MSAC Application 1725

Transanal Total Mesorectal Excision (taTME) for the treatment of rectal cancer and benign disease

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 Instructions 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. The separate MSAC Guidelines should be used to guide health technology assessment (HTA) content of the Application Form

Should you require any further assistance, departmental staff are available through the Health Technology Assessment Team (HTA Team) on the 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 (where relevant): CSSANZ
Corporation name: Colorectal Surgical Society of Australia and New Zealand (CSSANZ)
ABN: 75055544664
Business trading name: Colorectal Surgical Society of Australia and New Zealand

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 consultant acting on behalf on an applicant?

☐ Yes
☒ No

(b) If yes what is the Applicant(s) name that you are acting on behalf of?

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

☐ Yes
☒ No

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

N/A

(c) Have you engaged a consultant on your behalf?

☐ Yes
☒ No

PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

4. Application title

Transanal Total Mesorectal Excision (taTME) for the Treatment of Rectal Cancer

5. 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)

Colorectal cancer is the second most common cause of cancer death in Australia. For rectal cancer, surgery remains the mainstay of cure. Surgical technique is critical in ensuring the best outcomes in rectal cancer. However, resection of rectal tumours can be challenging due to difficulty in access especially in the narrow pelvis and in obesity. Achieving clear margins and harvesting the lymph node package by having a complete total mesorectal excision (TME) in patients undergoing rectal cancer resection is essential. Technical access to the low pelvis is also important in considering reconstruction, which is an important factor in cancer survivorship. For some patients, reconstruction is not possible or appropriate. However, for other patients joining the colon to the remaining rectum may allow them to have restoration of bowel function without compromising their oncological outcomes. TaTME has been described as a strategy to improve surgical access for resection and reconstruction in the low pelvis.

6. 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)

Technological evolution is important in improving our approach to rectal cancer to allow a tailored approach to each patient's needs. TaTME utilises a combined approach, by entering the TME plane from below using a transanal approach. This gives an alternative method of access to the low pelvis. Dissection is performed using both an abdominal approach and a transanal approach, which eventually meet. For patients with difficult pelvic anatomy and low rectal cancer this technique provides the possibility of enhanced precision in dissection, clear margins, and reconstruction. Therefore, it is important that there is appropriate support for the selected use of TaTME in rectal cancer in Australia. TaTME does have a significant learning curve and appropriate proctoring and quality assurance is essential. It is worth noting that Australia has had a more favourable experience with the learning curve in TaTME surgery compared to our European counterparts[1]. This is due to rigorous proctoring and training for TaTME in Australia. Recent publication shows good oncological outcomes in the Australian cohort[2].

1. Abbott SC, Stevenson ARL, Bell SW, Clark D, Merrie A, Hayes J, Ganesh S, Heriot AG, Warrier SK. An assessment of an Australasian pathway for the introduction of transanal total mesorectal excision (taTME). Colorectal Dis. 2018 Jan;20(1):O1-O6PMID: 29165862.
2. Lau S, Kong J, Bell S, Heriot A, Stevenson A, Moloney J, Hayes J, Merrie A, Eglinton T, Guest G, Clark D, Warrier S. Transanal mesorectal excision: early outcomes in Australia and New Zealand. Br J Surg. 2021 Mar 12;108(2):214-219. PMID: 33711138.

7. (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/technology:

N/A

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

N/A

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

- ☐ A new item which also seeks to allow access to the MBS for a specific health practitioner group
- ☒ A new item that is proposing a way of clinically delivering a service that is new to the MBS (in terms of new technology and/or population)
- ☐ A new item for a specific single consultation item
- ☐ A new item for a global consultation item(s)

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

- ☐ Yes
- ☒ No

(g) If yes, please advise:

N/A

8. What is the type of medical service/technology?

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

9. For investigative services, advise the specific purpose of performing the service

N/A

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

- ☐ Pharmaceutical / Biological
- ☐ Prosthesis or device
- ☒ No

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

N/A

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

N/A

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

N/A

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

N/A

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

N/A

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

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)?

N/A

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

☐ Yes
☐ No

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

Single and multi-use consumables that will be used are all in current use as part of minimally invasive surgery for rectal cancer. As it is a combined approach with both an abdominal and a perineal component, some minimally invasive items may be required in duplicate, e.g. multiuse minimally invasive camera, single use energy device e.g. harmonic. The **REDACTED** is used for the perineal component of the operation.

PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

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

All equipment used for TaTME is already in use in minimally invasive colorectal surgery in Australia.

(b) Has it been listed on the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)? If the therapeutic good has been listed on the ARTG, please state the ARTG identification numbers, TGA-approved indication(s), and TGA-approved purpose(s).

N/A

(c) If a medical device is involved, has the medical device been classified by TGA as a Class III OR Active Implantable Medical Device (AIMD) under the TGA regulatory scheme for devices?

☐ Class III
☐ AIMD
☒ N/A

(d) Is the therapeutic good classified by TGA for Research Use Only (RUO)?

N/A

15. (a) <u>If not listed on the ARTG</u>, is the therapeutic good to be used in the service exempt from the regulatory requirements of the *Therapeutic Goods Act 1989*?

N/A

(b) If the therapeutic good is <u>not ARTG listed</u>, is the therapeutic good in the process of being considered by TGA?

N/A

(c) If the therapeutic good is NOT in the process of being considered by TGA, is an application to TGA being prepared?

N/A

PART 4 – SUMMARY OF EVIDENCE

16. Provide one or more recent (published) high quality clinical studies that support use of the proposed health service/technology. At 'Application Form lodgement', please do not attach full text articles; just provide 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.	Observational Study	Fernández-Hevia M, Delgado S, Castells A, et al. Transanal total mesorectal excision in rectal cancer: short-term outcomes in comparison with laparoscopic surgery. *Annals of surgery*. 2015; 261:221-7.	This study evaluated short-term outcomes of TaTME and demonstrated that it is feasible and safe with a shorter surgical time and a lower early readmission rate.	https://pubmed.ncbi.nlm.nih.gov/25185463/	2015
2.	Observational Study	Abbott SC, Stevenson ARL, Bell SW, Clark D, Merrie A, Hayes J, Ganesh S, Heriot AG, Warrier SK. An assessment of an Australasian pathway for the introduction of transanal total mesorectal excision (taTME). Colorectal Dis. 2018 Jan;20(1):O1-O6. doi: 10.1111/codi.13964. PMID: 29165862.	This study demonstrated acceptable short-term outcomes following the introduction of TaTME in Australia, with intact TME in >98% of cases (n=133). It also describes the training pathway in Australasia.	https://pubmed.ncbi.nlm.nih.gov/29165862/	2018

	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
	Guideline, Systematic review and metaanalyses	Milone, M., Adamina, M., Arezzo, A., Bejinariu, N., Boni, L., Bouvy, N., de Lacy, F. B., Dresen, R., Ferentinos, K., Francis, N. K., Mahaffey, J., Penna, M., Theodoropoulos, G., Kontouli, K. M., Mavridis, D., Vandvik, P. O., & Antoniou, S. A. (2022). UEG and EAES rapid guideline: Systematic review, meta-analysis, GRADE assessment and evidence-informed European recommendations on TaTME for rectal cancer. *Surgical endoscopy*, *36*(4), 2221–2232. https://doi.org/10.1007/s00464-022-09090-4	This is a European guideline on the use of TaTME for rectal cancer. It provides a weak recommendation for TaTME in appropriate cases over other minimally invasive approaches to TME where expertise are available, and also provides a decision support tool.	https://link.springer.com/article/10.1007/s00464-022-09090-4	2022
3.	Systematic review and metanalyses	Lo Bianco S, Lanzafame K, Piazza CD, Piazza VG, Provenzano D, Piazza D. Total mesorectal excision laparoscopic versus transanal approach for rectal cancer: A systematic review and meta-analysis. Ann Med Surg (Lond). 2022 Jan 24;74:103260. doi: 10.1016/j.amsu.2022.103260. PMID: 35145658; PMCID: PMC8802044.	The meta-analysis demonstrated safety of TaTME for low and mid rectal cancer. They concluded that TaTME can lead to a high quality rectal cancer resection specimen with lower rates of circumferential margin positivity compared to other techniques. N=471	https://pubmed.ncbi.nlm.nih.gov/35145658/	2022

	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.	Observational Study	Ourô S, Ferreira M, Roquete P, Maio R. Transanal versus laparoscopic total mesorectal excision: a comparative study of long-term oncological outcomes. Tech Coloproctol. 2022 Apr;26(4):279-290. doi: 10.1007/s10151-022-02570-8. Epub 2022 Jan 20. PMID: 35050434.	Retrospective study in two Portugese centres demonstrated that TaTME appears to be comparable to lapTME, with similar long-term oncological outcomes. They did provide the caveat that it has a a demanding learning curve with risk of morbidity and should be used only for selected patients. They did have a higher rate of anastomosis at a shorter distance to the anal verge in the TaTME group, suggesting an advantage in making reconstruction feasible. (n= 44 TaTME, n=39 Lap TME)	https://pubmed.ncbi.nlm.nih.gov/35050434/	2022
5	Observational Study	Lau S, Kong J, Bell S, Heriot A, Stevenson A, Moloney J, Hayes J, Merrie A, Eglinton T, Guest G, Clark D, Warrier S. Transanal mesorectal excision: early outcomes in Australia and New Zealand. Br J Surg. 2021 Mar 12;108(2):214-219. doi: 10.1093/bjs/znaa098. PMID: 33711138.	This study shows good outcomes in the Australian experience of TaTME. The anastomotic leak rate was 8.1 per cent and there was no mortality within 30 days of surgery. There was a complete mesorectum in >95% of patients. Over a median follow-up of 22 months, the local recurrence rate was less than 2%. (N=308)	https://pubmed.ncbi.nlm.nih.gov/33711138/	2021
6	Systematic review and metanalysis	Choy KT, Yang TWW, Prabhakaran S, Heriot A, Kong JC, Warrier SK. Comparing functional outcomes between transanal total mesorectal excision (TaTME) and laparoscopic total mesorectal excision (LaTME) for rectal cancer: systematic review and metanalysis. Int J Colorectal Dis. 2021 Jun;36(6):1163-1174. doi: 10.1007/s00384-021-03849-2. Epub 2021 Feb 13. PMID: 33580808.	This review compared functional outcomes between laparoscopic and TaTME and demonstrated no difference in functional outcomes in TaTME.	https://pubmed.ncbi.nlm.nih.gov/33580808/	2021

	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	Observational study	Larach JT, Rajkomar AKS, Smart PJ, McCormick JJ, Heriot AG, Warrier SK. Beyond transanal total mesorectal excision: short-term outcomes of transanal total mesorectal excision in locally advanced rectal cancer requiring resection beyond total mesorectal excision. Colorectal Dis. 2021 Apr;23(4):823-833. doi: 10.1111/codi.15446. Epub 2020 Dec 19. PMID: 33217140.	This study examined the role of TaTME in non standard beyond TME resections. This study demonstrated a role for taTME as an additional tool in the resection of non standard beyond TME resections in highly selected patients in expert hands.	https://pubmed.ncbi.nlm.nih.gov/33217140/	2021

17. Identify yet-to-be-published research that may have results available in the near future (that could be relevant to your application). Do not attach full text articles; this is just a summary.

	Type of study design	Title of research (including any trial identifier if relevant)	Short description of research	Website link to research	Date
1.	Matched Cohort Trial	Jootun R, Cuk P, Ellebæk M, Andersen PV, Salomon S, Baatrup G, Al-Najami I, Khan J. Robotic vs. TaTME Rectal Surgery (ROTA STUDY) Matched Cohort Trial for Mid to Low Rectal Cancer Surgery Evaluation Trial in the Hands of an Experienced Surgeon. Int J Surg Protoc. 2022 Feb 18;26(1):7-13. doi: 10.29337/ijsp.163. PMID: 35280494; PMCID: PMC8855734.	This trial is in progress comparing standard robotic TME to transanal TME.	https://clinicaltrials.gov/ct2/show/NCT04200027	Ongoing trial

	Type of study design	Title of research (including any trial identifier if relevant)	Short description of research	Website link to research	Date
2.	Retrospective propensity matched study	Impact of the approach on conversion to open surgery during minimally invasive restorative total mesorectal excision for rectal cancer. Larach T, Warrier S, Heriot A et al. Manuscript submitted to Colorectal Disease – currently undergoing peer-review	This study evaluated 318 patients who had undergone MIS approach to rectal cancer at a single institution. Multiple logistic regression demonstrated that taTME was associated with a lower conversion rate compared to other techniques.	NA	2022

PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

18. **List all appropriate professional bodies/organisations representing the health professionals who provide the service. For MBS-related applications ONLY, please attach a brief 'Statement of Clinical Relevance' from the most relevant college/society.**

    The need for MBS items for TaTME in rectal cancer is highlighted in the Medicare Benefits Schedule Review Final Report on the Review of Colorectal Surgery MBS Items 2019 - Item 4.5.6 Recommendation 10- create three new items for the abdominal component of taTME for rectal cancer and four new items for the perineal component of taTME for rectal cancer.

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

    CSSANZ

20. **List the consumer organisations relevant to the proposed medical service (noting there is NO NEED to attach a support letter at the 'Application Lodgement' stage of the MSAC process):**

    Bowel Cancer Australia

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

    N/A

22. **Nominate two experts that can be contacted about the proposed medical service, and current clinical management of the condition:**

    Name of expert 1: **REDACTED**

    Telephone number(s): **REDACTED**

    Email address: **REDACTED**

    Justification of expertise: **REDACTED**

    Name of expert 2: **REDACTED**

    Telephone number(s): **REDACTED**

    Email address: **REDACTED**

    Justification of expertise: **REDACTED**

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

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

23. 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):

Rectal cancer is a significant burden of disease as one of the four most common causes of cancer death in Australia. Rectal cancer treatment includes radiotherapy, chemotherapy and surgery, with surgery forming the mainstay of cure. High quality rectal cancer surgery is essential as a total mesocolic excision with excision of the TME envelope is associated with improved survival. Achieving a TME can be technically challenging in the low narrow pelvis. Traditionally, rectal cancer surgery was performed with large abdominal incisions, "open surgery". However, in recent years minimally invasive surgery has taken over as the mainstay of rectal cancer surgery. This facilitates rectal cancer surgery with smaller incisions and improved functional recovery. The technical challenges of low rectal cancer and the opportunities posed by minimally invasive platforms has led to evolution of techniques and the introduction of taTME surgery to try and overcome these challenges. TaTME involves a dual approach, using both surgery from above (usually minimally invasive transabdominal surgery) and surgery from below where the TME is entered using minimally invasive techniques from the perineum. It is also used in selected benign cases to facilitate restoration of continuity.

24. Specify the characteristics of patients with (or suspected of having) the medical condition, who would be eligible for the proposed medical service/technology (including details on how a patient would be investigated, managed and referred within the Australian health care system, in the lead up to being eligible for the service):

Work up is in the standard fashion for rectal cancer, usually involving MRI pelvis, CT chest/abdomen/pelvis and an examination under anaesthetic and flexible sigmoidoscopy to assess tumour height and relationship to sphincters. Together these investigations are reviewed at a multidisciplinary meeting (MDT) to determine treatment strategy, which may involve other therapies prior to surgery, e.g. neoadjuvant chemoradiotherapy, depending on the tumour stage.

For those patients undergoing surgery for rectal cancer, TaTME is utilised for patients with low rectal cancer in centres with the appropriate expertise where the surgeon and MDT deem the taTME approach helpful in technically achieving a complete total mesorectal excision or facilitating reconstruction. It is also utilised in selected benign cases that would otherwise likely require a permanent stoma.

This service is already provided and the change is simply in the coding to acknowledge the technical complexity and dual-surgeon approach of this procedure.

PART 6b – INFORMATION ABOUT THE INTERVENTION

25. Describe the key components and clinical steps involved in delivering the proposed medical service/technology:

The key components of this procedure involve both an abdominal approach and a perineal approach. Usually this is performed using minimally invasive techniques, with a pneumoperitoneum and 2 or 3D visualisation of structures and dissection using an abdominal approach and a perineal approach. The abdominal and perineal approaches may be completed simultaneously.

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

No

27. **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

28. **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)?**

    Training is important in ensuring high quality TaTME surgery. Due to the requirement for a highly specialist skillset, this technique will be limited to surgeons and centres with a relatively high volume of rectal cancer surgery and sufficient TaTME surgery to maintain and develop skill.

29. **If applicable, identify any healthcare resources or other medical services that would need to be delivered <u>at the same time</u> as the proposed medical service:**

    General anaesthetic during the procedure

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

    Colorectal surgeons trained appropriately in the technique. Two surgeons are required usually to facilitate transabdominal and perineal approaches.

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

    No- this is a highly specialised technique

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

    Surgeons who have not completed appropriate training in TaTME surgery should not undertake it without appropriate proctoring.

33. **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:**

    Fellowship training or proctoring in TaTME surgery. The Australian training paradigm for taTME surgery has been shown to result in good outcomes.

34. **(a) Indicate the proposed setting(s) in which the proposed medical service will be delivered (select <u>ALL</u> 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

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

    Public and private patients attending appropriately trained surgeons requiring taTME resection of rectal cancer.

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

☒ Yes
☐ No – please specify below

PART 6c – INFORMATION ABOUT THE COMPARATOR(S)

36. 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). This includes identifying health care resources that are needed to be delivered at the same time as the comparator service):

Standard rectal cancer surgery- this may require a single surgeon rather than two as the perineal and abdominal component are not done simultaneously.

37. 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

38. (a) Will the proposed medical service/technology 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 yes, please outline the extent to which the current service/comparator is expected to be substituted

TaTME is a relatively niche procedure for only selected cases where traditional non-TaTME approaches have significant technical challenges. The abdominal requirement for these procedures would still exist and this is simply adding on sufficient detail to reflect the complexity and the potential requirement for dual-surgeon operating with often simultaneous abdominal and perineal approaches.

PART 6c CONTINUED – INFORMATION ABOUT ALGORITHMS (CLINICAL MANAGEMENT PATHWAYS)s

39. Define and summarise the CURRENT clinical management pathway (algorithm) that patients follow when they receive the COMPARATOR service (i.e. the landscape before the proposed service is introduced). An easy-to-follow flowchart is preferred, depicting the current clinical management pathway), but dot-points would be acceptable. Please include health care resources used in the current landscape (e.g. pharmaceuticals, diagnostics and investigative services, etc.).

Rectal cancer treatment currently follows a standard algorithm for management. This involves staging investigations with colonoscopy, MRI pelvis and CT chest abdomen and pelvis. These are used to determine if the tumour is locally advanced. If the tumour is locally advanced, neoadjuvant treatment is recommended followed by surgery. For early tumours, surgery may be recommended as the initial treatment. Treatment decisions are made at the colorectal multidisciplinary meeting (MDT). This also facilitates surgical planning, e.g. consideration of whether a taTME approach would be beneficial.

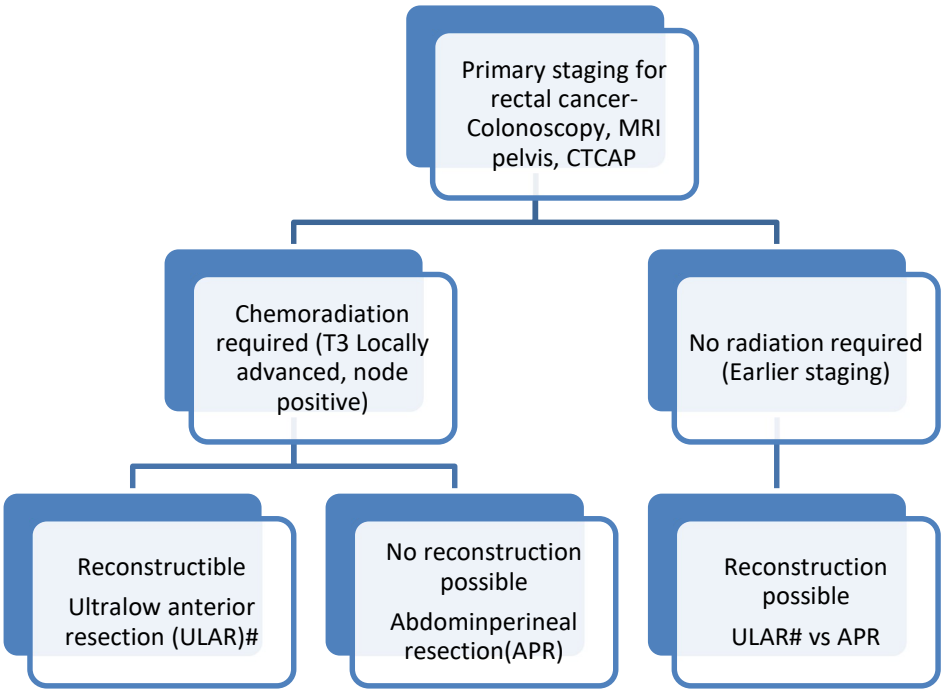

Figure 1: Clinical management algorithm

Notes: # taTME particularly useful in facilitating low reconstruction in low rectal cancers who otherwise may be offered a permanent stoma (APR).

Figure 1 shows that early rectal cancers go for surgery, many locally advanced cancers receive a combination of chemotherapy and radiation therapy prior to surgery.

40. Define and summarise the PROPOSED clinical management pathway (algorithm) that patients would follow <u>after</u> the proposed service/technology is introduced, including variation in health care resources.

The pathway would be the same as standard rectal cancer treatment pathway. If after discussion at the MDT, a taTME approach was recommended this would then be undertaken.

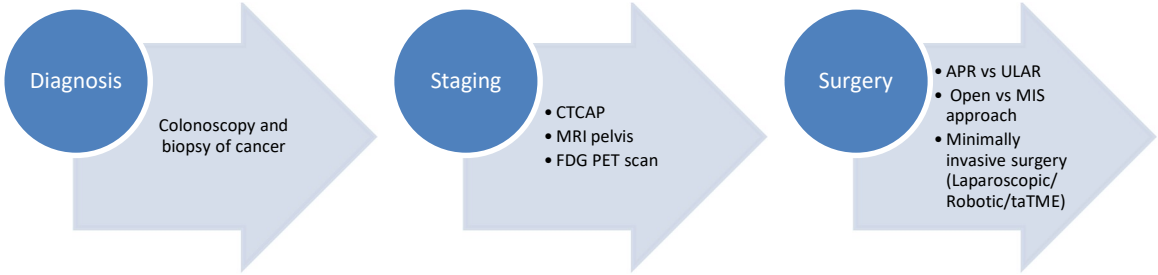

Figure 2: Usual pathway for rectal cancer patients

<u>PART 6d – INFORMATION ABOUT CLINICAL OUTCOMES</u>

41. 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):

TaTME can facilitate improved access to the low pelvis. There were concerns internationally regarding recurrence following TaTME but this has not been replicated in an Australian context, likely due to the training pathway in Australasia.

42. Please state what the overall clinical claim is:

TaTME can facilitate improved precision in TME surgery in patients with difficult to access tumours and facilitate reconstruction in selected patients where it would otherwise be impossible.

43. List the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be measured in assessing the clinical claim for the proposed medical service/technology (versus the comparator):

Completeness of TME, recurrence, survival, reconstruction rates, functional outcome

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

44. Estimate the prevalence and/or incidence of the condition in the proposed population:

The age standardised rate for rectal cancer is 53 per 1000000 per year. Only a small proportion of these patients would require a taTME approach.

45. Estimate the number of times the proposed medical service/technology would be delivered to a patient per year:

The technique of TaTME will be performed by a limited number of surgeons in specialised centres with the expertise to deliver high quality taTME. Australian expert consensus is that a minimum of 25 rectal cancer cases per year should be carried out in the unit and a minimum of five taTME cases per year.

How many years would the proposed medical service/technology be required for the patient?

For individual patients this will be a once off at the time of their surgery for rectal cancer

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

20-30

47. Estimate the anticipated uptake of the proposed medical service/technology 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.

Uptake is predicted to remain relatively low as patient selection is key and this technique is required for a. relatively small proportion of rectal cancer patients and is only performed by a small number of highly subspecialised rectal cancer surgeons.

PART 8 – COST INFORMATION

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

The taskforce has recommended the following costings in recommendation 10:

Trans-abdominal component of an ultra-low anterior resection where the rectal dissection is performed by a technique involving the use of a digital viewing platform and pneumopelvis (trans-anal total mesorectal excision) ($1364.60)

Trans-abdominal component of a restorative proctocolectomy where the rectal dissection is performed by a technique involving the use of a digital viewing platform and pneumopelvis (trans-anal total mesorectal excision). ($1507.40)

Trans-abdominal component of an abdomino-perineal resection of rectum and anus where the rectal dissection is performed by a technique involving the use of a digital viewing platform and pneumopelvis (trans-anal total mesorectal excision). ($1031.35)

Trans-abdominal component of a pan-proctocolectomy where the rectal dissection is performed by a technique involving the use of a digital viewing platform and pneumopelvis via the perineal incision. ($1150.35)

Perineal component of an ultra-low anterior resection or restorative proctocolectomy with stapled anastomosis where the rectal dissection is performed by a technique involving the use of a digital viewing platform and pneumopelvis (trans-anal total mesorectal excision). ($1202.05)

Perineal component of an ultra-low anterior resection or restorative proctocolectomy with partial inter-sphincteric dissection and hand sewn colo-anal anastomosis where the rectal dissection is performed by a technique involving the use of a digital viewing platform and pneumopelvis (trans-anal total mesorectal excision). ($1483.20)

Perineal component of an abdomino-perineal resection or rectum and anus or pan- proctocolectomy where the rectal dissection is performed by a technique involving the use of a digital viewing platform and pneumopelvis (trans-anal total mesorectal excision). ($1031.35)

49. Specify how long the proposed medical service/technology typically takes to perform:

5-6 hours. May add an additional hour to a standard ultralow anterior resection.

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

320AR: Trans-abdominal component of an ultra-low anterior resection where the rectal dissection is performed by a technique involving the use of a digital viewing platform and pneumopelvis (trans-anal total mesorectal excision) ($1364.60)

320TC: Trans-abdominal component of a restorative proctocolectomy where the rectal dissection is performed by a technique involving the use of a digital viewing platform and pneumopelvis (trans-anal total mesorectal excision). ($1507.40)

320HP: Trans-abdominal component of an abdomino-perineal resection of rectum and anus where the rectal dissection is performed by a technique involving the use of a digital viewing platform and pneumopelvis (trans-anal total mesorectal excision). ($1031.35)

320PC: Trans-abdominal component of a pan-proctocolectomy where the rectal dissection is performed by a technique involving the use of a digital viewing platform and pneumopelvis via the perineal incision. ($1150.35)

320ST: Perineal component of an ultra-low anterior resection or restorative proctocolectomy with stapled anastomosis where the rectal dissection is performed by a technique involving the use of a digital viewing platform and pneumopelvis (trans-anal total mesorectal excision). ($1202.05)

320HS: Perineal component of an ultra-low anterior resection or restorative proctocolectomy with partial inter-sphincteric dissection and hand sewn colo-anal anastomosis where the rectal dissection is performed by a technique involving the use of a digital viewing platform and pneumopelvis (trans-anal total mesorectal excision). ($1483.20)

320EA: Perineal component of an abdomino-perineal resection or rectum and anus or pan-proctocolectomy where the rectal dissection is performed by a technique involving the use of a digital viewing platform and pneumopelvis (trans-anal total mesorectal excision). ($1031.35)

51. If public funding is sought through an <u>alternative (non-MBS) funding arrangement</u>, please draft a service description to define the population and usage characteristics that defines eligibility for the service/technology.

N/A