Australian Government

Department of Health

MSAC Application 1685:

Ventral rectopexy for the treatment of rectal prolapse and intussusception

Ratified

PICO Confirmation

Summary of PICO/PPICO criteria to define question(s) to be addressed in an Assessment Report to the Medical Services Advisory Committee (MSAC)

Table 1 PICO for ventral rectopexy in patients with rectal prolapse or high-grade intussusception PICO Set 1

Component	Description
Population	There are two subpopulations for this application: a. Patients with full-thickness rectal prolapse (Grade V Oxford Rectal Prolapse Scale) b. Patients with high-grade rectal intussusception (Grade III and Grade IV Oxford Rectal Prolapse Scale) with severe symptoms who have failed to improve with conservative management. High-grade rectal intussusception is defined by the applicant as where there is proven descent of the full-thickness of the rectal wall into the anal canal. Severe symptoms include faecal incontinence, obstructed defecation, and rectal ulceration.
Intervention	Minimally invasive ventral rectopexy
Comparator/s	For patients with rectal prolapse (subpopulation a) the comparators are: • abdominal rectopexy (other than by minimally invasive ventral rectopexy), whether alone or as part of a resection rectopexy • perineal repair using a Delorme's procedure. For patients with high-grade intussusception (subpopulation b) the comparator is: • continued conservative management • abdominal rectopexy • intra-anal Delorme's procedure.

Outcomes	**Patient relevant**
	
	Relevant safety outcomes include:
	• adverse events arising from the intervention and comparator procedures (e.g. postoperative infection, intestinal perforation, fistula)
	• adverse events associated with mesh use
	• mortality
	• hospital readmission.
	
	Primary effectiveness outcomes include:
	• symptom remission – for example, minutes per toilet attempt, bloating, pain, rates of constipation (including new-onset constipation and/or resolution of constipation), rates of faecal incontinence, laxative use
	• recurrence of prolapse or intussusception
	• frequency of revision procedures
	• Patient reported outcomes measured using validated, objective severity scoring systems, for example:
	  ○ Cleveland Clinic Constipation Scoring System (CCSS)
	  ○ The obstructed defecation scale

Component	Description
	○ PAC-SYM ○ Vaizey Score ○ PAC-QOL. **Healthcare system outcomes** These include: • length of hospital stay • costs associated with the intervention and comparator procedures, including costs of: ○ appointments ○ pre-procedure workup ○ the procedure ○ consumables ○ the hospital stay ○ follow-up ○ monitoring ○ any subsequent interventions required • costs associated with adverse events for the intervention and comparator • revision procedures following the recurrence of external rectal prolapse or high-grade rectal intussusception.
Assessment questions	What is the safety, effectiveness, and cost-effectiveness of ventral rectopexy versus abdominal rectopexy, resection rectopexy, or Delorme's procedures in patients with rectal prolapse? What is the safety, effectiveness, and cost-effectiveness of ventral rectopexy versus abdominal rectopexy, intra-anal Delorme's procedure, or conservative management in patients with high-grade intussusception?

Purpose of application

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

The applicant has advised that ventral rectopexy is currently performed in Australia and is reimbursed under MBS item 32117 (RECTAL PROLAPSE, abdominal rectopexy of). However, the applicant has stated that item 32117 does not reflect the increased technical difficulty of ventral rectopexy; therefore, the item is often co-claimed with items for pelvic floor repair or colposacrosuspension (MBS items 35595 or 35597). 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 applicant claimed that:

- Compared with abdominal rectopexy the proposed intervention has superior safety (fewer adverse events and faster recovery) and superior effectiveness (lower rates of postoperative constipation).
- 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.
- Compared with perineal repair using Delorme's procedure the proposed intervention has superior effectiveness (lower risk of recurrence) and noninferior safety.
- Compared with conservative management (for patients with high-grade intussusception) the proposed intervention has superior effectiveness and inferior safety.

PICO criteria

Population

The applicant has proposed the following populations for this application:

a. patients with full-thickness rectal prolapse (Grade V Oxford Rectal Prolapse Scale)
b. patients with high-grade rectal intussusception (Grade III and IV Oxford Rectal Prolapse Scale) with severe symptoms who have failed to improve with conservative management.

High-grade rectal intussusception is defined by the applicant as where there is proved descent of the full-thickness of the rectal wall into the anal canal on imaging studies. Severe symptoms include faecal incontinence, obstructed defecation and rectal ulceration.

PASC noted the difficulties of diagnosing high-grade rectal intussusception based on its symptoms at presentation and thus recommended the use of diagnostic imaging studies (defaecography / proctography).

PASC recommended the use of objective scoring systems in evaluating symptoms, which may include obstructed defecation, faecal incontinence, and ulceration.

PASC noted that high grade rectal intussusception includes both individuals rated as Grade III and Grade IV on the Oxford Rectal Prolapse Scale.

While the two subpopulations represent different stages of the disease and may have different treatment strategies, the applicant has indicated that they should be considered as a single population for the

purposes of funding decision-making. In other words, both subpopulations should be included under the same MBS item number.

Definition of the condition

Rectal prolapse can generally be divided into two categories: external rectal prolapse and internal rectal prolapse. Internal rectal prolapse is also termed rectal intussusception (van der Schans et al. 2018). Complete (full-thickness) rectal prolapse, which is also termed procidentia, is the full-thickness circumferential protrusion of all layers of the rectal wall (rectum) through the anus (Tou et al. 2015, Bordeianou et al. 2014). Rectal intussusception is defined as a funnel-shaped infolding (similar to a telescope mechanism) of the rectal wall that occurs during the process of defaecation (Wijffels et al. 2010). It has been hypothesised that rectal prolapse is a gradually evolving process that passes through various radiologically identifiable stages. Several authors have suggested that rectal intussusception may be the first stage of a progressive anomaly that eventually leads to a full-thickness external prolapse (Wijffels et al. 2010, Devadhar 1965, Ihre and Seligson 1975, Brodén and Snellman 1968). Bordeianou et al. (2014) suggested that rectal prolapse begins with an internal intussusception that can only be seen on defaecography, followed by mucosal prolapse and eventually a full-thickness rectal prolapse. This is consistent with the applicant's description of the two subpopulations as representing a continuum of disease. The Oxford Rectal Prolapse Grade, a radiological grading system, is used to categorise the extent of the prolapse (Table 2) (Wijffels et al. 2010).

Table 2 The Oxford Rectal Prolapse Grade

	Grade of rectal prolapse	Radiological characteristics of rectal prolapse
Internal		
Recto-rectal intussusception (RRI)	I (high rectal)	Descends no lower than proximal limit of the rectocele
	II (low rectal)	Descends into the level of the rectocele, but not onto sphincter/anal canal
Rectal-anal intussusception (RAI)	III (high anal)	Descends onto sphincter/anal canal
	IV (low anal)	Descends into sphincter/anal canal
External (ERP)		
External rectal prolapse (ERP)	V (overt rectal prolapse)	Protrudes from anus

Source: Reproduced from Wijffels et al. (2010).

Although the specific cause of rectal prolapse remains unclear, there are some reported risk factors (Madiba et al. 2005). These include an abnormally deep pouch of Douglas (the cavity between the rectum and the posterior wall of the uterus), lax muscles in the pelvic floor and anal canal, weak internal and external anal sphincters (generally with evidence of pudendal nerve neuropathy) and abnormal fixation of the rectum with a mobile mesorectum and lax lateral ligaments (Madiba et al. 2005). Other predisposing factors include neurological illnesses, connective tissue disorders, and high parity (Marshman et al. 1987, Karasick and Spettell 1997).

Prevalence

Rectal prolapse can occur at any stage of life; however, it is most likely in children and people over 50 (Jacobs et al. 1997, Wassef et al. 1986, Madiba et al. 2005, Hatch and Steele 2013). In children, it is most commonly diagnosed before 3 years of age, and more commonly in boys (Hatch and Steele 2013). For adults, it is more frequently diagnosed in individuals over 50 and is nine times more likely in women than in men (Wijffels et al. 2010). The incidence reported in adults is 0.25–0.43%, which increases to 1% when

the population is adults older than 65 (Stein and Stein 2006, Kairaluoma and Kellokumpu 2005, Patel and Lembo 2006).

Clinical presentation

Patients with external rectal prolapse can present with a myriad of symptoms. Full-thickness external rectal prolapse is generally associated with a large rectal mass or bulge, which may or may not spontaneously reduce at the completion of a bowel movement or cessation of straining (Bordeianou et al. 2014). Patients with rectal prolapse can also present with non-specific complaints including fullness or a lump inside the rectum, constipation, faecal incontinence, obstructed defecation, mucus drainage and bleeding (Bordeianou et al. 2008, Varma et al. 2011). Some patients may also experience rectal incarceration or strangulation, which is associated with a large, immobile rectal mass (Bordeianou et al. 2014). Patients with rectal intussusception may have similar symptoms to patients with external rectal prolapse, with the possible addition of obstructed defecation and severe abdominal pain (Bordeianou et al. 2014). Many patients who have rectal intussusception remain asymptomatic. For 35% of asymptomatic females, intussusception is apparent in defaecography (Dvorkin et al. 2005).

Diagnosis of rectal prolapse and intussusception

Rectal prolapse is a clinical diagnosis based on patient history and physical examination findings (Bordeianou et al. 2014, Hatch and Steele 2013). In some cases, rectal prolapse can be easily reproduced by simple abdominal pressure (i.e. Valsalva) or bending and squatting. It may also be reproduced when the patients strains while in a lateral or jack-knifed position (Bordeianou et al. 2014, Hatch and Steele 2013). It may be necessary to examine the patient in the squatting position or even on the commode to stimulate defecation (Hatch and Steele 2013). Patients can also be encouraged to document the prolapse photographically at home if they feel uncomfortable (Bordeianou et al. 2014). The hallmark finding of complete rectal prolapse is the protrusion of concentric rectal rings through the anus (Hatch and Steele 2013). Associated information to be obtained from the patient includes a full history of the patient's symptoms (including stool consistency), and details about faecal incontinence, constipation and evidence of obstructed defecation (Bordeianou et al. 2014). If diagnosis is difficult, an enema may be warranted to help induce the prolapse in patients with a strong subjective history but difficulties with visual examination (Hatch and Steele 2013). Digital rectal examination should also be completed. If a prolapse or intussusception has been diagnosed, a colonoscopy should be conducted to exclude a lesion as the cause of the prolapse or intussusception (Hatch and Steele 2013).

With respect to internal rectal prolapse (intussusception), PASC noted the difficulties of diagnosing high-grade rectal intussusception based on its symptoms at presentation and thus recommended the use of diagnostic imaging studies (defaecography / proctography).

Current management

External rectal prolapse is a definitive indication for surgery (unless surgery is contraindicated for the patient), because it cannot be resolved through conservative therapy alone (Hatch and Steele 2013, Bordeianou et al. 2017). For rectal intussusception, the decision to operate is more subtle – surgical intervention is restricted to symptomatic cases with a certain degree of prolapse and where conservative management has failed (van der Schans et al. 2018).

Conservative management

For individuals with rectal intussusception, minimally symptomatic prolapse, or who are poor surgical candidates, conservative management may provide some benefits (Hatch and Steele 2013). Biofeedback and physical therapy (pelvic floor exercises) can help patients with obstructed defecation and incontinence (Khaikin and Wexner 2006). As a last line conservative therapy, for individuals unable to have surgery, a

perineal pad may be used to act as a truss (Hatch and Steele 2013). However, these conservative measures do not reverse or correct a prolapsed pelvic organ. They are essentially temporising or palliative procedures (Hatch and Steele 2013).

Operative management

Any surgical procedure must be tailored to the patient's overall medical condition. There are many operative procedures described in the literature, so the choice of procedure is usually dictated by the comorbidities of the patient, the surgeon's preference and experience, and the patient's age and bowel function (Bordeianou et al. 2017). Some of the more common procedures have been documented below, and they are generally categorised as abdominal or perineal procedures.

For high-grade rectal intussusception management, the applicant states that abdominal rectal prolapse repair procedures have been shown to be ineffective, whereas ventral rectopexy has been shown to be effective.

For operative rectal prolapse management, the current standard of care in Europe is ventral rectopexy (van der Schans et al. 2018). The applicant has also reported that ventral rectopexy is increasingly becoming the procedure of choice for most Australian colorectal surgeons when managing rectal prolapse. Expert advice is that most abdominal repairs in Australia are ventral rectopexy (Expert Colorectal Surgeon 2021).

Other abdominal procedures include suture rectopexy, posterior prosthetic or mesh rectopexy, anterior sling rectopexy, ventral rectopexy and resection rectopexy (Frykam-Goldberg procedure) (Hatch and Steele 2013). Minimally invasive approaches include laparoscopic rectopexy and robotic techniques.

Perineal approaches include perineal proctosigmoidectomy (Altemeier's procedure), mucosal sleeve resection (Delorme procedure), and anal encirclement (Thiersch procedure) (Hatch and Steele 2013).

Surgical options have traditionally been avoided for internal intussusception because of high postoperative rates of persistent symptoms. Individuals with refractory or debilitating cases of internal intussusception may benefit from any of several surgical procedures, including stapled transanal rectal resection, traditional suture rectopexy, and ventral rectopexy (Hatch and Steele 2013).

Rationale

When determining the appropriate population for ventral rectopexy, the populations with the greatest clinical needs, and the populations for which it has been trialled must be considered.

Clinical need

When consulted, an independent clinical expert agreed that the population outlined in the application was appropriate (Expert Colorectal Surgeon 2021). Further, both the applicant and clinical expert considered that overall MBS utilisation would not change with the listing of the proposed item, because all patients currently requiring surgical repair were receiving it under existing items.

Trial populations

An important consideration when determining eligibility for ventral rectopexy is whether there is an evidence base to support the intervention for the intended population. Many studies have looked at this intervention and the summary of the observed population is included below. Most studies included patients with rectal prolapse; evidence from the intussusception subpopulation is more limited.

Two recent randomised controlled trials included patients with full-thickness rectal prolapse (Lundby et al. 2016, Hidaka et al. 2019).

Several case studies have been published using ventral rectopexy in patients with full-thickness rectal prolapse. D'Hoore et al. (2004) included patients aged 22–88 who had full-thickness external rectal prolapse. Additionally, five patients presented with a recurrent rectal prolapse 1–6 years after previous Delorme's mucosectomy. Wijffels et al. (2011) looked at patients with full-thickness external rectal prolapse; all were over the age of 80 years.

Three further recent case studies had broader population inclusion criteria. Collinson et al. (2010) included individuals with internal rectal prolapse (intussusception) – more specifically, those with grade III–IV (recto-anal) internal rectal prolapse or significantly severe symptoms of obstructed defecation with or without faecal incontinence, who had previously tried and failed standard medical management, and fibre supplementation. Most patients had also undergone unsuccessful biofeedback therapy. Evans et al. (2015) included patients aged 15–82 with internal rectal prolapse, external rectal prolapse or rectocele, vault prolapse and sigmoidocele (Evans et al. 2015). Tsunoda et al. (2021) studied a population with recto-anal intussusception and/or rectocele (Tsunoda et al. 2021).

PASC noted no further changes regarding the population stated.

Intervention

The intervention for this application is minimally invasive ventral rectopexy.

Overview

It has been reported that ventral rectopexy has gained acceptance as a safe and effective approach in the treatment of rectal intussusception and rectal prolapse (Loh and Umanskiy 2021). Ventral rectopexy addresses rectal intussusception with or without rectal prolapse when the lead point is located anteriorly (Loh and Umanskiy 2021). The procedure was first described 30 years ago (Loygue et al. 1984) but has since been modified to be 'performed laparoscopically with dissection anteriorly into the rectovaginal spectrum with limited posterior dissection to preserve rectal innervation. A single mesh is then anchored to the sacral promontory and placed on the distal rectum' (D'Hoore et al. 2004).

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'.

Operative procedure

The procedure can be performed laparoscopically or using a master-slave robotic platform. The applicant has provided the following description of the procedure:

A phosphate enema is administered to ensure the rectum is emptied of stool immediately prior to the procedure. General anaesthetic with muscle relaxant is administered. Prophylactic antibiotics are administered. A urinary catheter is inserted. The patient is positioned in the Lloyd-Davis position (supine with the legs flexed at hips and knees by means of stirrups such that the perineum can be viewed). A pneumoperitoneum is established and a laparoscope inserted via a port at the umbilicus. Commonly three other ports are placed. The patient is placed in a head-down position. The small bowel loops are removed from the pelvis, the sigmoid colon retracted superiorly and the uterus (if present) retracted anteriorly. The procedure is completed using a minimally invasive technique utilising traditional laparoscopic equipment or a master-slave robotic platform. The peritoneum over the sacral promontory is incised and the peritoneal incision is continued in an inverted 'J' pattern down the right side of the rectum, across the Pouch of Douglas and up to the left side of the rectum to the level of the mid-rectum. Dissection then

proceeds in the rectovaginal septum until the pelvic floor is reached. Redundant peritoneum attached to the front of the rectum is excised and discarded. A prosthesis (synthetic mesh or biological graft) is then fashioned into a strip 20 cm long and 3 cm wide. A series of sutures are placed to attach the prosthesis to the rectum along the length of the exposed rectum. A suture or two is used to attach the prostheses to the superior part of the vagina. The superior end of the prosthesis is attached to the sacral promontory with sutures or a disposable tacking device. The peritoneum is the closed to completely bury the prosthesis. Port sites are closed.

Postoperatively the patient can eat and drink immediately. The urinary catheter is removed early. The patient is allowed home when comfortable and confident which is usually the first or second postoperative day. The patient is reviewed by the surgeon a few weeks following surgery and discharged from follow-up if appropriate.

PASC noted that the interventions can be stratified based on the type of prosthesis used (either synthetic mesh or biological graft).

Comparator(s)

For patients with rectal prolapse, the applicant has stated the following procedures as the comparators to ventral rectopexy:

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

PASC noted that the Altemeier's procedure may not be an appropriate comparator for external rectal prolapse due to the concern with the limited number of procedures completed in Australia.

A technical description of these procedures is provided below.

For patients with high-grade intussusception, the applicant has proposed continued conservative management as the appropriate comparator. Expert advice, however, is that these patients could be treated using an internal Delorme's procedure or an abdominal mesh rectopexy.

PASC noted that abdominal rectopexy may be a comparator to minimally invasive ventral rectopexy for high grade rectal intussusception.

PASC noted that intra-anal Delorme's procedure may be a comparator to ventral rectopexy for high grade rectal intussusception when excision of the rectum is required. They reported that this operation is performed within the anal canal rather than via the perineum, as would be the case with the Delorme's procedure for external rectal prolapse.

It was noted that the stapled transanal rectal resection procedure was described about 15 years ago and has largely been abandoned. It uses a series of staples to get a similar outcome to an intra-anal Delorme's procedure and because of the high complication rate it has largely fallen out of favour. There is also no separate MBS item number for the stapled transanal rectal resection procedure, and it has been reviewed by the MBS Review Taskforce for colorectal surgery and it was deemed that it didn't need a separate MBS item number.

Therefore, the comparators for this subpopulation are:

- continued conservative management

- abdominal rectopexy
- intra-anal Delorme's procedure.

Abdominal rectopexy (MBS item 32117)

Abdominal rectopexy can include suture rectopexy, posterior prosthetic or mesh rectopexy, and anterior sling rectopexy. The applicant states that abdominal rectopexy can be performed by either an open or laparoscopic approach. Suture rectopexy is when the rectum is mobilised and sutured or tacked to the sacral fascia. During the recovery, adhesions and fibrosis from the dissection secure the rectum to the presacral fascia, which may lead to a reduction in recurrence (Hatch and Steele 2013). This procedure is associated with variations in postoperative constipation rates. Posterior prosthetic or mesh rectopexy incorporates the insertion of a mesh or prosthetic posterior to the rectum (posterior mesh rectopexy) or anteriorly as a sling secured posteriorly to the sacral promontory (Ripstein procedure). This procedure also has variable rates of postoperative constipation (Hatch and Steele 2013). The applicant stated the postoperative care for open abdominal rectopexy includes 'return to ward postoperatively. Clear fluids immediately postoperatively. Recommence diet at surgeon's discretion (usually when patient passing flatus). Remove urinary catheter when patient comfortable to mobilise to toilet. Discharge after several days of observation when patients pain is controlled with oral analgesia, bowels open and patient self-caring.' The postoperative care of laparoscopic abdominal rectopexy as stated by the applicant includes 'return to ward postoperatively. Clear fluids immediately postoperatively. Recommence diet next day and remove urinary catheter. Discharge after 1 to 2 days when patient opening bowels and self-caring' (Applicant 2021b).

Resection rectopexy (MBS item 32117 with 32024)

The applicant has advised that 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 a resection rectopexy (Frykman 1955).

After rectal mobilisation, the surgeon resects the sigmoid colon and a tension-free colorectal anastomosis is created (Frykman 1955). Before the placement of sutures, the rectum is elevated as high as possible out of the pelvis and sutures are placed prior to bowel resection and tied after the anastomosis (Safar and Vernava 2008, Laubert et al. 2013). The applicant gave the postoperative procedure for resection rectopexy as follows: 'return to ward postoperatively. Clear fluids immediately postoperatively. Recommence diet at surgeon's discretion, commonly this occurs once the patient is passing flatus. Discharge after several days observation (3–5 laparoscopic and 5–7 open) when surgeon confident that the patient has not suffered a septic complication'.

The applicant stated 'resection rectopexy is effective in controlling rectal prolapse without causing constipation; however, this comes at the cost of a more complicated operation and the risk of the life-threatening complication of anastomotic leak'. This surgery is recommended for patients with significant constipation and/or pre-existing diverticular disease that would warrant resection and should be avoided in patients with preoperative faecal incontinence (Van Geluwe et al. 2014). The applicant stated that resection rectopexy is considered the 'gold standard' procedure for younger patients with rectal prolapse.

Perineal repair using Delorme's procedure (MBS item 32111)

'Delorme's procedure involves stripping the mucosa of the prolapsing rectum from the sphincters and muscularis propria, followed by plication of the muscularis propria and reanastomosis of the mucosal ring' (Hatch and Steele 2013). The procedure is well tolerated and can be performed under spinal anaesthesia.

Post-procedure, 'the patient is returned to postoperative ward, diet recommended immediately postoperatively; providing the patient is comfortable, they can be discharged the next day following review by Allied Health practitioners if they are elderly, review by surgeon in outpatient clinic/rooms after one month and discharge if stable and prolapse controlled'.

Recurrence rates following Delorme's procedure are up to 38% (Lechaux et al. 1995). Furthermore, Sielezneff et al. (1999) have reported that Delorme's procedure is especially prone to failure in cases of proximal procidentia and rectosacral separation on defaecography, faecal incontinence, chronic diarrhoea, or perineal descent equal to or greater than 9 cm on straining. Delorme's procedure should be avoided in individuals with these symptoms or conditions (Sielezneff et al. 1999). Because of high recurrence rates, the applicant has advised that this procedure is usually only used in an elderly frail population.

Outcomes

PASC has noted that the outcome measures should be extended to include validated, objective severity scoring systems, these may include the Cleveland Clinic Constipation Scoring System (CCSS), the obstructed defecation scale, PAC-SYM, Vaizey score, and PAC-QOL.

PASC noted that the rate of constipation including new onset constipation and/or resolution of constipation, rate of faecal incontinence and laxative use, which were listed in the PICO as primary outcome measures could all be classified as different types of the same primary outcome measure, namely symptom remission measures.

Patient outcomes

Relevant safety outcomes include:

- adverse events arising from the intervention and comparator procedures (e.g. postoperative infection, intestinal perforation, fistula)
- adverse events associated with mesh use
- mortality
- hospital readmission.

Primary effectiveness outcomes include:

- symptom remission – for example, minutes per toilet attempt, bloating, pain, rates of constipation (including new-onset constipation and/or resolution of constipation), rates of faecal incontinence, laxative use
- recurrence of prolapse or intussusception
- frequency of revision procedures
- Patient reported outcomes measured using validated, objective severity scoring systems, for example:
    - Cleveland Clinic Constipation Scoring System (CCSS)
    - The obstructed defecation scale
    - PAC-SYM
    - Vaizey Score
    - PAC-QOL.

PASC noted that defaecography, although gold standard for diagnosing recurrence of internal rectal prolapse in the trial setting, was impractical as a diagnostic tool for all patients with suspected recurrence to undergo in a clinical setting.

Healthcare system outcomes

These include:

- costs associated with the intervention and comparator procedures, including costs of
    - appointments
    - pre-procedure workup
    - the procedure
    - consumables
    - the hospital stay
    - follow-up
    - monitoring
    - any subsequent interventions required
- costs associated with adverse events for the intervention and comparator
- revision procedures following the recurrence of external rectal prolapse or high-grade rectal intussusception.

PASC noted that the need for revision procedures following the recurrence of external rectal prolapse or high-grade rectal intussusception should be included in the analysis. This should include rates of revision and type of procedure performed.

Rationale

Expert advice is that prolapse recurrence should be measured at 1 and 3 years postoperatively (Expert Colorectal Surgeon 2021).

PASC noted that the recurrence follow up should be one year minimum and that three years would provide a more robust measure from the consumer point of view.

The applicant has advised that the type of mesh used in the ventral rectopexy procedure may affect the outcomes. For example, synthetic mesh may be associated with higher rates of adverse events (although applicant noted these are rare), whereas biological mesh may be associated with higher rates of prolapse recurrence. *The assessment phase should ensure the impact of mesh type on outcomes is considered.*

PASC noted that if there is evidence that will allow it, the outcomes can be stratified based on the type of prosthesis used (either synthetic mesh or biological graft).

Clinical management algorithms

The current and proposed clinical management algorithms for subpopulation a (patients with rectal prolapse) and subpopulation b (patients with high-grade intussusception) are provided in Figure 1 through Figure 4.

PASC noted the clinical management algorithms.

Figure 1 Current clinical management algorithm for subpopulation a: patients with rectal prolapse (grade V)

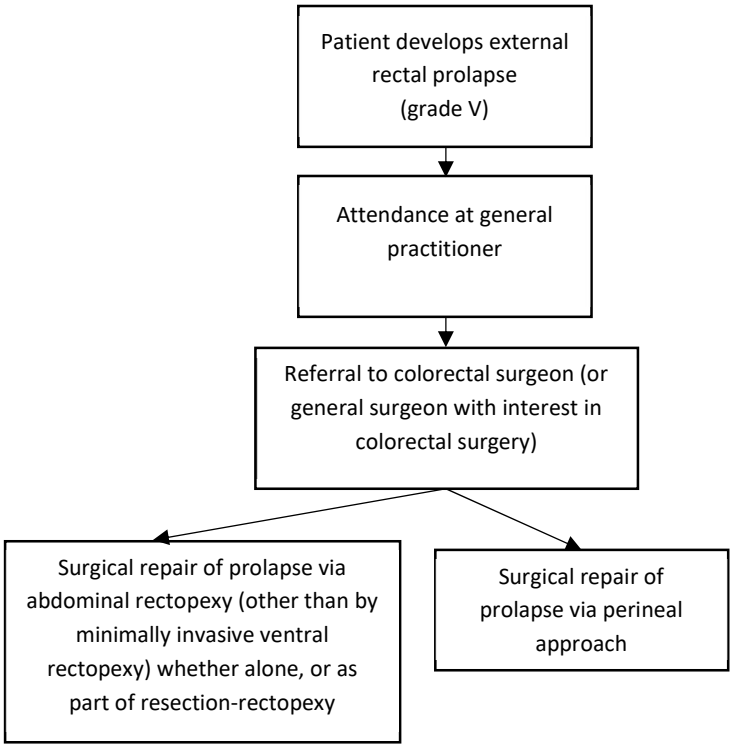


Figure 2 Proposed clinical management algorithm for subpopulation a: patients with rectal prolapse (grade V)

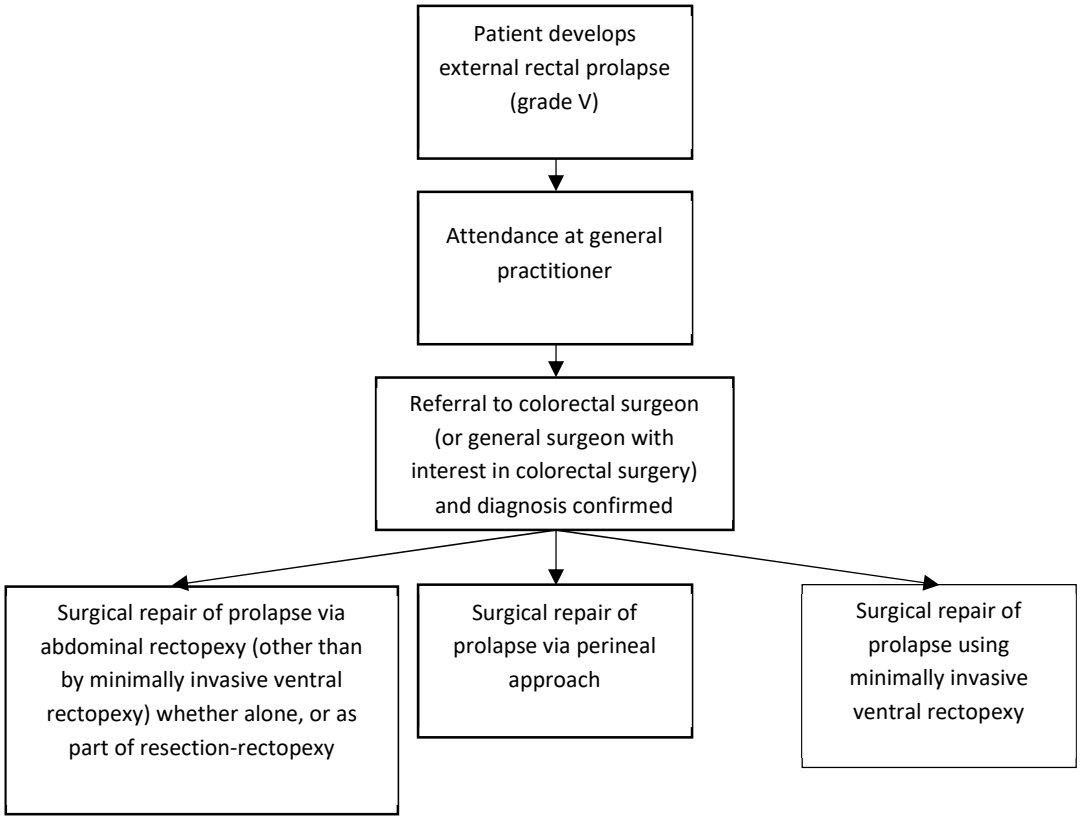


Figure 3 Current clinical management algorithm for subpopulation b: patients with high-grade intussusception

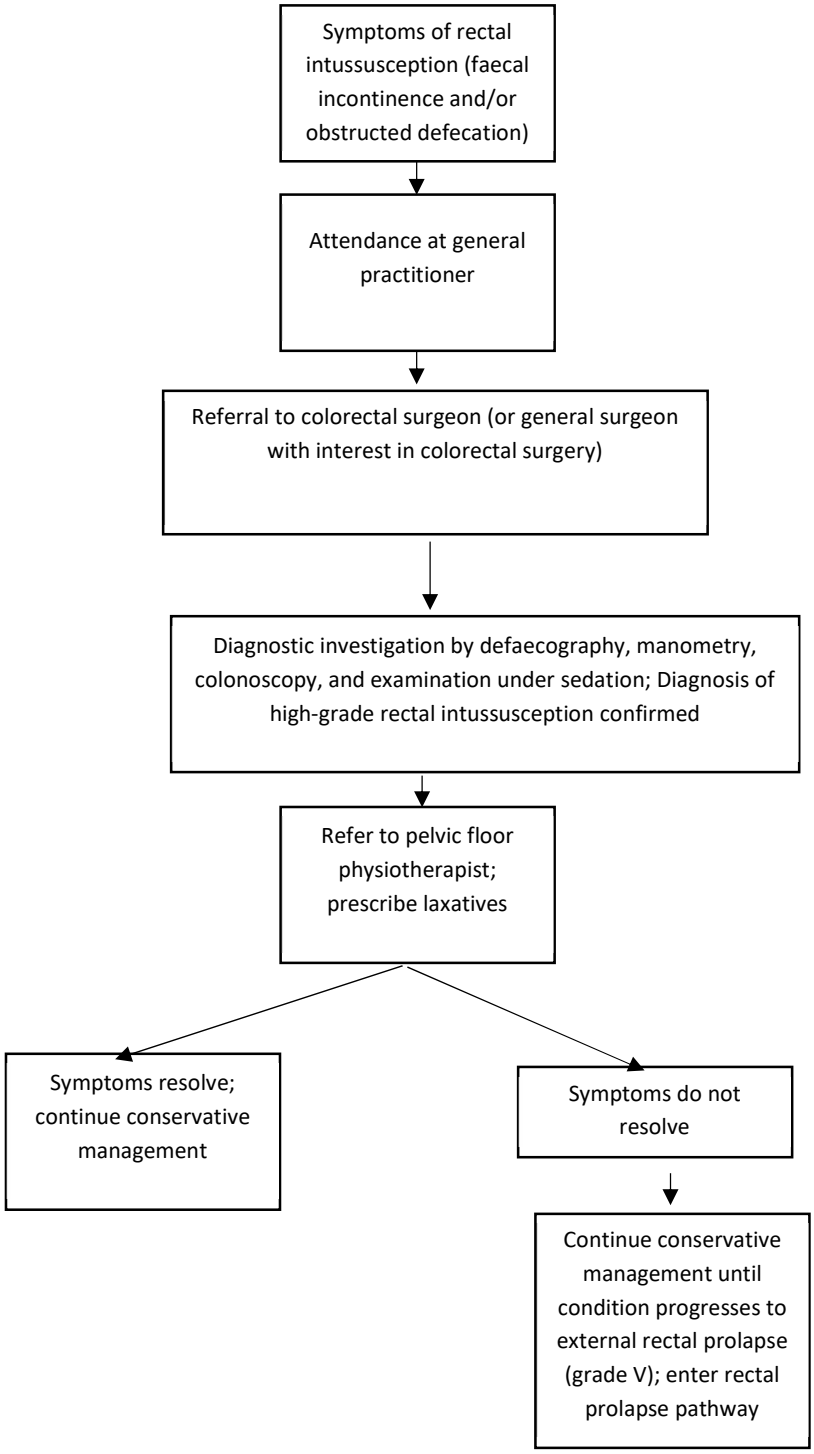
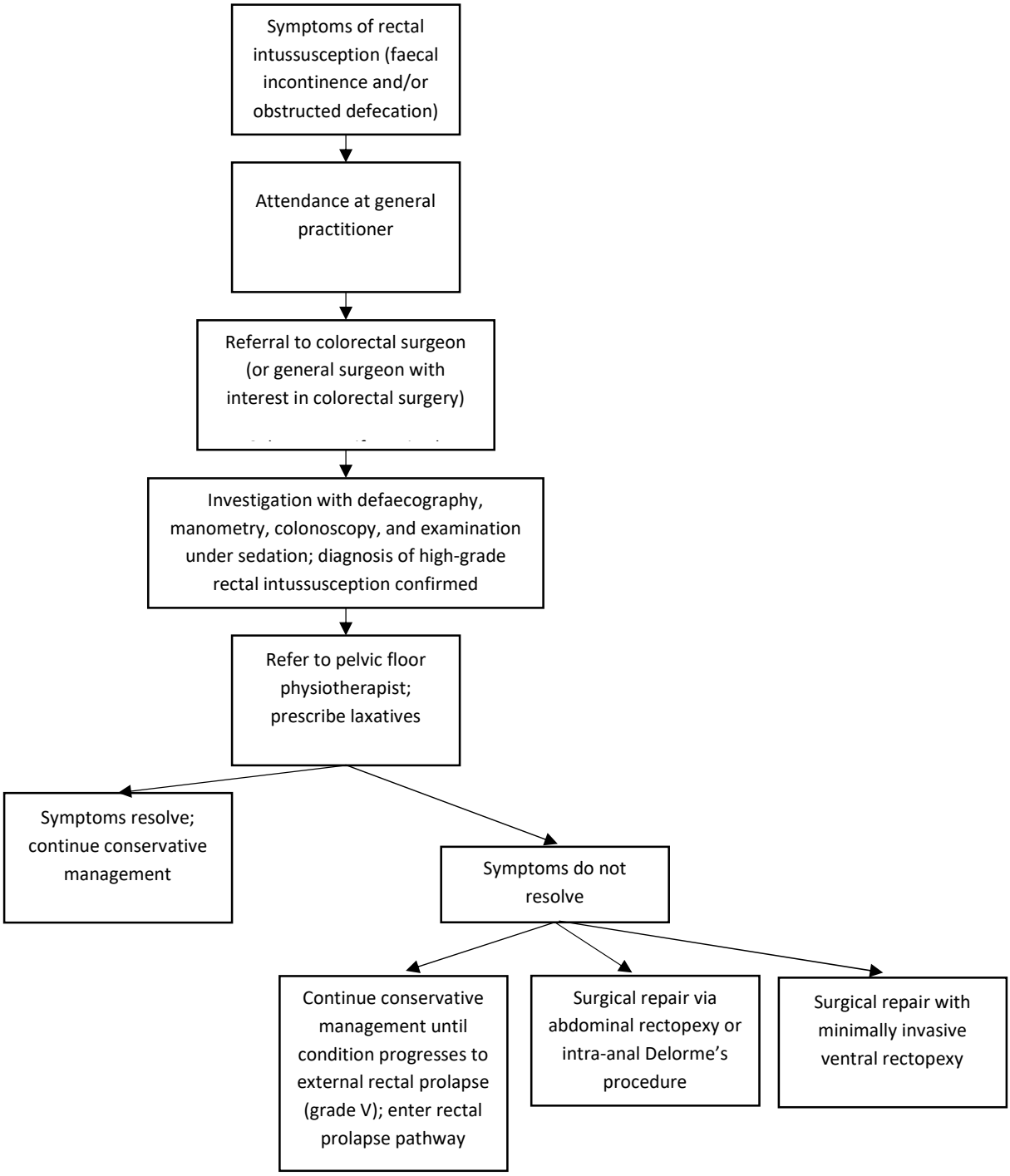


Figure 4 Proposed clinical management algorithm for subpopulation b: patients with high-grade intussusception



Proposed economic evaluation

PASC noted the clinical claims and proposed economic evaluations.

Based on the clinical claims of this application, and considering the matrix in Table 3, the proposed economic evaluations, given the comparators for each of the two subpopulations, is presented below:

a. Patients with full-thickness rectal prolapse (grade V):
   - for the comparison of ventral rectopexy with abdominal rectopexy, a cost-effectiveness analysis (CEA)/cost-utility analysis (CUA) is required (**superior safety, superior effectiveness**)
   - for the comparison of ventral rectopexy with resection rectopexy, a CEA/CUA is required (**superior safety, noninferior effectiveness**)
   - for the comparison of ventral rectopexy with perineal repair using Delorme's procedure, a CEA/CUA is required (**noninferior safety, superior effectiveness**)
   - for the comparison of ventral rectopexy to perineal repair using Altemeier's procedure, a CEA/CUA is required (**superior safety, superior effectiveness**).

b. Patients with high-grade rectal intussusception (grade III-IV):
   - for the comparison of ventral rectopexy with conservative management, a CUA is required (**inferior safety, superior effectiveness**).
   - For the additional comparison of ventral rectopexy with abdominal rectopexy, the applicant has not made a claim about the clinical safety and effectiveness and therefore the appropriate economic evaluation has not been defined.
   - For the additional comparison of ventral rectopexy with intra-anal Delorme's procedure, the applicant has not made a claim about the clinical safety and effectiveness and therefore the appropriate economic evaluation has not been defined.

Table 3 Classification of comparative effectiveness and safety of the proposed intervention, compared with its main comparator, and guide to the suitable type of economic evaluation

Comparative safety	Comparative effectiveness			
	Inferior	Uncertain[a]	Noninferior[b]	Superior
Inferior	Health forgone: need other supportive factors	Health forgone possible: need other supportive factors	Health forgone: need other supportive factors	? Likely CUA
Uncertain[a]	Health forgone possible: need other supportive factors	?	?	? Likely CEA/CUA
Noninferior[b]	Health forgone: need other supportive factors	?	CMA	CEA/CUA
Superior	? Likely CUA	? Likely CEA/CUA	CEA/CUA	CEA/CUA

CEA=cost-effectiveness analysis; CMA=cost-minimisation analysis; CUA=cost-utility analysis

? = reflect uncertainties and any identified health trade-offs in the economic evaluation, as a minimum in a cost-consequences analysis

[a] 'Uncertainty' covers concepts such as inadequate minimisation of important sources of bias, lack of statistical significance in an underpowered trial, detecting clinically unimportant therapeutic differences, inconsistent results across trials, and trade-offs within the comparative effectiveness and/or the comparative safety considerations.

[b] An adequate assessment of 'noninferiority' is the preferred basis for demonstrating equivalence.

Proposal for public funding

The applicant has proposed the following MBS item for ventral rectopexy. Minor amendments by the assessment group are shown in red (Table 4).

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 ($1,532.85 vs $1,040.20), the applicant has advised that abdominal rectopexy was often co-claimed with an item for anterior resection to perform a resection rectopexy ($1,419.90). The total cost for the combined procedure is $2,460.10.

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 Table 4). 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 cost $2,242.00) or 32117 + 35597 (total cost $2,573.05).

The applicant has acknowledged that where ventral rectopexy replaces Delorme's procedure (MBS item 32111; $660.40) 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.

Table 4 Proposed MBS item (proposed amendments marked up in red)

Category 3 – T8 Subgroup 2 (Colorectal)
MBS item XXXXX VENTRAL RECTOPEXY. Treatment of external rectal prolapse or symptomatic high-grade (grade III or IV, Oxford Rectal Prolapse Scale) internal rectal prolapse by minimally invasive surgery involving and including 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. (Note: Items 35595 and 35597 not to be co-claimed by the same surgeon claimingXXXXX. 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.) Multiple Operation Rule (Anaes.) (Assist.)
Fee: $1532.85 Benefit: 75% = $1,149.65

PASC noted its preference for the neutral descriptor terminology "minimally invasive surgery" rather than specifying robotic or laparoscopic surgery.

PASC noted that symptomatic high-grade internal prolapse is defined as Grade III and IV according to the Oxford Rectal Prolapse Scale and this information needs to be included in the item descriptor.

The applicant has advised that ventral rectopexy is currently being performed for patients with either rectal prolapse or high-grade intussusception under existing MBS item number 32117 with or without co-claiming for pelvic floor repair or colposacrosuspension procedures (MBS items 35595 or 35597).. Expert advice is that the proposed listing is unlikely to change expected utilisation (Expert Colorectal Surgeon 2021). In 2020–21, MBS item 32117 was claimed 644 times. Both the applicant and clinical expert estimated that at least 50% of these were for ventral rectopexy procedures.

Expert advice is that at least 50% of procedures currently claimed under item 32117 are for ventral rectopexy procedures, and that 20–30% of these procedures are for patients with intussusception. This is consistent with the applicant's estimate of current utilisation.

An MBS data request may be required to establish how often MBS item 32117 (abdominal rectopexy) is co-claimed with:

- item 32024 (rectum, high restorative anterior resection) for resection rectopexy procedures
- items 35595 (laparoscopic or abdominal pelvic floor repair) or 35597 (sacral colpopexy) for existing ventral rectopexy procedures.

Summary of public consultation input

Input was received from two (2) organisations:

- Private Health Australia (PHA)
- Australian Association of Stomal Therapy Nurses (AAST).

PHA was generally supportive of the application, and AAST was very supportive.

Benefits

PHA and AAST 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.

PASCwas noted that the literature doesn't 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 these complications do exist but at very low levels, approximately 1% as documented in the literature.

The applicant noted that whilst synthetic mesh may have a potentially higher incidence of complications, erosion, and more complex surgical procedures in other operative settings, in the context of ventral rectopexy, the applicant considered synthetic mesh to be of lower cost and the risk of erosion or complications low when used by experienced surgeons, compared to biological mesh.

Next steps

PASC noted the applicant has requested to progress its application as a department contracted assessment report (DCAR).

Applicant Comments on the PICO Confirmation

Nil.

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