioperative parameters Safety Costs	No
Luglio et al. (2017)	40	Pseudo-RCT (alternate allocation to intervention or comparator) 12 months	<i>Serious</i>	Females with full-thickness rectal prolapse	Functional outcomes Recurrence	Yes
Madbouly et al. (2018)	74	Retrospective cohort study 12 months	<i>Serious</i>	All consecutive patients with complete rectal prolapse	Perioperative parameters Safety Functional outcomes Recurrence Quality of life	Yes
Yumiba et al. (2022)	95	Retrospective cohort study NR	<i>Serious</i>	Consecutive patients treated with laparoscopic rectopexy for complete rectal prolapse	Perioperative parameters Safety Functional outcomes Recurrence	Yes
<b>Population A, minimally invasive ventral rectopexy vs resection rectopexy</b>						
Carvalho et al. (2018)	187	Retrospective cohort study 12 months	<i>Critical (functional outcomes)</i> <i>Serious (other outcomes)</i>	Consecutive patients with full-thickness rectal prolapse	Functional outcomes Recurrence Quality of life	Yes
Formijne Jonkers et al. (2014)	68	Retrospective cohort study Mean 42 months (LVMR) and 57 months (LRR)	<i>Serious</i>	All patients undergoing LVMR or LRR for full-thickness rectal prolapse	Perioperative parameters Safety Functional outcomes Recurrence	Yes

References	N	Design/duration	Risk of bias	Patient population	Outcome(s)	Use in modelled evaluation
Lechaux et al. (2005)	48	Retrospective cohort study 6 months	<i>Serious</i>	Consecutive patients undergoing laparoscopic surgery for full-thickness ERP	Perioperative parameters Functional outcomes Recurrence	Yes
<b>Population A, minimally invasive ventral rectopexy vs Delorme's procedure</b>						
Emile et al. (2017)	50	RCT 18 months	<i>Some concern</i>	Patients with primary full-thickness rectal prolapse	Safety Functional outcomes Recurrence Quality of life	Yes
Hu et al. (2022)	51	Retrospective cohort study 24 months	<i>Critical</i>	Males undergoing abdominal or perineal repair for ERP	Safety Functional outcomes Recurrence Quality of life	Yes
Ng et al. (2022)	83	Retrospective cohort study Mdn 12 months	<i>Serious</i>	All patients undergoing surgery for PCFPF	Perioperative parameters Safety Functional outcomes Recurrence	Yes
<b>Population A, LVMR vs RVMR</b>						
Faucheron et al. (2016)	20	Prospective cohort study 30 days	<i>Serious</i>	Consecutive patients undergoing day case VMR for total rectal prolapse (75%) or deep enterocele	Perioperative parameters Safety Costs	Yes
Mehmood et al. (2014)	51	Prospective cohort study 12 months	<i>Serious</i>	All consecutive patients undergoing VMR for ERP	Perioperative parameters Safety Functional outcomes Recurrence Quality of life	Yes
<b>Population B, minimally invasive ventral rectopexy vs conservative management</b>						
Grossi et al. (2022)	28	Stepped-wedge RCT 24 weeks	<i>High</i>	Patients with IRP (RAI or RRI) determined by clinical examination and defecography	Safety Functional outcomes Quality of life	No

References	N	Design/duration	Risk of bias	Patient population	Outcome(s)	Use in modelled evaluation
Makela-Kaikkonen et al. (2016a) Makela-Kaikkonen et al. (2016b) Makela-Kaikkonen et al. (2019) Laitakari et al. (2020)	30	RCT 5 years	<i>Some concerns</i>	Females with symptomatic RAI (73%) or ERP (27%)	Safety Functional outcomes Quality of life Costs and economic analysis Restoration of anatomy	Yes
Albayati et al. (2017)	51	Retrospective case series Mdn 21.5 months	<i>High</i>	Patients with RAI ± rectocele (82%) or ERP (18%)	Safety Functional outcomes Recurrence	No
Collinson et al. (2010)	75	Prospective case series Mdn 12 months	<i>High</i>	Patients with radiologically confirmed IRP (grade III-IV), symptoms of ODS and faecal incontinence and failed standard management	Perioperative parameters Safety Functional outcomes Recurrence	No
Consten et al. (2015)	671	Cohort study, MC Mdn 33.9 months	<i>High</i>	All consecutive patients with Oxford grade III-IV IRP with symptoms of ODS and faecal incontinence, ± rectocele and/or enterocele	Safety Functional outcomes Recurrence	No
Degasperi et al. (2020)	50	Prospective case series 12 months	<i>High</i>	Consecutive female patients undergoing LVMR for ODS and IRP	Safety Functional outcomes Recurrence Quality of life	No
Franceschilli et al. (2015)	100	Prospective case series 12 months	<i>Low</i>	Consecutive patients with IRP grade III-IV and FISI ≥10 and/or CCCS ≥5	Safety Functional outcomes Recurrence	No
Gosselink et al. (2013)	72	Prospective case series Mdn 12 months	<i>Low</i>	Consecutive patients with IRP grade III-IV and faecal incontinence not responding to maximum medical treatment and undergoing surgery	Safety Functional outcomes	No

References	N	Design/duration	Risk of bias	Patient population	Outcome(s)	Use in modelled evaluation
Gosselink et al. (2015)	50	Prospective case series 12 months	<i>Low</i>	Consecutive patients with faecal incontinence who underwent LVMR	Safety Functional outcomes Recurrence Quality of life	No
Laitakari et al. (2022)	401	Retrospective matched-pair cohort study, MC Mdn 3 years (LVMR) and 3.3 years (RVMR)	<i>Serious</i>	Consecutive female patients who underwent VMR for symptomatic IRP (76%) or ERP (24%)	Perioperative parameters Safety Functional outcomes Quality of life	No
Sileri et al. (2012)	34	Prospective case series Mdn 12 months	<i>Low</i>	Consecutive patients with IRP undergoing LVMR	Safety Functional outcomes Recurrence	No
Tsunoda et al. (2021)	26	Case series 7 years	<i>Low</i>	All patients with RAI and/or rectocele who underwent LVMR	Safety Functional outcomes Quality of life Recurrence	No

CCCS=Cleveland Clinic constipation score; DB=double blind; ERP=external rectal prolapse; FISI=Faecal Incontinence Severity Index; IRP=internal rectal prolapse; LRR=laparoscopic resection rectopexy; LVMR=laparoscopic ventral mesh rectopexy; MC=multicentre; Mdn=median; NR=not reported; ODS=obstructed defecation syndrome; PCFP=posterior compartment pelvic floor prolapse; RAI=recto-anal intussusception; RCT=randomised controlled trial; RRI=recto-rectal intussusception; RVMR=robotic ventral mesh rectopexy; VMR=ventral mesh rectopexy

## 11. Comparative safety

### 11.1 Population A

Fifteen papers with 1,101 patients contributed data on the safety of minimally invasive ventral rectopexy for full-thickness rectal prolapse.

Most studies reported no postoperative mortality after ventral rectopexy or comparator surgical procedures (only one perioperative death due to colon perforation was reported, after abdominal rectopexy<sup>9</sup>).

Most studies reported no statistically significant differences in adverse event rates arising from the surgical treatment of full-thickness rectal prolapse. Only one study<sup>10</sup> at serious risk of bias found laparoscopic ventral mesh rectopexy had significantly less postoperative complications than laparoscopic resection rectopexy. It should be noted that none of the studies was powered for safety outcomes. Pooled data are presented in Figure 1.

<sup>9</sup> Gleditsch, D., Wexels, W. A., & Nesbakken, A. (2018). Surgical options and trends in treating rectal prolapse: long-term results in a 19-year follow-up study. *Langenbeck's Archives of Surgery*, 403(8), 991-998.

<sup>10</sup> Formijne Jonkers, H. A., Maya, A., Draaisma, W. A., Bemelman, W. A., Broeders, I. A., Consten, E. C. J., & Wexner, S. D. (2014). Laparoscopic resection rectopexy versus laparoscopic ventral rectopexy for complete rectal prolapse. *Techniques in coloproctology*, 18(7), 641-646.



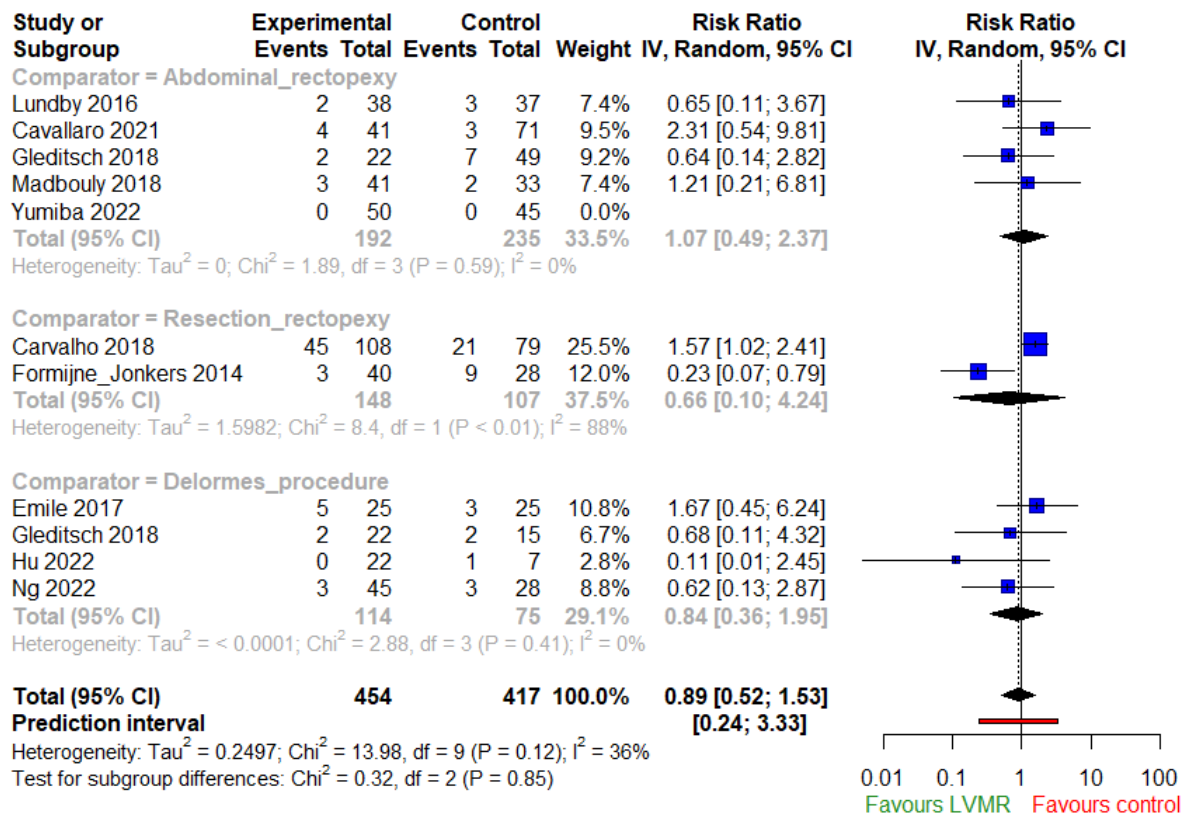


Figure 1 Adverse events arising from surgical procedures for treatment of full-thickness rectal prolapse

Mesh-related adverse events were reported by four studies; the evidence was non-comparative because none of the studies used mesh in the comparator procedure. Complication rates ranged from 0-2.4%, with a pooled proportion of 2% (95% CI 1% to 5%; Figure 2). There was no indication of differences between biological grafts and synthetic mesh materials in the identified evidence.

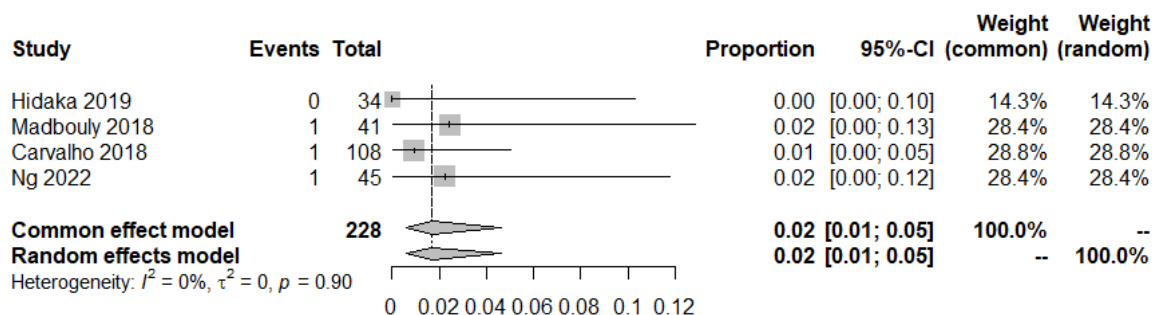


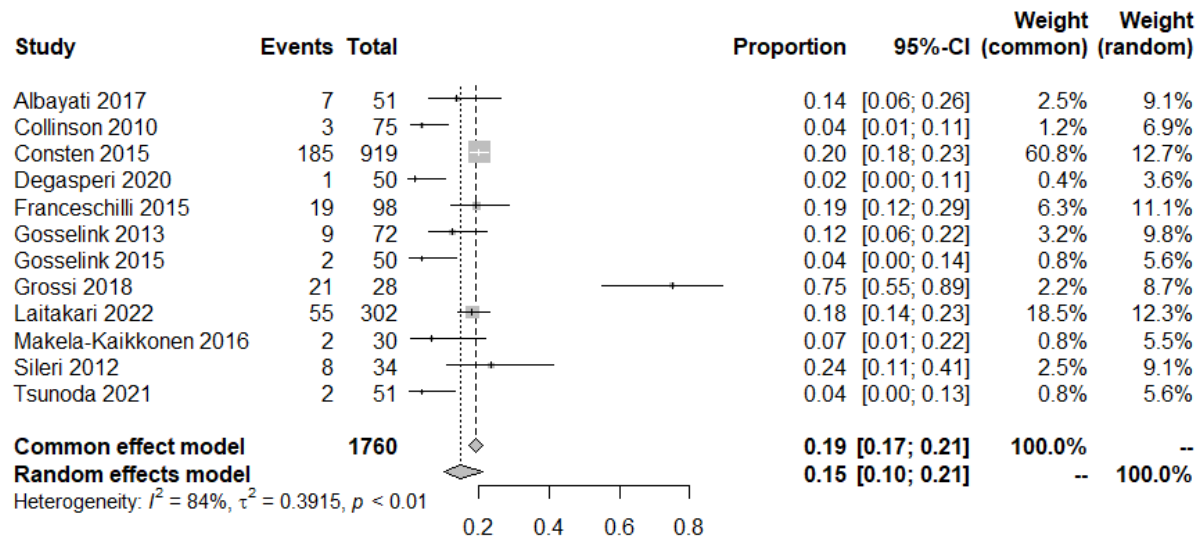
Figure 2 Pooled analysis of mesh-related adverse events after minimally invasive ventral rectopexy for full-thickness rectal prolapse

## 11.2 Population B

Twelve studies with 1,762 patients contributed data on the safety of minimally invasive ventral rectopexy for rectoanal intussusception.

Most studies reported no postoperative mortality after minimally invasive ventral rectopexy (only one perioperative death due to urosepsis was reported<sup>11</sup>).

Pooled data for adverse event rates are presented in **Figure 3**. Complication rates ranged from 3.5-75%, with a pooled proportion of 15% (95% CI 10% to 21%). This pooled result was skewed by the outlier results reported by one RCT<sup>12</sup>. If excluded, the complication rates ranged from 3.5-25%, with a pooled proportion of 13% (95% CI 10% to 18%).



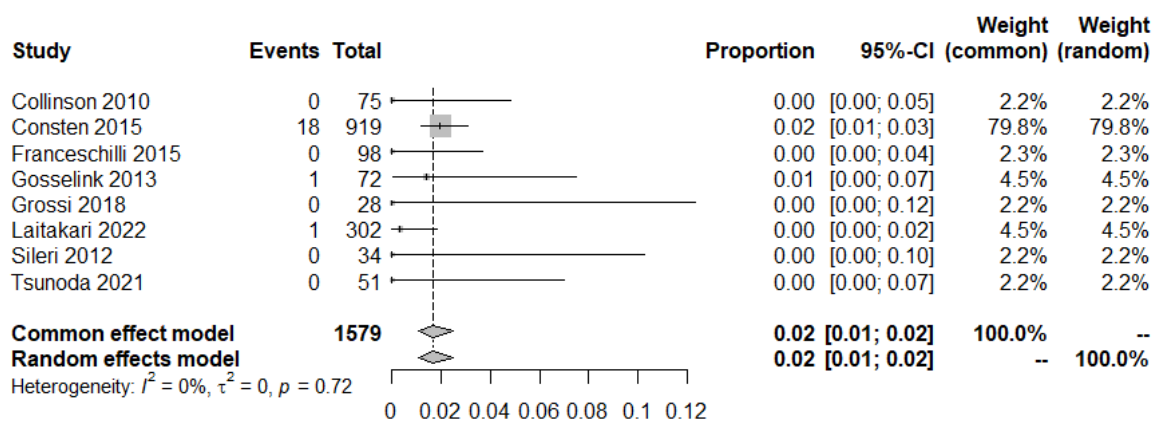
**Figure 3 Pooled analysis of adverse events after minimally invasive ventral rectopexy for rectoanal intussusception**

Mesh-related adverse events were reported by eight studies. Five studies reported no mesh-related complications and three studies reported complication rates in a range of 0.3-4.6%, with a pooled proportion of 2% (95% CI 1% to 2%; **Figure 4**). There was no indication of differences between biological and synthetic mesh materials in the identified evidence.

<sup>11</sup> Consten, E. C., van Iersel, J. J., Verheijen, P. M., Broeders, I. A., Wolthuis, A. M., & D’Hoore, A. (2015). Long-term outcome after laparoscopic ventral mesh rectopexy. *Annals of surgery*, 262(5), 742-748.

<sup>12</sup> Grossi et al. (2018) reported that while the complications they observed had possible causality related to the procedure, none of them had any long-term sequelae

Grossi, U., Stevens, N., McAlees, E., Lacy-Colson, J., Brown, S., Dixon, A., ... & Knowles, C. H. (2018). Stepped-wedge randomised trial of laparoscopic ventral mesh rectopexy in adults with chronic constipation: study protocol for a randomized controlled trial. *Trials*, 19(1), 1-19.



**Figure 4 Pooled analysis of mesh-related adverse events after minimally invasive ventral rectopexy for rectoanal intussusception**

Minimally invasive ventral rectopexy for full-thickness rectal prolapse is of similar safety to abdominal rectopexy, resection rectopexy and perineal Delorme's procedure. The evidence was judged to be of moderate quality.

Minimally invasive ventral rectopexy for rectoanal intussusception is less safe than continued conservative management. The evidence was judged to be of low quality. No comparative evidence was found for the comparators of abdominal rectopexy and intra-anal Delorme's procedure.

## 12. Comparative effectiveness

### 12.1 Population A

Twelve papers with data from 916 patients reported on functional outcomes (as patient-reported outcome measures, PROMs, or symptom remission measures) of relevant surgical procedures for full-thickness rectal prolapse. Due to considerable heterogeneity in outcome measures and reporting, data could not be pooled. Most studies demonstrated significant improvement of symptoms (obstructed defecation, constipation and faecal incontinence) after both intervention and comparator surgical procedures, but no significant differences between the functional outcomes of minimally invasive ventral rectopexy and comparator procedures. Notably, the two RCTs comparing ventral rectopexy with abdominal rectopexy and with perineal Delorme's procedure found no difference between arms, and four other cohort studies found no difference between the procedures either. Two cohort studies<sup>13,14</sup> found ventral rectopexy significantly

<sup>13</sup> Luglio, G., Tarquini, R., Giglio, M. C., Sollazzo, V., Peltrini, R., Sacco, M., ... & Bucci, L. (2017). Ventral mesh rectopexy versus conventional suture technique: a single-institutional experience. *Aging Clinical and Experimental Research*, 29(1), 79-82.

<sup>14</sup> Madbouly, K. M., & Youssef, M. (2018). Laparoscopic ventral rectopexy versus laparoscopic wells rectopexy for complete rectal prolapse: long-term results. *Journal of Laparoendoscopic & Advanced Surgical Techniques*, 28(1), 1-6.

better than abdominal rectopexy, and two studies found comparator procedures superior<sup>15,16</sup>, however, both of these studies had either technical or reporting issues and important risk of bias. Several of the non-randomised studies had issues with confounding due to significant differences in baseline characteristics of the intervention and comparator group. The clinical significance of the differences in symptom remission between the procedures was not addressed in any of the studies.

Of note, there was some indication in the literature that in a proportion of patients, the symptom improvement may wane over time. However, most long-term studies suffered significant losses to follow-up, making the long-term data less reliable. Some studies also reported worsening or new onset of symptoms in a proportion of patients (range, 0-14%).

The secondary outcomes of quality of life were largely consistent with the primary functional outcomes, with significant improvements observed in the before-after comparison. Laparoscopic ventral mesh rectopexy was significantly better than abdominal rectopexy procedures in two studies. Data could not be pooled due to the heterogeneity of measures used.

Sixteen papers with data from 1,041 patients reported on prolapse recurrence. While the difference between minimally invasive ventral rectopexy and individual comparators (abdominal rectopexy, resection rectopexy and perineal Delorme's procedure) was not statistically significant, ventral rectopexy was found to have statistically significantly lower recurrence rates when considering all comparator procedures together (RR=0.58, 95% CI 0.38 to 0.88; **Figure 5**). This was the only statistically significant difference supporting the claim of superior effectiveness of ventral rectopexy over comparators and was used to justify the economic model, however, the clinical validity of this approach is uncertain given the differences between different procedure groups and patient selection bias. Revision procedures were relatively rare, and no statistically significant differences were found in revision rates between the procedures.

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<sup>15</sup> Lechaux, D., Trebuchet, G., Siproudhis, L., & Campion, J. P. (2005). Laparoscopic rectopexy for full-thickness rectal prolapse: a single-institution retrospective study evaluating surgical outcome. *Surgical Endoscopy And Other Interventional Techniques*, 19(4), 514-518.

<sup>16</sup> Hu, B., Zou, Q., Xian, Z., Su, D., Liu, C., Lu, L., ... & Ren, D. (2022). External rectal prolapse: abdominal or perineal repair for men? A retrospective cohort study. *Gastroenterology Report*, 10, goac007.

## Pooled analysis of recurrence rates after minimally invasive ventral rectopexy for full-thickness rectal prolapse

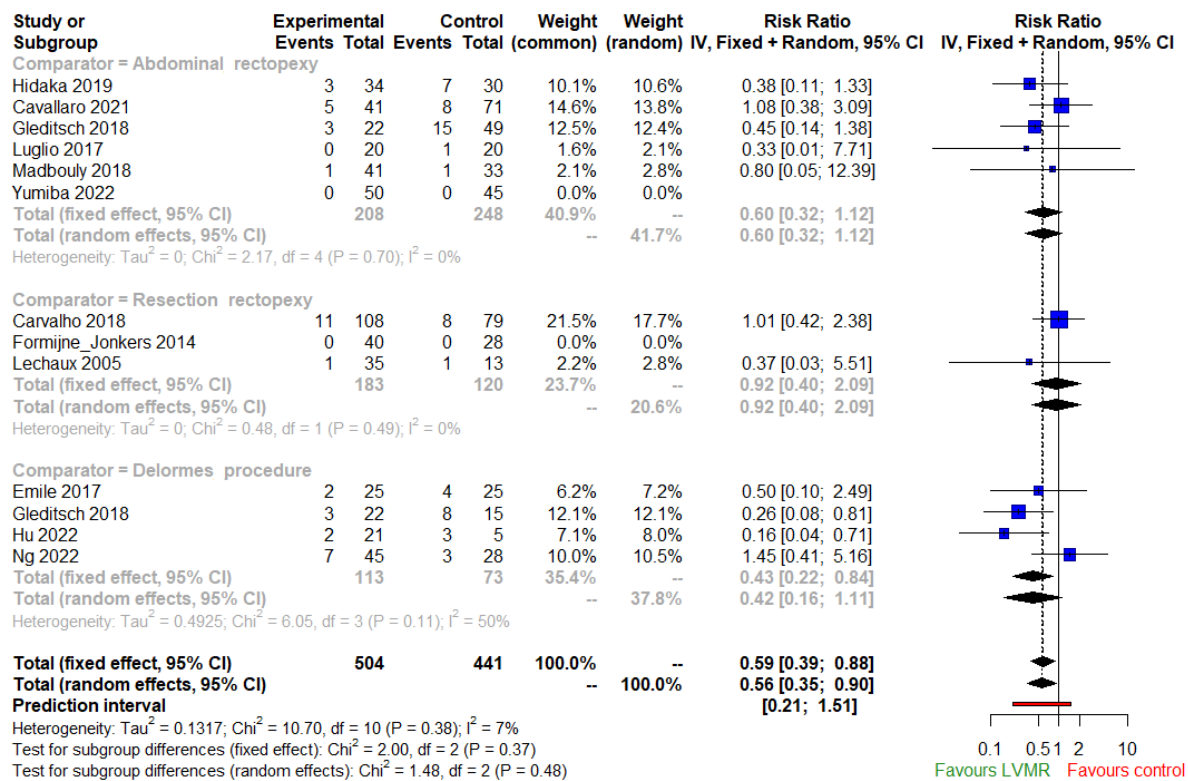


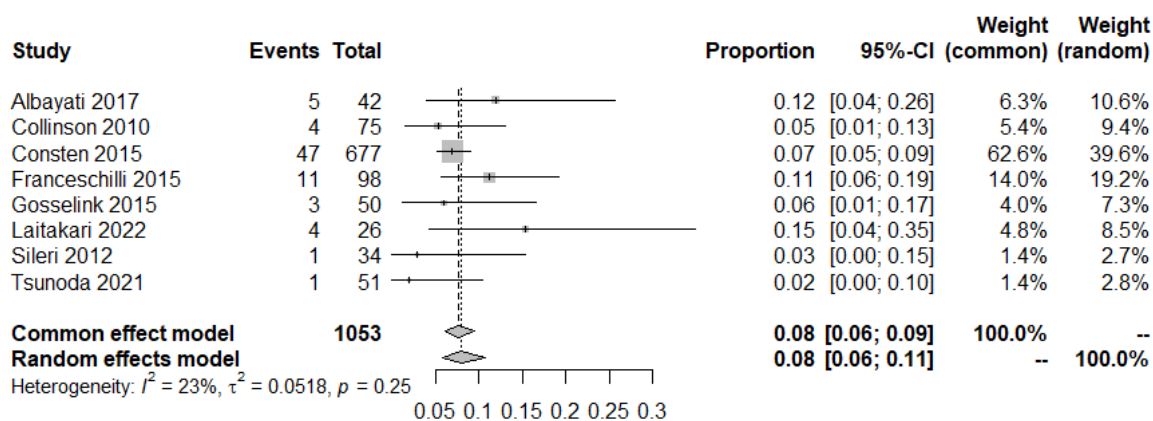
Figure 5 Pooled analysis of recurrence rates after minimally invasive ventral rectopexy for full-thickness rectal prolapse

## 12.2 Population B

Twelve papers with data from 999 patients reported on functional outcomes (as PROMs or symptom remission measures) of minimally invasive ventral rectopexy for rectoanal intussusception *versus* conservative management. Due to considerable heterogeneity in outcome measures and reporting, data could not be pooled. Most studies demonstrated significant improvement of symptoms (obstructed defecation, constipation and faecal incontinence) after minimally invasive ventral rectopexy, consistent with the body of evidence identified for Population A. The duration of this effect is uncertain, studies with longer follow-up suggest symptom recurrence in a proportion of patients. Some studies also reported worsening or new onset of symptoms in a proportion of patients (range, 0-14%).

The secondary outcomes of quality of life were largely consistent with the primary functional outcomes, with statistically significant improvements observed in the before-after comparison. The two RCTs found clinically important improvements in quality of life after LVMR. Data could not be pooled due to the heterogeneity of measures used.

Nine papers with data from 1,129 patients reported on prolapse recurrence. Recurrence rates ranged from 2.0-11.9%, with a pooled proportion of 8% (95% CI 6% to 11%; **Figure 6**). Revision procedure rates ranged from 2.0-24.0%, with a pooled proportion of 10% (95% CI 5% to 18%).



**Figure 6 Pooled analysis of recurrence rates after minimally invasive ventral rectopexy for rectoanal intussusception**

Although all studies except for one case series<sup>17</sup> were conducted overseas, no serious applicability concerns were identified. The evidence was considered to be largely applicable to the Australian setting.

Minimally invasive ventral rectopexy for full-thickness rectal prolapse is more effective than abdominal rectopexy, resection rectopexy and perineal Delorme's procedure, mainly due to the lower recurrence rates. The evidence was judged to be of moderate quality.

Minimally invasive ventral rectopexy for rectoanal intussusception is more effective than continued conservative management. The evidence was judged to be of low quality. No comparative evidence was found for the comparators of abdominal rectopexy and intra-anal Delorme's procedure.

## Clinical claim

The applicant claimed that:

- For patients with external rectal prolapse, compared with abdominal rectopexy the proposed intervention has superior safety (fewer adverse events and faster recovery) and superior effectiveness (lower rates of postoperative constipation).
- For patients with external rectal prolapse, compared with resection rectopexy (abdominal rectopexy with anterior resection) the proposed intervention has equivalent effectiveness, but superior safety (reduced pelvic sepsis and anastomotic leak) and requires a shorter hospital stay.
- For patients with external rectal prolapse compared with perineal repair using Delorme's procedure the proposed intervention has superior effectiveness (lower risk of recurrence) and noninferior safety.
- For patients with rectoanal intussusception, compared with conservative management the proposed intervention has superior effectiveness and inferior safety.

<sup>17</sup> Albayati, S., Morgan, M. J., & Turner, C. E. (2017). Laparoscopic ventral rectopexy for rectal prolapse and rectal intussusception using a biological mesh. *Colorectal Disease*, 19(9), 857-862.

No claims were made for the effectiveness and safety of ventral rectopexy in patients with rectoanal intussusception compared with abdominal rectopexy or intra-anal Delorme's procedure.

### **Population A**

The use of minimally invasive ventral rectopexy results in superior effectiveness compared with abdominal rectopexy, resection rectopexy or perineal Delorme's procedure in patients with full-thickness rectal prolapse.

The use of minimally invasive ventral rectopexy results in noninferior safety compared with abdominal rectopexy, resection rectopexy or perineal Delorme's procedure in patients with full-thickness rectal prolapse.

### **Population B**

The use of minimally invasive ventral rectopexy results in superior effectiveness compared with continued conservative management in patients with rectoanal intussusception.

The use of minimally invasive ventral rectopexy results in inferior safety compared with continued conservative management in patients with rectoanal intussusception.

## **13. Economic evaluation**

While the DCAR labelled the economic analysis as a cost consequence-analysis, this has been amended to more accurately reflect the fact that this was a cost comparison (as no health outcomes were included). The economic evaluation presents an incremental cost of ventral rectopexy compared with abdominal rectopexy and Delorme's procedure in patients with rectoanal intussusception and full-thickness rectal prolapse. Additionally, the combined results of the incremental cost of minimally-invasive ventral rectopexy are presented for both populations.

It is noted that while a cost-effectiveness analysis was deemed appropriate in terms of the clinical claims, this type of analysis was not undertaken. This was because, although there was some quality-of-life data available in the literature, these data were heterogenous in terms of patient characteristics, recording methodologies and procedures evaluated. Further, the only utility values that were identified did not correspond to the health states in the model (which related to recurrence, as the only statistically significant differences identified in the clinical effectiveness). As such, a partial economic analysis has been undertaken, and therefore no conclusions on the cost-effectiveness of MIVR can be made. The key differences between the intervention and comparators were determined through post procedural recurrent rates of rectal prolapse and costs of hospitalisation associated with the surgical repair of rectal prolapse.

A summary of key characteristics of the economic evaluation is provided in Table 5.

**Table 5 Summary of the economic evaluation**

Component	Description
Perspective	Health care system perspective
Population	There are two populations for this application: A. Patients with full-thickness rectal prolapse (Grade V Oxford Rectal Prolapse Scale) B. Patients with rectoanal intussusception (Grade III and Grade IV Oxford Rectal Prolapse Scale) with severe symptoms who have failed to improve with conservative management. Rectoanal intussusception is defined by the applicant as proven descent of the full-thickness of the rectal wall into the anal canal. Severe symptoms include faecal incontinence, obstructed defecation, and rectal ulceration.
Prior testing	N/A <sup>a</sup>
<ul style="list-style-type: none"> <li>Comparators</li> </ul>	For patients with rectal prolapse (population A) the comparators are: <ul style="list-style-type: none"> <li>abdominal rectopexy (other than by minimally invasive ventral rectopexy), whether alone or as part of a resection rectopexy</li> <li>perineal repair using a Delorme's procedure.</li> </ul> For patients with rectoanal intussusception (population B) the comparator is: <ul style="list-style-type: none"> <li>abdominal rectopexy</li> </ul>
Type(s) of analysis	Cost comparison
Outcomes	Primary outcome for all scenarios is the total incremental cost per procedure
Time horizon	Lifetime
Computational method	Decision tree analysis
Generation of the base case	Modelled evaluation
Health states	N/A
Cycle length	N/A
Transition probabilities	Sources outlined in Table 48 of the DCAR.
Discount rate	N/A
Software	TreeAge Pro 2019

<sup>a</sup> Prior testing would occur in all treatment arms and therefore there will be no difference in the cost of this testing across procedures. As such the cost of prior testing was not considered in the model.

<sup>b</sup> Continued conservative management was listed as a comparator for population B in the Ratified PICO, however as the cost of conservative management is consistent across all arms, this comparator was not considered in the model.

The model was conducted in TreeAge Pro 2019 using a decision tree model to determine the cost differences between each procedure. Key inputs into the model include procedural costs sourced from MBS online, recurrence rates determined by a meta-analysis conducted for the DCAR and the cost of hospitalisation for all procedures.

Due to limited published and readily available cost-effectiveness data for populations A (rectal prolapse) and B (rectoanal intussusception), various assumptions are required in the model. It is noted that recurrence rates for all procedures in the population with full-thickness rectal prolapse are used as a proxy in both populations. This is due to limited availability of data for patients with rectoanal intussusception, meaning that a comparative meta-analysis could not be conducted. As such, the structure of the economic model is not separated between the two populations as the differentiating factor (recurrence rates) between procedures is consistent across both populations. The differentiating factor in the economic model between the full-thickness rectal prolapse and the rectoanal intussusception populations would have been the rate of recurrence of disease (either rectal prolapse or rectoanal intussusception) and therefore the need for a



revision procedure, and as the same recurrence rate is used across both populations, there is no longer a need to stratify by population as each strata would produce the same outcome.

Additionally, while conservative management was listed as a comparator for Population B, the proportion of people with rectoanal intussusception that utilise conservative treatment is not subject to change post the listing of the proposed MBS item for minimally-invasive ventral rectopexy. This is because patients that fall into this group will continue to undertake conservative management with or without the introduction of a new MBS item due to conservative management being the mainstay of treatment for this group. Therefore, as the utilisation and cost of conservative management does not differ between the intervention and comparators pre and post the listing of the proposed MBS item, there will be a net zero offset in the cost of this procedure and as such it was not included in the decision tree.

The recurrence rates of disease, and therefore the rates of patients requiring a revision procedure, have been determined through meta-analysing data sourced from various studies for all procedures. As presented in the clinical evaluation in Section 2, the results of the meta-analysis show that when considered in isolation, there is no statistical difference between the intervention and the proposed comparators in terms of recurrence rates across both populations. However, it is noted that the sample sizes analysed in each study are small and therefore there is a degree of uncertainty in calculating this rate, and a possibility of underestimating the impact of the different procedures. As such, the overall population risk ratio which aggregates the total population across minimally-invasive ventral rectopexy compared abdominal rectopexy, resection rectopexy, Delorme's procedure and RVMR was used to decrease uncertainty. When using this population, the meta-analysis determined a statistically significant result between recurrence rates for minimally-invasive ventral rectopexy and its comparative procedures.

The total cost of hospitalisation for each procedure was sourced from Independent Hospital Pricing Authority National Hospital Cost Data Collection (NHCDC) Round 22 to 24. It was confirmed by the Department that the DRG for all procedures is G02C, Major Small and Large Bowel Interventions, Minor Complexity.

Overall results of the economic evaluation are detailed in Table 6 comparing the costs of ventral rectopexy (plus recurrence) compared with abdominal rectopexy and Delorme's procedure (plus recurrence). As previously stated, the key difference between procedures is the cost of the procedure and the recurrence of disease associated with each procedure (including the hospitalisation costs). The results therefore present the costs of undertaking minimally-invasive ventral rectopexy plus one revision procedure (required in 9% of patients) compared with the cost of undertaking the other two procedures plus revision procedure (required in 16% of patients).

Overall, an incremental cost saving of \$507 is apparent for minimally-invasive ventral rectopexy compared with Delorme's procedure and \$1,273 when compared with abdominal rectopexy when considering the total cost of each procedure. Additionally, as the rate of recurrence for minimally-invasive ventral rectopexy is lower compared with all other procedures, hypothetically in the long run as uptake increases for this procedure better outcomes for patients in both populations will be realised.

Table 6 details the total cost and incremental cost of minimally-invasive ventral rectopexy when compared with abdominal rectopexy and Delorme's procedure. It is noted that costs have been rounded to the nearest dollar.

**Table 6 Incremental cost of ventral rectopexy**

Strategy	Cost	Incremental Cost
Ventral rectopexy	\$22,553	-
Abdominal rectopexy	\$23,826	-\$1,273
Delorme's procedure	\$23,060	-\$507

There is a degree of uncertainty surrounding the recurrence rates for minimally-invasive ventral rectopexy, abdominal rectopexy and Delorme's procedure. As such, a sensitivity analysis was conducted to test the total population risk ratio confidence interval at 95% for each individual procedure and the population-specific risk ratio in different scenarios. This allowed a systematic approach in identifying the degree to which the recurrence rate impact the model. The change in the incremental cost of each procedure was assessed as the main outcome in the analysis.

Higher and lower risk ratios were tested for abdominal rectopexy and Delorme's procedure. These values were determined by calculating the 95% confidence interval risk ratios from the base case risk ratio (0.38; 0.88). When the risk ratio is decreased from 0.58 to 0.38, minimally-invasive ventral rectopexy is less costly compared to both procedures. However, in the scenario where the risk ratio for Delorme's procedure is increased to 0.88, ventral rectopexy is only less costly than abdominal rectopexy and has an incremental cost of \$675 compared to Delorme's procedure.

Risk ratios calculated by meta-analysing procedure-specific study results were tested in multiple scenarios. In the first scenario the risk ratio was calculated by analysing the total population in studies that compared ventral rectopexy with abdominal rectopexy (0.60). The second scenario considers the risk ratio calculated by totalling the population in studies that compared ventral rectopexy compared with Delorme's procedure (0.42). Both scenarios presented an incremental cost saving for ventral rectopexy.

An additional scenario analysis was conducted using MBS data provided by the Department on the number of patients receiving revision surgeries for minimally-invasive ventral rectopexy, abdominal rectopexy and Delorme's procedure within 10 years of their previous surgery. The MBS data available presents figures for the number of patients who have had the same revision procedure as their first procedure a second or subsequent time. These data showed that 9% of patients had a subsequent minimally-invasive ventral rectopexy, 6.5% had a subsequent abdominal rectopexy and 6.2% had a subsequent Delorme's procedure over 2019-20 to 2021-22. However, the Department has noted a number of limitations associated with the interpretation of this data, as outlined in Section 3.3.

It is noted that the relapse rates in the base case model are based on two factors: the recurrence rate in minimally-invasive ventral rectopexy and the comparative difference (relative risk) between minimally-invasive ventral rectopexy, abdominal rectopexy and Delorme's procedure. As the aim is to quantify the difference between minimally-invasive ventral rectopexy and its comparators, the impact of the risk ratio is more relevant than the individual MBS relapse rate for all procedures. As such, this scenario considers where minimally-invasive ventral rectopexy is 9% and the relapse rate for the comparators is calculated based on the comparative difference between minimally-invasive ventral rectopexy and the comparators (16% for both abdominal rectopexy and Delorme's procedure). Including the baseline relapse rate for minimally-invasive ventral rectopexy based on real world data will increase the certainty of the analysis. The results of this analysis again present an incremental cost saving for ventral rectopexy). Finally, the recurrence rate for ventral rectopexy was in a sensitivity analysis at 7% and 13%. Similarly, the results present an incremental cost saving for ventral rectopexy in comparison to both procedures.

Finally, a scenario analysis was conducted to assess the impact of patients that receive a different revision procedure after the initial procedure. It may be more likely that patients choose abdominal rectopexy or minimally-invasive ventral rectopexy over Delorme's procedure as a revision procedure. This is because Delorme's procedure is considered to have higher recurrence of disease and more complications as per the PICO 'Because of high recurrence rates, the applicant has advised that this procedure is usually only used in an elderly frail population'. As such, two scenarios were considered; a scenario where the cost of a revision procedure for minimally-invasive ventral rectopexy is the same as the cost of abdominal rectopexy and another scenario where the cost of a revision procedure for abdominal rectopexy is the same as the cost of minimally-invasive ventral rectopexy. The results of this analysis show that in both scenarios where the revision procedure has been changed to reflect an alternative procedure (minimally-invasive ventral rectopexy or abdominal rectopexy), a cost saving is realised.

## 14. Financial/budgetary impacts

The financial implications of listing minimally-invasive ventral rectopexy on the Medicare Benefits Schedule (MBS) for both patients with full-thickness rectal prolapse and rectoanal intussusception were estimated using a market share approach.

To determine the financial impact of listing MBS Item for minimally-invasive ventral rectopexy on the MBS, the change in service usage of ventral rectopexy, abdominal rectopexy, Delorme's procedure (intra-anal and perineal) and proposed minimally-invasive ventral rectopexy MBS item were forecasted. This was determined by evaluating the number of patients claiming and co-claiming for MBS items associated with the surgical repair of rectal prolapse in populations A (rectal prolapse) and B (rectoanal intussusception), separately and combined. It is noted claim data sourced for MBS item 32111 (Delorme's procedure) is not separated by the procedural approach (intra-anal or perineal) and therefore the approach is assumed to be agnostic across populations.

The total number of patients claiming for 32117 (ventral rectopexy and abdominal rectopexy combined) was provided by the Department and is based on MBS claims data. As stated in the ratified PICO, the applicant and clinical expert estimate that 'at least 50% of procedures currently claimed under MBS item 32117 are for ventral rectopexy procedures, and 20-30% of these procedures are for patients with rectoanal intussusception.' As other available data are limited, it is assumed that the number of services claimed for each respective procedure was evenly split (50%) across both populations. Additionally, in line with the ratified PICO, the proportion of ventral rectopexy procedures claimed for rectoanal intussusception was 30%, and therefore it is assumed that 70% of the ventral rectopexy procedures are claimed for full-thickness rectal prolapse. This assumption is consistent across all procedures, including Delorme's procedure due to limitations of available and relevant data.

MBS item 32117 is also often co-claimed with either pelvic floor repair (35595), Colposacrosuspension (35597) or anterior resection (32024). It is not possible with the available data to determine which of these items are claimed for ventral rectopexy or abdominal rectopexy, and therefore it was assumed that co-claimed items 35595 and 35597 are claimed for ventral rectopexy and 32024 is claimed for abdominal rectopexy. This follows the same logic described in the ratified PICO that states 'items 35595 and 35597 are often co-claimed with item 32117' and 'abdominal rectopexy is often co-claimed with an item for anterior resection (32024) to perform a resection rectopexy'. Service use data was sourced directly from the Department for MBS items 32117, 35595, 35597 and 32024, and from the Department of Human Services for MBS item 32111.

Based on advice from the Department and for the purpose of calculating the cost of anaesthesia to the MBS in all scenarios, minimally-invasive ventral rectopexy was defined as claims for item 32117 co-claimed with item 35595 and/or 35597. As such, the cost and proportional use of anaesthesia items associated with minimally-invasive ventral rectopexy were attributed to patients that utilise MBS item 32117 co-claimed with item 35595 and/or 35595. Similarly, abdominal rectopexy was defined as claims for item 32117 without co-claims of item 35595 and/or 35597. Therefore, all variations of claims that include item 32117 but not item 35595 and/or 35597 were attributed to abdominal rectopexy. This method of costing anaesthesia differs from the definition of claims described in the above paragraph, however as the cost and utilisation of these procedures are small there will be minimal cost differences between the two approaches.

As provided by the Department and based on 2021-2022 MBS data, the most commonly claimed anaesthesia items for each procedure were included in the model. Ventral rectopexy anaesthesia items include 20806, 20841 and 20844, abdominal rectopexy anaesthesia items include 20806, 20841 and 20840, and Delorme's procedure anaesthesia items include 20902, 20740 and 20810. As the proportion of claims for these items and subsequently the respective procedures were not equal to 100%, a weighted average was used to determine the utilisation of these items across each procedure.

An inflation rate of 5% has been applied to claims data for 32117 and the proposed MBS item over six years and is calculated using the last 10 years of claims data for item 32117. Although the moving average of claims data is often used to determine the inflation rate, claims data for 32117 prior to 2012 is inconsistent and unreliable. This is likely due to the instability of claims data typically around the first few years of listing an item and therefore data from 2012-2022 provides a more realistic view of claiming trends. Additionally, Delorme's procedure assumed an inflation rate of 8% which reflects the average annual growth of claims data for Delorme's procedure from 2012-2022.

As noted in the clinical evaluation section, there is a statistically significant difference in recurrence rates between the intervention and comparators, and as such the cost of recurrence was included in the financial model. As detailed in the economic evaluation, recurrence rates were meta-analysed and consisted of various sources outlined in Section 2. Due to limited availability of data surrounding rectoanal intussusception, the recurrence rates for all procedures in this group of patients is assumed to be the same as the rates used for population A. It is noted that the prevalent population rather than the incident population was used to calculate the total number of patients where revision procedures were required as the time to recurrence can occur between 3 to 48 months post procedure (Gleditsch et al., 2018).

The PICO notes that with the proposed listing of minimally-invasive ventral rectopexy on the MBS, a proportion of Delorme's procedures would be replaced by ventral rectopexy. Therefore, using the replacement rate of Delorme's procedure with ventral rectopexy (15%), the total number of patients for whom ventral rectopexy replaces Delorme's procedure was calculated. It was agreed with the Department and clinical experts that there is insufficient evidence surrounding the replacement rate and therefore this proportion was tested in a threshold analysis.

It is noted that some patients undergoing a ventral rectopexy may face out of pocket costs, including the cost of a prosthesis (mesh or graft) and a laparoscopic tacking device if used, subject to their private health insurance coverage. Many of the meshes and the laparoscopic tacking device typically used in ventral rectopexy procedures are listed on the Prostheses List, so private health insurers will cover the cost of these consumables through the payment of a benefit, if the patient is covered. The benefits for meshes and grafts range from \$72 to \$721 and

the benefit for the laparoscopic tacking device is \$374 (noted that the tacking device will be removed from the prostheses list).

Under the proposed MBS item for minimally-invasive ventral rectopexy, a surgeon will have the discretion to use a medical surgical assistant to assist with the procedure and will be able to claim surgical assistance item 51300 or 51303. This is currently the case for ventral and abdominal rectopexies (performed under item 32117) and Delorme's procedures (previously performed under item 32111 and now performed under item 32233). These surgical assistance items are derived fees (set as a 20 percent of the schedule fee), so if the introduction of the proposed MBS item is expected to lead to higher schedule fees (taking co-claims and the multiple operation rule into account) then it is expected that surgical assist costs will also be higher. As the additional surgical assistant costs are predicted to be small, these costs have not been factored into the financial model.

The difference in utilisation of ventral rectopexy, abdominal rectopexy, Delorme's procedure, proposed minimally-invasive ventral rectopexy MBS item and anaesthesia items associated with these procedures are detailed in Table 7 for populations A (rectal prolapse).

**Table 7**      **Difference in utilisation of MBS items for patients with full-thickness rectal prolapse that undertake ventral rectopexy under the proposed minimally-invasive ventral rectopexy MBS Item over six years (2022-2027)**

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
<b>Difference in utilisation of services</b>						
Total claims for 20806 (anaesthesia item)	109	117	126	136	146	157
Total claims for 20841 (anaesthesia item)	2	2	3	3	4	5
Total claims for 20844 (anaesthesia item)	26	27	29	31	33	35
Total claims for 20840 (anaesthesia item)	-9	-10	-10	-10	-11	-12
Total claims for 20902 (anaesthesia item)	-108	-117	-126	-135	-146	-157
Total claims for 20740 (anaesthesia item)	-10	-11	-12	-13	-14	-15
Total claims for 20810 (anaesthesia item)	-7	-8	-8	-9	-10	-10
Ventral rectopexy under 32117	-309	-324	-339	-356	-373	-390
Abdominal rectopexy under 32117	0	0	0	0	0	0
Delorme's procedure under 32111	-125	-135	-146	-157	-169	-182
Proposed MBS item for minimally-invasive ventral rectopexy	435	459	485	513	542	573

VR=Ventral Rectopexy, AR=Abdominal Rectopexy, MBS=Medical Benefits Scheme

The number of patients reflects data provided by the Department on the number of episodes claimed for each procedure. It is noted that the number of patients is not always equivalent to the number of episodes (as some patients may require more than one episode of care). For these procedures, the number of patients and number of episodes are not equivalent but are within a difference of about 0.5% of the true patient population.

Claims data for MBS item 32117 includes claims of 32117 as a standalone item and with other items, except for 32024, 35595 and 35597.

Below details the difference in utilisation of the intervention (proposed minimally-invasive ventral rectopexy MBS item) and comparators (abdominal rectopexy and Delorme's procedure), and their associated anaesthesia MBS items. All claims include changes in utilisation of recurrence rates and co-claimed items for population B (rectoanal intussusception).

**Table 8 Utilisation and difference in the of number of patients with rectoanal intussusception that undertake ventral rectopexy under the proposed minimally-invasive ventral rectopexy MBS Item over six years (2022-2027)**

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
<b>Difference in utilisation of services</b>						
Total claims for 20806 (anaesthesia item)	47	50	54	58	63	67
Total claims for 20841 (anaesthesia item)	1	1	1	1	2	2
Total claims for 20844 (anaesthesia item)	11	12	12	13	14	15
Total claims for 20840 (anaesthesia item)	-4	-4	-4	-4	-5	-5
Total claims for 20902 (anaesthesia item)	-46	-50	-54	-58	-63	-67
Total claims for 20740 (anaesthesia item)	-4	-5	-5	-5	-6	-6
Total claims for 20810 (anaesthesia item)	-3	-3	-4	-4	-4	-4
Ventral rectopexy under 32117	-132	-139	-145	-152	-160	-167
Abdominal rectopexy under 32117	0	0	0	0	0	0
Delorme's procedure under 32111	-54	-58	-62	-67	-73	-78
Proposed MBS item for minimally-invasive ventral rectopexy	186	197	208	220	232	245

VR=Ventral Rectopexy, AR=Abdominal Rectopexy, MBS=Medical Benefits Scheme

The number of patients reflects data provided by the Department on the number of episodes claimed for each procedure. It is noted that the number of patients is not always equivalent to the number of episodes (as some patients may require more than one episode of care). For these procedures, the number of patients and number of episodes are not equivalent but are within a difference of about 0.5% of the true patient population.

Claims data for MBS item 32117 includes claims of 32117 as a standalone item and with other items, except for 32024, 35595 and 35597.

All procedures are performed in-hospital and therefore a 75% benefit is applied to the scheduled MBS fee. Where items are co-claimed, the Multiple Operations Rule (MOR) was applied where the second and third highest cost for surgical co-claimed items are charged at 50% and 25%, respectively. For example, the cost of co-claimed items 32117, 35595 and 32024 is \$1,082 + (50% x \$996) + (25% x \$495) = \$1,704.

The MBS costs associated with treating patients with full thickness rectal prolapse in a world without the proposed minimally-invasive ventral rectopexy item is estimated to be approximately \$1,162,592 (year 1), and in a world with the proposed minimally-invasive ventral rectopexy item is estimated to be approximately \$1,220,868 (year 1).

**Table 9 Cost of listing the proposed minimally-invasive ventral rectopexy MBS item, patients with full-thickness rectal prolapse**

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
<b>Increase in costs to the MBS (full-thickness rectal prolapse)</b>						
<b>World without proposed MBS item</b>						
Cost to the MBS	\$1,050,344	\$1,113,258	\$1,180,166	\$1,251,336	\$1,327,053	\$1,407,625
Other MBS costs	\$112,248	\$119,215	\$126,639	\$134,552	\$142,988	\$151,982
Net cost to the MBS budget	\$1,162,592	\$1,232,473	\$1,306,805	\$1,385,888	\$1,470,041	\$1,559,607
<b>World with proposed MBS item</b>						
Cost to the MBS	\$1,101,237	\$1,169,053	\$1,241,289	\$1,318,248	\$1,400,255	\$1,487,656
Other MBS costs	\$119,630	\$127,144	\$135,156	\$143,701	\$152,816	\$162,542
Net cost to the MBS budget	\$1,220,868	\$1,296,197	\$1,376,445	\$1,461,949	\$1,553,071	\$1,650,197
<b>Difference in cost to MBS</b>						
Cost to the MBS budget	\$58,276	\$63,724	\$69,640	\$76,061	\$83,030	\$90,590

For patients with rectoanal intussusception, the cost of the proposed MBS item to the MBS in year 1 is approximately \$523,407 in the scenario without the proposed item and \$545,218 in the scenario where minimally-invasive ventral rectopexy MBS listed.

**Table 10 Cost of listing the proposed minimally-invasive ventral rectopexy MBS item, patients with rectoanal intussusception**

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
<b>Increase in costs to the MBS (full-thickness rectal prolapse)</b>						
World without proposed MBS item						
Cost to the MBS	\$523,407	\$553,872	\$586,216	\$620,562	\$657,041	\$695,794
Other MBS costs	\$56,329	\$59,707	\$63,301	\$67,124	\$71,191	\$75,520
Net cost to the MBS budget	\$579,735	\$613,579	\$649,517	\$687,686	\$728,233	\$771,313
<b>World with proposed MBS item</b>						
Cost to the MBS	\$545,218	\$577,784	\$612,412	\$649,239	\$688,414	\$730,092
Other MBS costs	\$59,492	\$63,105	\$66,951	\$71,045	\$75,403	\$80,045
Net cost to the MBS budget	\$604,710	\$640,889	\$679,363	\$720,284	\$763,817	\$810,138
<b>Difference in cost to MBS</b>						
Cost to the MBS budget	\$24,975	\$27,310	\$29,846	\$32,598	\$35,584	\$38,824

When combining results for both population A (rectal prolapse) and B (intussusception), listing the proposed minimally-invasive ventral rectopexy MBS item would result in an increase in MBS expenditure over 6 years of \$83,251 (year 1) and \$129,414 (Year 6).



**Table 11 Total combined cost to the Australian healthcare system for the listing of minimally-invasive ventral rectopexy**

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
<b>Combined costs to the healthcare budget</b>						
World without the MBS item						
Full-thickness rectal prolapse	\$26,729,303	\$28,492,355	\$30,377,373	\$32,393,114	\$34,548,982	\$36,855,074
Rectoanal intussusception	\$12,924,378	\$13,750,193	\$14,631,636	\$15,572,622	\$16,577,347	\$17,650,315
Total (combined full-thickness rectal prolapse and rectoanal intussusception)	\$39,653,681	\$42,242,547	\$45,009,009	\$47,965,736	\$51,126,329	\$54,505,389
World with the MBS item						
Full-thickness rectal prolapse	\$26,787,579	\$28,556,079	\$30,447,012	\$32,469,175	\$34,632,012	\$36,945,664
Rectoanal intussusception	\$12,949,353	\$13,777,503	\$14,661,482	\$15,605,219	\$16,612,931	\$17,689,139
Total (combined full-thickness rectal prolapse and rectoanal intussusception)	\$39,736,932	\$42,333,582	\$45,108,494	\$48,074,394	\$51,244,942	\$54,634,803
<b>Difference in costs (increase in costs)</b>						
Full-thickness rectal prolapse	\$58,276	\$63,724	\$69,640	\$76,061	\$83,030	\$90,590
Rectoanal intussusception	\$24,975	\$27,310	\$29,846	\$32,598	\$35,584	\$38,824
Total (combined full-thickness rectal prolapse and rectoanal intussusception)	\$83,251	\$91,034	\$99,485	\$108,659	\$118,614	\$129,414

A sensitivity analysis was conducted to assess key outcomes at different thresholds to evaluate the change in the financial impact for each testing parameter. These outcomes include the difference in the net cost to the MBS and healthcare budget for both populations A (rectal prolapse) and B (rectoanal intussusception) combined.

The model was most sensitive to the replacement rate of minimally invasive ventral rectopexy with Delorme's procedure and the inflation rate of Delorme's procedure. When the replacement rate altered by  $\pm 10\%$  from the base case (15%), the difference in costs to the healthcare budget changed by approximately 95% by year 6. Similarly, when the growth rate of Delorme's procedure was increased by 10% to 18% from the base case (8%), the difference in costs to the healthcare budget changed by approximately 82% by year 6. For all other inputs tested at the 10% threshold in the analysis, the maximum change to the difference in the healthcare budget was 15%.

## 15. Other relevant information

No additional relevant information is provided.

## 16. Key issues from ESC to MSAC

### Main issues for MSAC consideration

#### Clinical issues:

- For population A (patients with full-thickness rectal prolapse), VR has non-inferior safety and superior effectiveness compared with abdominal rectopexy, resection rectopexy or perineal Delorme's procedure (moderate-quality evidence).
- For population B (patients with rectoanal intussusception), VR has inferior safety and superior effectiveness compared with continued conservative management (low-quality evidence). No evidence was found to compare it against usual surgical techniques (abdominal rectopexy and intra-anal Delorme's procedure) in this population, but these techniques are used in clinical practice and are relevant comparators.
- Small patient numbers in each reported group make the studies underpowered; follow-up times are limited, meaning longer-term outcomes are unclear. However, no significant safety concerns were detected in the evidence base and longer-term follow up is likely to demonstrate superiority due to reduced relapse rates.

#### Economic issues:

- The economic evaluation does not match that specified in the PICO and is constrained by lack of data.
- The economic evaluation found that when recurrence rates were considered, the intervention is cost-effective relative to usual care. If clinical benefits are realised in practice (lower recurrence rates; better facility performance as surgeons become familiar with the technique) cost-effectiveness will further improve.

#### Financial issues:

- Listing this item will incur a cost to the MBS over the next 6 years, but is cost-saving over a patient's lifetime.

#### Fee and Item descriptor issues:

- The fee of \$1,557.40 is reasonable as it is comparable with sacral colpopexy in terms of surgical difficulty, and is more technically difficult than suture rectopexy or posterior mesh rectopexy.
- ESC suggested the item descriptor include reference to the need to use diagnostic imaging to confirm diagnosis of rectoanal intussusception (population B); and to the use of a prosthetic mesh and full mobilisation of the anterior plane of the rectum to the pelvic floor to differentiate VR from other rectopexy procedures. ESC also considered that removal of the reference to the Oxford scale and that a restriction to two VR procedures per patient was reasonable.

#### Other relevant information:

- VR is gaining favour as the preferred technique among colorectal surgeons. It is unlikely that more evidence could be obtained from RCTs in the future, as surgeons would be unwilling to randomise patients to the alternative techniques.

### ESC discussion

ESC noted that this is an application from the Colorectal Surgical Society of Australia and New Zealand requesting Medicare Benefits Schedule (MBS) listing of ventral rectopexy (VR) for treatment of rectal prolapse and rectoanal intussusception. MSAC has not previously considered VR for treatment of these conditions.

ESC noted that VR is currently performed in Australia. It has been reimbursed under MBS item 32117 (abdominal rectopexy), because a specific item for VR did not exist. The applicant has stated item 32117 does not reflect the increased technical difficulty of VR and it is therefore often co-claimed with MBS items 35595 (pelvic floor repair) or 35597 (colposacrosuspension).

The Colorectal Subcommittee of the MBS Taskforce recommended a new item be created for VR to differentiate it from other abdominal rectal prolapse repairs and to allow for a suitable fee. In July 2022 the Australian Government amended MBS item 32117 to exclude ventral mesh rectopexy and introduced a new temporary item for VR (MBS item 32118).

ESC noted that the applicant proposed two populations for this procedure:

- population A – full-thickness rectal prolapse (Grade V Oxford Rectal Prolapse Scale).
- population B – rectoanal intussusception (Grade III and IV Oxford Rectal Prolapse Scale) with severe symptoms who have failed to improve with conservative management.

ESC considered that the MBS item descriptor should remove references to the Oxford scale and replace them with descriptive terminology. A reference to the Oxford scale could be included in an Explanatory Note if required.

ESC considered that the item descriptor should include wording referring to the use of a prosthetic mesh and full mobilisation of the anterior plane of the rectum to the pelvic floor to differentiate it from other rectopexy procedures.

ESC considered that confirmation of internal rectal prolapse through the use of appropriate diagnostic imaging be added to the item descriptor as a prerequisite to use. ESC however considered that it was unnecessary to specify the required diagnostic imaging modalities (e.g. defaecography or proctography) as these may change over time.

ESC noted a specialist collective group response from the Urogynaecological Society of Australasia (UGSA) was supportive of VR. The response questioned the inclusion of the “associated pelvic floor repair incorporating the fixation of the uterosacral and cardinal ligaments to rectovaginal and pubocervical fascia for symptomatic upper vaginal prolapse” phrase in the item descriptor, as this is not an intrinsic component of VR. ESC noted that this phrase had been included to ensure that, when it is used, it is considered part of the operation and not co-claimed separately. ESC considered that the existing wording “where relevant” before the pelvic floor repair phrase was sufficient to indicate that this was not an intrinsic part of the procedure. ESC considered that simplifying the wording around this (for example, “including, where relevant, pelvic floor repair for symptomatic upper vaginal vault prolapse”) may be appropriate.

ESC considered that multidisciplinary team discussions were not required for patient selection, as it is difficult to achieve in private practice and a requirement could limit patient access to VR.

ESC considered that no age limitations should apply to the item descriptor. Although the relevant conditions are more common in older people, they can occur at any age. ESC noted that a 14-day aftercare period is appropriate, which matches MBS items 32117 (abdominal rectopexy) and 35597 (sacral colpopexy). VR usually involves a one-night stay in hospital (Type A private health insurance category).

ESC considered that it is reasonable to allow VR to be performed twice on the same patient. Revision may occasionally be needed but is difficult due to scar tissue and adhesions. If VR failed twice, a different procedure would likely be used, so a limit of two VR procedures is reasonable.

ESC considered that VR should be performed by a colorectal surgeon, or general surgeons with a sub-specialist interest in colorectal surgery (as is the case with the currently used items for this procedure). Restricting the item to colorectal surgeons only could exclude patients in regional areas from having access to the procedure. ESC considered that no mandate for further specific

training was required as accredited colorectal surgeons and those with a sub-speciality in colorectal surgery would be adequately trained in this procedure as part of their standard training.

ESC summarised that the item descriptor requires some re-wording. Proposed changes would include: removing the references to the Oxford scale and replacing them with descriptive terminology; referring to the need for diagnostic imaging to confirm diagnosis of internal rectal prolapse; and referring to the use of prosthetic mesh and full mobilisation of the anterior plane of the rectum to the pelvic floor.

ESC considered the proposed fee (\$1,557.40) to be reasonable as the surgical complexity of the procedure is comparable with sacral colpopexy (also \$1557.40) and is more difficult than rectopexy techniques covered under MBS item 32117 (\$1,328).

ESC noted that no consumer responses were received during public consultation for this application. Consumer concerns identified in the literature may include mesh complications, which can require further surgery to repair.<sup>18</sup>

ESC noted the comparators for VR in the DCAR as follows:

- For population A (external prolapse), the comparators were abdominal rectopexy, resection rectopexy and mucosal sleeve resection (also called Delorme's procedure).
- For population B (rectoanal intussusception) the comparator was continued conservative management.

ESC noted the two other relevant comparators for population B stated in the PICO (abdominal rectopexy and intra-anal Delorme's procedure) did not have enough data to be considered. This limited the Department-contracted assessment report (DCAR) analysis.

ESC noted that the DCAR supported the clinical safety claim that VR has non-inferior safety compared with abdominal rectopexy, resection rectopexy or perineal Delorme's procedure for population A (moderate-quality evidence) and inferior safety compared with continued conservative management for population B (low-quality evidence). ESC considered the safety claims to be uncertain as none of the studies were powered for safety outcomes and follow-up times were limited, making longer-term outcomes unclear.

Regarding comparative effectiveness, ESC noted the DCAR supported the clinical effectiveness claim that VR has:

- superior effectiveness compared with abdominal rectopexy, resection rectopexy and perineal Delorme's procedure for population A, mainly due to the lower recurrence rates (moderate-quality evidence)
- superior effectiveness compared with continued conservative management for population B (low-quality evidence). Again, no comparative evidence was found for the effectiveness of alternative surgical techniques of abdominal rectopexy and intra-anal Delorme's procedure.

ESC noted that for both populations, there was considerable heterogeneity in outcome measures and reporting and so data could not be pooled across studies. While the difference between VR and the individual comparators was not statistically significant for any outcomes, VR was found to have statistically significantly lower recurrence rates when considering all comparator

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<sup>18</sup> Loh KC & Umanskiy K (2021). [Ventral rectopexy](#). *Clinics in Colon and Rectal Surgery* 34(1):62–68.

procedures together (10% compared with 18% respectively). ESC noted that this was the only statistically significant difference supporting the claim of superior clinical effectiveness of VR compared with all comparators.

ESC noted the applicant's statement in its pre-ESC response that more than 60% of colorectal surgeons in Australia, the UK and the USA now regard VR as the preferred operation for rectal prolapse. ESC agreed that the technique is gaining momentum and is likely to replace other options over time and noted that this meant that equipoise between VR and other techniques has been lost, reducing the likelihood of further comparative clinical studies.

ESC noted that the DCAR conducted a cost-consequence analysis, rather than a cost-effectiveness analysis/cost-utility analysis as stipulated in the PICO. ESC noted that the DCAR stated that no utilities were available to apply to health states to inform a cost-utility analysis, and so the DCAR quantified the incremental cost per procedure over a lifetime. ESC noted that as no statistically significant differences were identified across procedures in terms of adverse events, length of hospital stay or utilities, the economic model in the DCAR used the post-procedural recurrence rates of rectal prolapse (10.44% for VR, 18% for abdominal rectopexy and 18% for Delorme's procedure). Populations A and B were not differentiated in the model due to insufficient data.

ESC noted the incremental cost per procedure over a lifetime (including the costs of recurrences) was less for VR compared with abdominal rectopexy (incremental cost -\$1,273) and Delorme's procedure (-\$507). ESC noted the sensitivity analysis showed that VR is less costly compared to abdominal rectopexy and Delorme's procedure in almost all scenarios.

ESC noted the cost-consequence approach used by the DCAR differed from the PICO statement due to lack of robust comparative outcome data, uncertainty and limited data surrounding adverse events with each procedure. ESC considered however that the significant difference in recurrence rate should translate into a meaningful clinical benefit and ultimately affect health outcomes, but that the data from the studies was limited in terms of follow-up. ESC acknowledged the limitations of the clinical data and considered that the DCAR took a pragmatic approach given the limitations of the evidence.

ESC therefore considered that when considering recurrence rates, the intervention is cost-effective relative to usual care. If further clinical benefits are realised in practice the cost-effectiveness of the intervention will improve.

ESC noted that the applicant's pre-ESC response raised several issues with the data used in the economic evaluation and assumptions, including the short follow-up period for the included studies and likelihood that the available literature overestimates the recurrence and complications for VR given improvements related to the learning curve and additional experience of surgeons currently. ESC agreed with the applicant that relative outcomes from VR will likely improve over time as surgeons become more proficient with the technique.

ESC noted the financial impact estimate that over the next 6 years there would be modest additional costs to the MBS due to the higher initial cost of VR and additional anaesthesia. These additional costs rose from \$83,251 in Year 1 to \$129,414 in Year 6. These results are sensitive to the replacement rate between VR and Delorme's procedure (assumed 15%) and the inflation rate of the cost of Delorme's procedure (8%).

ESC noted that other costs related to the procedure that may affect the financial impact were not included in the model. These include costs of prosthetic mesh, laparoscopic tacking device and increased use of disposables. ESC further noted that diagnostic imaging would be conducted as part of the work up for the conditions and would not be a cost specific to VR and did not need to be included in the assessment.

## **17. Applicant comments on MSAC's Public Summary Document**

The CSSANZ thanks the MSAC and the authors of the DCAR for their hard work and is in agreement with their conclusions and decisions.

## **18. Further information on MSAC**

MSAC Terms of Reference and other information are available on the MSAC Website: [visit the MSAC website](#)