



Australian Government

Department of Health

Application 1685

Ventral rectopexy for the treatment of rectal prolapse and intussusception

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

Please use this template, along with the associated Application Form Guidelines to prepare your application. Please complete all questions that are applicable to the proposed service, providing relevant information only. Applications not completed in full will not be accepted.

Should you require any further assistance, departmental staff are available through the Health Technology Assessment Team (HTA Team) on the contact numbers and email below to discuss the application form, or any other component of the Medical Services Advisory Committee process.

Email: hta@health.gov.au

Website: www.msac.gov.au

PART 1 – APPLICANT DETAILS

1. Applicant details (primary and alternative contacts)

Corporation/partnership details: Colorectal Surgical Society of Australia and New Zealand

Corporation name:

ABN:

Business trading name:

Primary contact name: REDACTED

Primary contact numbers

Business: **REDACTED**

Mobile: **REDACTED**

Email: **REDACTED**

Alternative contact name: REDACTED

Alternative contact numbers

Business: **REDACTED**

Mobile: **REDACTED**

Email: **REDACTED**

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

Yes

No

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

Yes

No

PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

3. Application title

Ventral Rectopexy for the treatment of Rectal Prolapse and Intussusception

4. Provide a succinct description of the medical condition relevant to the proposed service (no more than 150 words – further information will be requested at Part F of the Application Form)

Rectal prolapse is a debilitating condition resulting from the rectum intussuscepting past the anal sphincter such that the rectal mucosa extrudes beyond the anal margin. It causes pain, faecal incontinence, mucous discharge and bleeding. If the rectum intussuscepts into the anal canal but not past the sphincter this too can cause symptoms of faecal incontinence, pain, disordered evacuation and ulceration of the rectal mucosa.

Both conditions are more common in women and later in life.

5. Provide a succinct description of the proposed medical service (no more than 150 words – further information will be requested at Part 6 of the Application Form)

Ventral rectopexy is a minimally invasive treatment for rectal prolapse and rectal intussusception that has gained widespread popularity over the last 2 decades. The procedure involves dissecting between the rectum and vagina (or bladder, seminal vesicles and prostate in the rare occasions when the condition affects a man) and then suturing a strip shaped prostheses (synthetic mesh or biological graft) to the ventral surface of the rectum and dorsal surface of the vagina and attaching the other end of the implant to the sacral promontory. The procedure is very similar to, the gynaecological procedure for vaginal prolapse, Sacral Colpopexy (MBS no. 35597). The prostheses then suspends the rectum and stops the rectum intussuscepting into and past the anal sphincter.

6. (a) Is this a request for MBS funding?

- Yes
 No

(b) If yes, is the medical service(s) proposed to be covered under an existing MBS item number(s) or is a new MBS item(s) being sought altogether?

- Amendment to existing MBS item(s)
 New MBS item(s)

(c) If an amendment to an existing item(s) is being sought, please list the relevant MBS item number(s) that are to be amended to include the proposed medical service:

Not applicable

(d) If an amendment to an existing item(s) is being sought, what is the nature of the amendment(s)?

Not applicable

(e) If a new item(s) is being requested, what is the nature of the change to the MBS being sought?

Not applicable

(f) Is the proposed service seeking public funding other than the MBS?

- Yes
 No

(g) If yes, please advise:

Not applicable

7. What is the type of service:

- Therapeutic medical service
- Investigative medical service
- Single consultation medical service
- Global consultation medical service
- Allied health service
- Co-dependent technology
- Hybrid health technology

8. For investigative services, advise the specific purpose of performing the service (which could be one or more of the following):

- i. To be used as a screening tool in asymptomatic populations
- ii. Assists in establishing a diagnosis in symptomatic patients
- iii. Provides information about prognosis
- iv. Identifies a patient as suitable for therapy by predicting a variation in the effect of the therapy
- v. Monitors a patient over time to assess treatment response and guide subsequent treatment decisions

9. Does your service rely on another medical product to achieve or to enhance its intended effect?

- Pharmaceutical / Biological
- Prosthesis or device
- No

10. (a) If the proposed service has a pharmaceutical component to it, is it already covered under an existing Pharmaceutical Benefits Scheme (PBS) listing?

Not applicable

(b) If yes, please list the relevant PBS item code(s):

Not applicable

(c) If no, is an application (submission) in the process of being considered by the Pharmaceutical Benefits Advisory Committee (PBAC)?

Not applicable

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

Not applicable

11. (a) If the proposed service is dependent on the use of a prosthesis, is it already included on the Prostheses List?

- Yes
- No

A variety of prostheses are used by different practitioners, many of these are repurposed hernia meshes or hernia biological grafts. Only one has been specifically marketed for use in Ventral Rectopexy, BioDesign® Rectopexy Graft (BRG) (Cook Biotech Inc, West Lafayette, IN). The most commonly used prostheses used in Australia are listed below.

(b) If yes, please provide the following information (where relevant):

Billing code(s): ET100
Trade name of prostheses: BioDesign Rectopexy Graft
Clinical name of prostheses: BioDesign Rectopexy Graft
Other device components delivered as part of the service: N/A

Billing code(s): MS033
Trade name of prostheses: Titanized Mesh Implant
Clinical name of prostheses: TiMesh
Other device components delivered as part of the service: N/A

Billing code(s): AS182
Trade name of prostheses: Permacol Biological Implant
Clinical name of prostheses: Permacol
Other device components delivered as part of the service: N/A

Billing code(s): JJ566
Trade name of prostheses: Prolene Mesh
Clinical name of prostheses: Prolene Mesh
Other device components delivered as part of the service: N/A

(c) If no, is an application in the process of being considered by a Clinical Advisory Group or the Prostheses List Advisory Committee (PLAC)?

Not applicable

(d) Are there any other sponsor(s) and / or manufacturer(s) that have a similar prosthesis or device component in the Australian market place which this application is relevant to?

Not applicable

(e) If yes, please provide the name(s) of the sponsor(s) and / or manufacturer(s):

Not applicable

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

Commonly a laparoscopic tacking device is used to secure the prostheses to the sacral promontory. There are a variety of devices that are effective for this job e.g. ProTack by Medtronic (Billing code AS045 ARTG 181429). Sutures can also be used to attach the prosthesis to the sacral promontory.

PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

- 13. (a) If the proposed medical service involves the use of a medical device, in-vitro diagnostic test, pharmaceutical product, radioactive tracer or any other type of therapeutic good, please provide the following details:**

Ventral Rectopexy uses a prosthesis to suspend the rectum from the sacral promontory and thus prevent it from prolapsing. A variety of different prostheses are used in Australia and are mostly re-purposed meshes and biological hernia grafts. The four commonest prostheses used in Australia are listed.

Type of therapeutic good: BioDesign Rectopexy Graft
Manufacturer's name: Cook Biotech Inc.
Sponsor's name: Endotherapeutics

Type of therapeutic good: Titanized Mesh Implant
Manufacturer's name: GFE, Nuremberg, Germany
Sponsor's name: Medical Specialities Australasia

Type of therapeutic good: Permacol Biological Implant
Manufacturer's name: Sofradim Production, France
Sponsor's name: Medtronic Australasia

Type of therapeutic good: Prolene Mesh
Manufacturer's name: Johnson and Johnson
Sponsor's name: Johnson and Johnson Pty Ltd.

- (b) Is the medical device classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?**

The synthetic meshes (Titanized Mesh and Prolene Mesh) are Class IIb.

Biological grafts (BioDesign and Permacol) are Class III

- 14. (a) Is the therapeutic good to be used in the service exempt from the regulatory requirements of the *Therapeutic Goods Act 1989*?**

- Yes
 No

- (b) If no, has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?**

- Yes (if yes, please provide details below)
 No

BioDesign

ARTG listing, registration or inclusion number: 317940

TGA approved indication(s), if applicable: N/A

TGA approved purpose(s), if applicable: The BioDesign® Rectopexy Graft is intended to support / reinforce soft tissue in surgical procedures for open and laparoscopic repair of rectal prolapse / rectal intussusception. This device is not intended to be used via a transvaginal approach. The device is supplied sterile and intended for one time use.

Titanized Mesh

ARTG listing, registration or inclusion number: 97288

TGA approved indication(s), if applicable: N/A

TGA approved purpose(s), if applicable: Soft Tissue Support

Permacol Biological Implant

ARTG listing, registration or inclusion number: 269662

TGA approved indication(s), if applicable: N/A

TGA approved purpose(s), if applicable: Permacol™ surgical implant is intended for permanent implantation in humans and is indicated for the reconstruction, recontouring and reformation of human soft connective tissue, particularly where loss of dermis has occurred, and as a supporting tissue in surgical procedures such as abdominal wall hernias and defects.

ARTG listing, registration or inclusion number: 181429

TGA approved indication(s), if applicable: N/A

TGA approved purpose(s), if applicable: For the repair of hernia and other fascial deficiencies that require the addition of a reinforcing or bridging material to obtain the desired surgical result

15. If the therapeutic good has not been listed, registered or included in the ARTG, is the therapeutic good in the process of being considered for inclusion by the TGA?

Not applicable

16. If the therapeutic good is not in the process of being considered for listing, registration or inclusion by the TGA, is an application to the TGA being prepared?

Not applicable

PART 4 – SUMMARY OF EVIDENCE

17. Provide an overview of all key journal articles or research published in the public domain related to the proposed service that is for your application (limiting these to the English language only). Please do not attach full text articles, this is just intended to be a summary.

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
1.	Case Series	Long-term outcome of laparoscopic ventral rectopexy for total rectal prolapse. D’Hoore A et.al. British Journal of Surgery 91(11):1500-5, 2004 Nov	First description of the technique demonstrating long-term control of prolapse in 40 of 42 patients and improvement in incontinence and constipation scores.	UI 15499644	November 2004
2.	Case Series	Laparoscopic ventral rectopexy for internal rectal prolapse: short-term functional results. Collinson R et.al Colorectal Disease 12(2):97-104, 2010 Feb	A case series of 75 patients with internal rectal prolapse (rectal intussusception) managed by ventral rectopexy demonstrating significant improvements in incontinence and constipation scores.	UI 19788493	February 2010
3.	Case Series	Laparoscopic ventral rectopexy for external rectal prolapse is safe and effective in the elderly. Does this make perineal procedures obsolete? Wijffels N et.al. Colorectal Disease. 13(15):561-6,2011 May	A case series of 80 consecutive patients from two centres of patients 80 years or over (range 80-97) demonstrating no cases of mortality, one major complication and recurrence in 3% with a median follow up of 23 months.	UI 20184638	May 2011

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
4.	Retrospective Review	A Multicentre Collaboration to Assess the Safety of Laparoscopic Ventral Rectopexy Evans C et. al. Diseases of the Colon and Rectum. 58(8):799-807,2015 Aug	5 centre retrospective review of prospectively maintained databases. 2203 patients. Mesh erosions identified in 45 patients (2.0%) of which 18 required trans-abdominal corrective surgery. Synthetic mesh had higher erosion rate than biological grafts and polyester mesh had higher rates of erosion than polypropylene.	UI 26163960	August 2015
5.	Randomised Controlled Study	Bowel function after laparoscopic posterior sutured rectopexy versus ventral mesh rectopexy for rectal prolapse: a double-blind randomised single-centre study. Lundby L et.al. The Lancet. Gastroenterology & Hepatology. 1 (4):291-297, 2016 12.	A small RCT with 12 months follow up comparing laparoscopic ventral rectopexy to a laparoscopic sutured posterior rectopexy. No statistically significant difference in improvement in functional outcomes. No recurrences in ventral group and 2 recurrences in posterior rectopexy group. Probably study was under-powered and follow up period too short. Please note that a subsequent publication (see below ref. 8) describes the long-term results after 5 years of follow up in this trial. Ventral rectopexy was significantly superior.	UI 28404199	December 2016
6.	Meta-analysis	Outcome of laparoscopic ventral mesh rectopexy for full-thickness external rectal prolapse: a systematic review, meta-analysis, and meta-regression analysis of the predictors for recurrence Emile SH et.al Surgical Endoscopy. 33(8):2444-2455,2019 08.	Meta-analysis of 17 studies with a total of 1242 patients. Demonstrating a weighted mean complication rate of 12.4% and a recurrence rate of 2.8% after median 23 months follow up. Constipation and incontinence improved in 71 and 79.3% respectively. Authors conclude that ventral rectopexy is safe and effective.	UI 31041515	August 2019

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
7.	Case-matched Study	Impact of Suture Type on Erosion Rate After Laparoscopic Ventral Mesh Rectopexy: A Case-Matched Study. Tejedor P et.al. Diseases of the Colon & Rectum. 62(12):1512-1517,2019 12.	High volume single institution. 495 cases of laparoscopic ventral mesh rectopexy (60% performed with non-absorbable sutures for attaching mesh to rectum and vagina and 40% with absorbable sutures). Overall mesh erosion rate was 2% with all occurring in non-absorbable sutures. No erosions in 199 consecutive patients where absorbable sutures used.	UI 31254202	December 2019
8.	Randomised Controlled Trial	Functional Outcome after Laparoscopic Posterior Sutured Rectopexy Versus Ventral Mesh Rectopexy for Rectal Prolapse: Six-year Follow-up of a Double-blind, Randomized Single-center Study. Hidaka J et al. EClinicalMedicine. 29(16):18-22 2019 8.	A long-term follow up of a previously published small RCT (see above Ref. 5) comparing VR with posterior sutured rectopexy. Whereas no advantage was seen in bowel function scores at one year follow up at 6 years follow up the results in the VR group were significantly superior. Furthermore there was a clear trend to reduced recurrence in the VR group 8.8% vs 23.3% (p=0.11).	PMID: 31832616	August 2019

18. Identify yet to be published research that may have results available in the near future that could be relevant in the consideration of your application by MSAC (limiting these to the English language only). Please do not attach full text articles, this is just intended to be a summary.

None identified

PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

- 19. List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the service (please attach a statement of clinical relevance from each group nominated):**

Colorectal Surgical Society of Australia and New Zealand

Section of Colorectal Surgery, Royal Australasian College of Surgeons

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

N/A

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

N/A

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

N/A

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

REDACTED

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

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

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

Full Thickness Rectal prolapse is defined as a protrusion of all layers of the rectum past the anal canal. In the early stages the prolapse will only occur when the patient is defaecating and will reduce spontaneously. With time the symptoms almost invariably deteriorate such that the prolapse occurs more readily and can become increasingly difficult to reduce even with digital pressure. The prolapse usually causes marked faecal and mucous incontinence. A non-reducible prolapse causes severe pain and attendance at an Emergency Department is essential in this situation. It is unusual to be able to manage rectal prolapse without surgical intervention for the remainder of the patient's life.

Incidence is 2.5 cases per 100,000 per annum. It has a female:male ratio of 10:1. It is more common in later life but can occur at any age. Previous pregnancy and connective tissue disorders are risk factors.

Rectal intussusception is defined as descent of the full-thickness of the rectal wall such that it descends towards or into the anal canal. It can vary in its symptoms from being completely asymptomatic to causing severe symptoms including faecal incontinence, obstructed defaecation and rectal ulceration resulting in stricture formation.

The incidence of rectal intussusception is unknown as it is often asymptomatic and the symptoms are often confused with other diagnoses or unrecognised by medical practitioners. Surgical management of patients with rectal intussusception is only indicated when there is proven descent into the anal canal (high grade intussusception) and symptoms are severe and conservative management with pelvic floor physiotherapy has failed to improve the patient's symptoms.

25. Specify any characteristics of patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed medical service, including any details of how a patient would be investigated, managed and referred within the Australian health care system in the lead up to being considered eligible for the service:

External rectal prolapse is easily diagnosed by clinical examination of the perineum and asking the patient to bear down. If the prolapse cannot be "produced" on clinical examination on the examination couch the patient can be examined whilst straining on the toilet or by examination under anaesthetic. In the era of mobile phones with cameras the patient can be asked to take a photograph of their own prolapse and show this to the surgeon they are consulting rather than have to be examined in the bathroom which can be embarrassing for the patient.

Almost all patients with external rectal prolapse should be offered surgical repair with bed-bound nursing home residents being an exception.

Rectal intussusception cannot be reliably diagnosed by clinical examination alone and defaecating imaging studies are required. Traditionally this was a Fluoroscopic Defaecating Proctogram. More recently a Magnetic Resonance Evacuation Proctogram has gained popularity.

The indications for surgical repair of rectal intussusception are if the patient has severe symptoms that are significantly impacting their quality of life and has failed conservative management with pelvic floor physiotherapy.

All patients should be investigated with a colonoscopy if they haven't had one in recent years to exclude synchronous pathology prior to surgery.

26. Define and summarise the current clinical management pathway *before* patients would be eligible for the proposed medical service (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway up to this point):

External prolapse flow:

Develop an external rectal prolapse > Attendance at General Practitioner > Referral to a colorectal surgeon or general surgeon with an interest in colorectal surgery > Colonoscopy (if not done recently) > pre-operative work up.

Rectal intussusception flow:

Develop symptoms of faecal incontinence and / or obstructed defaecation pattern constipation > Attendance at General Practitioner > Referral to a colorectal surgeon with an interest in pelvic floor disorders > Investigation with defaecating imaging studies, anal manometry, colonoscopy and examination under sedation > diagnosis of high grade rectal intussusception proven > referral to pelvic floor physiotherapist > review with surgeon > pre-operative work up only if patient has severe symptoms despite trial of pelvic floor physiotherapy and conservative management.

PART 6b – INFORMATION ABOUT THE INTERVENTION

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

The procedure is performed in a hospital operating theatre and very commonly the patient will have a 1 or 2 night stay in hospital but can also be performed as a day case procedure in selected patients. Admission is on the day of surgery. 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 3 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 right side of the rectum to the level of the mid-rectum. Dissection then proceeds in the recto-vaginal 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 20cm long and 3cm 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 closed to completely bury the prosthesis. Port sites are closed.

Post-operatively 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 1st or 2nd Post-operative day. The patient is reviewed by the surgeon a few weeks following surgery and discharged from follow up if appropriate.

28. Does the proposed medical service include a registered trademark component with characteristics that distinguishes it from other similar health components?

No

29. If the proposed medical service has a prosthesis or device component to it, does it involve a new approach towards managing a particular sub-group of the population with the specific medical condition?

No

30. If applicable, are there any limitations on the provision of the proposed medical service delivered to the patient (i.e. accessibility, dosage, quantity, duration or frequency):

No

31. If applicable, identify any healthcare resources or other medical services that would need to be delivered at the same time as the proposed medical service:

General anaesthesia.

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

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.

33. If applicable, advise whether the proposed medical service could be delegated or referred to another professional for delivery:

Not appropriate.

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

Colorectal surgeons (or general surgeons with a sub-specialist interest in colorectal surgery) with adequate training and expertise in Ventral Rectopexy.

35. If applicable, advise what type of training or qualifications would be required to perform the proposed service, as well as any accreditation requirements to support service delivery:

FRACS (General Surgery) would be a minimum qualification. Post fellowship training in colorectal surgery highly desirable.

36. (a) Indicate the proposed setting(s) in which the proposed medical service will be delivered (select ALL relevant settings):

- Inpatient private hospital (admitted patient)
- Inpatient public hospital (admitted patient)
- Private outpatient clinic
- Public outpatient clinic
- Emergency Department
- Private consulting rooms - GP
- Private consulting rooms – specialist
- Private consulting rooms – other health practitioner (nurse or allied health)
- Private day surgery clinic (admitted patient)
- Private day surgery clinic (non-admitted patient)
- Public day surgery clinic (admitted patient)
- Public day surgery clinic (non-admitted patient)
- Residential aged care facility
- Patient's home
- Laboratory
- Other – please specify below

(b) Where the proposed medical service is provided in more than one setting, please describe the rationale related to each:

N/A

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

- Yes
- No

PART 6c – INFORMATION ABOUT THE COMPARATOR(S)

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

This MSAC application was a recommendation of the Colorectal Sub-committee of the MBS Taskforce.

There already is a generic number for abdominal repair of rectal prolapse (32117) however this is for a posterior mobilisation and repair and does not reflect the increased technical difficulty of a minimally invasive Ventral Rectopexy. In contrast to the abdominal procedures of past decades, Ventral Rectopexy avoids posterolateral rectal mobilisation and thereby minimizes the risk of postoperative constipation. Minimally invasive Ventral Rectopexy is a very similar procedure to Laparoscopic Sacral Colpopexy (35597) which is for the management of vaginal vault prolapse. The Colorectal Sub-committee of the MBS Taskforce recommended a new item number be created for Ventral Rectopexy in order to differentiate the procedure from other abdominal rectopexies and establish a fee that was the similar to Laparoscopic Sacral Colpopexy. Ventral Rectopexy also provides the opportunity to concomitantly address anterior compartment (vaginal) prolapse and other pelvic floor hernias such as an enterocele. Furthermore, ventral rectopexy has been shown to be effective for the management of high grade rectal intussusception whereas other abdominal rectal prolapse repair procedures have been shown to be ineffective. As 32117 is for a rectal prolapse it was thought the new item number for Ventral Rectopexy should reflect that the procedure is different to traditional rectopexy and indicated in management of high grade highly symptomatic rectal intussusception.

Unlike ventral rectopexy, which is rarely combined with an anterior resection, abdominal rectopexy is often accompanied by a high anterior resection (32024), a so called “Resection-rectopexy”. The reason for this is that traditional rectopexy is associated with a high incidence of troublesome new onset constipation. Denervation of the hindgut through posterior and lateral mobilisation of the rectum in traditional rectopexy is thought to be the reason for this. Resection-rectopexy attempts to compensate for this by resecting much of the denervated hindgut. There is good evidence that 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. Prior to the adoption of Ventral Rectopexy, the resection-rectopexy was considered the ‘gold standard’ procedure for younger patients with rectal prolapse. Ventral rectopexy avoids constipation as the dissection is only ventral to the rectum which does not cause denervation of the rectum and synchronous anterior resection is therefore rarely required.

There are also a couple of procedures for repair / resection of rectal prolapse done via a perineal approach. The most commonly used is a Delorme’s procedure. This is a so called “mucosal reduction procedure” In this procedure the surgeon resects the mucosa circumferentially off of the prolapsed rectum, plicates the exposed muscle, reduces the plicated muscle and then anastomoses the proximal and distal edges of the mucosa together. The procedure is well tolerated and can be done under spinal anaesthesia. However, it is associated with a very high recurrence rate and is therefore usually used only in elderly frail patients. There is good evidence that ventral rectopexy is as well tolerated in elderly patients leading many to question the utility of Delorme’s procedure. Furthermore, Delorme’s procedure reduces the capacitance and volume of the rectum which may lead to worse bowel function.

Altmeier’s procedure (also known as Perineal Recto-sigmoidectomy) is a perineal procedure where the entire prolapsed rectum is resected and a colo-anal anastomosis is performed. Like Delorme’s procedure it is associated with a high risk of recurrence. The colo-anal anastomosis can also leak causing serious pelvic sepsis or peritonitis. The removal of the rectum itself causes marked alteration to bowel habit analogous to ‘low anterior resection syndrome’. For all these reasons Altmeier’s procedure is rarely performed in Australia.

39. Does the medical service (that has been nominated as the comparator) have an existing MBS item number(s)?

- Yes (please list all relevant MBS item numbers below)
 No

32117 Abdominal Rectopexy (combined with 32024 in the case of resection-rectopexy)

32111 Delorme's procedure

32112 Perineal Recto-sigmoidectomy (Altmeier procedure)

40. Define and summarise the current clinical management pathway/s that patients may follow *after* they receive the medical service that has been nominated as the comparator (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway that patients may follow from the point of receiving the comparator onwards, including health care resources):

Following surgery the management is slightly different depending on which procedure they have had.

Delorme's procedure

- Return to post-operative ward.
- Diet recommenced immediately post-operatively.
- 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 out-patient clinic / rooms after 1 month and discharge if stable and prolapse controlled

Altmeier's procedure

- Return to ward post-operatively.
- Clear fluids immediately post-operatively.
- Recommence diet at surgeon's discretion, the surgeon will need to be satisfied that the anastomosis has sealed. This time will vary widely from patient to patient and surgeon to surgeon.
- Discharge after several days observation when surgeon confident that the patient has not suffered a septic complication.

Abdominal Rectopexy (open)

- Return to ward post-operatively.
- Clear fluids immediately post-operatively.
- 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 patient's pain is controlled with oral analgesia, bowels open and patient self-caring.

Abdominal Rectopexy (laparoscopic)

- Return to ward post-operatively.
- Clear fluids immediately post-operatively.
- Recommence diet next day and remove urinary catheter.
- Discharge after 1 to 2 days when patient opening bowels and self-caring.

Resection – Rectopexy (open or laparoscopic)

- Return to ward post-operatively.
- Clear fluids immediately post-operatively.
- 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.

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

- In addition to (i.e. it is an add-on service)
- Instead of (i.e. it is a replacement or alternative)

(b) If instead of (i.e. alternative service), please outline the extent to which the current service/comparator is expected to be substituted:

Ventral rectopexy will entirely replace the comparator procedures when performed. The procedure is increasingly becoming the procedure of choice for most Australian Colo-rectal surgeons who manage rectal prolapse. It is unknown exactly how many ventral rectopexies are currently being performed and how many will be performed in years to come.

42. Define and summarise how current clinical management pathways (from the point of service delivery onwards) are expected to change as a consequence of introducing the proposed medical service, including variation in health care resources (Refer to Question 39 as baseline):

Ventral rectopexy is associated with a recovery time that is as quick as the least invasive procedure for rectal prolapse (Delorme’s procedure) but with a much lower recurrence rate. Revision surgery is therefore greatly reduced after Ventral Rectopexy. Overall the healthcare costs will most likely be less overall with use of ventral rectopexy compared to Delorme’s procedure because of reduced recurrence of rectal prolapse requiring further management. Ventral rectopexy is rarely accompanied by Anterior Resection.

Ventral rectopexy is associated with less constipation than posterior rectopexy which will reduce use of laxatives and further surgical appointments, investigations and management and provide improved function and quality of life for the patients.

Resection-rectopexy has the addition of a high anterior resection as part of the procedure which is co-charged as item number 32024. Hospital stay is longer for resection – rectopexy. due to the higher risk of post-operative complications such as pelvic sepsis and anastomotic leak.

PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME

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

Ventral rectopexy is an effective minimally invasive procedure for rectal prolapse that is associated with a rapid recovery, low rates of recurrence, low rates of new onset constipation and high rates of improvement of faecal incontinence and constipation.

Ventral rectopexy also has efficacy in the management of highly symptomatic high-grade rectal intussusception which no other procedure for rectal prolapse has ever shown an efficacy.

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

- Superiority
- Non-inferiority

45. Below, list the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be specifically measured in assessing the clinical claim of the proposed medical service versus the comparator:

Safety Outcomes:

- Low mortality and morbidity even in the elderly.
- Low rates of prosthesis complication (erosion and infection).

Clinical Effectiveness Outcomes:

- Low rates of recurrence of rectal prolapse.
- Rapid recovery from minimally invasive surgery.
- High rates of improved faecal continence and constipation scores.
- Low rates of new onset constipation.

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

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

In the financial year 2016/2017 across all of Australia item number 32111 (Delorme's procedure) was claimed 950 times, 32112 (perineal recto-sigmoidectomy) 37 times and 32117 (abdominal rectopexy) 671 times. As the population ages there may be more cases of rectal prolapse. It may also be the case that the popularity of Delorme's procedure will recede as Ventral Rectopexy gains popularity which may reduce the overall incidence of surgery as Delorme's procedure has a high recurrence rate.

How many times 32117 was used for ventral rectopexy for correction of rectal intussusception is unknown. In most surgeons' practice cases where ventral rectopexy is used for intussusception is much less common than when it is used for full thickness rectal prolapse.

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

Ventral rectopexy will be used only once in the patient's lifetime in over 90% of cases as recurrence rates are reported to be less than 10%.

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

Ventral rectopexy is a 'stand-alone' operation that will only be performed once in the vast majority of patients.

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

See answer to question 46.

50. Estimate the anticipated uptake of the proposed medical service over the next three years factoring in any constraints in the health system in meeting the needs of the proposed population (such as supply and demand factors) as well as provide commentary on risk of 'leakage' to populations not targeted by the service:

The procedure is already being done and is currently claimed as item number 32117. This is often also combined with some form of pelvic floor repair or colposacrosuspension, as indicated, with co-claiming either 35595 or 35597. If ventral rectopexy is recognised by MSAC and a new item number created for it as recommended by the Colorectal Sub-committee of the MBS Taskforce Committee the use of the new number will see a corresponding reduction in the use of number 32117, 35595 and 32997.

PART 8 – COST INFORMATION

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

As stated above Ventral Rectopexy takes the place of Abdominal Rectopexy. The only cost implication is that if the Colorectal Sub-committee of the MBS Taskforce Committee’s recommendation that the fee for Ventral Rectopexy is increased to make it the same as Sacral Colpopexy. This will result in an increased fee for ventral rectopexy compared to abdominal rectopexy; however, as anterior resection was traditionally claimed with abdominal rectopexy for those having a resection – rectopexy the overall cost to MBS may be little or even there might be a cost saving. Similarly, an appropriate item number and fee for ventral rectopexy would negate the co-claiming of concomitant anterior compartment or pelvic floor repair, providing further overall cost saving. If Ventral Rectopexy increasingly takes the place of Delorme’s procedure there may be some increased costs to MBS; however, the much reduced rate of recurrence will likely offset this cost completely over time.

An appropriate item number and fee for Ventral Rectopexy, as suggested by the Colorectal Sub-committee of the MBS taskforce, will rarely be co-claimed with any other item number with the possible exception of division of adhesions in the unusual situation where a patient has extensive adhesions that take more than 45 minutes to divide (30724).

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

Ventral Rectopexy usually takes between 90 and 180 minutes operating time depending on surgeon experience and patient factors. The patient also requires general anaesthetic, positioning on the operating table and prepping and draping. With change around time between patients it is unlikely to be possible to perform the procedure on more than 1 to 2 patients during a single 4 hour operating session.

53. If public funding is sought through the MBS, please draft a proposed MBS item descriptor to define the population and medical service usage characteristics that would define eligibility for MBS funding.

Below is the description recommended by the Colorectal Sub-committee of the MBS Taskforce Committee. The fee is the same fee as for Sacral Colpopexy as of July 1st 2021.

Category 3 – T8 Sub-group 2 (Colorectal)
Proposed new item number 32118
<p>VENTRAL RECTOPEXY. Treatment of external rectal prolapse or symptomatic high grade internal rectal prolapse by laparoscopy or robotic-assistance involving and including dissection of the recto-vaginal 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 32118. 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>
Fee: \$1519.20