MSAC Application 1789

Computed tomography (CT) colonography for the detection of colorectal polyps and colorectal cancer

PICO Set 6

Population

Describe the population in which the proposed health technology is intended to be used:
Patients for whom a repeat colonic evaluation is required due to inadequate bowel preparation for the patient's previous examination or the previous examination was incomplete.

Colorectal cancer is major disease within Australia and often presents at a relatively late phase. The symptoms are often vague and non-specific and these patients typically first present to General Practitioners. Given that colorectal cancer is a major cause of morbidity and mortality in Australia, GP's will frequently investigate patients in whom they have significant clinical suspicion. GP's are excellent at this as has previously been accepted by MSAC, Gastroenterologists and Colorectal Surgeons. This is evident by the ability of GP's to refer for direct access colonoscopy and for direct access to Barium Enema.

CT Colonography is non-inferior to colonoscopy and is vastly superior to Barium Enema for the detection of colorectal cancer and polyps with advanced histology.

All diagnostic colonic examinations require a cathartic bowel preparation, and this is the same for colonoscopy and CTC. There are multiple reasons why bowel prep can be ineffective, leaving residual faecal material within the colon. CTC gives additional faecal tagging, turning residual faecal material white on imaging, and allowing radiologists to see through the fluid and for 'computer cleansing'. These are not options for colonoscopy and patients with poor prep have non-diagnostic studies that require repeat examinations for.

A proportion of colonoscopy studies are incomplete, which is usually defined as failure to visualise the ileocaecal junction and appendiceal orifice. GESA and the conjoint committee state that 95% of studies need to be complete. However this leaves up to 50,000 incomplete CTC examinations every year in Australia.

Studies indicate that the incomplete rate may be as high as 15% depending upon the patient population and health care setting. An incomplete examination increases the rates of break through cancer and we know that these are more common in the right colon. MSAC has accepted this as an indication for CT already (item number 56553) but in that item specifies that the referrer must be an endoscopist. This disempowers the GP and the patient.

Specify any characteristics of patients with, or suspected of having, the medical condition, who are proposed to be eligible for the proposed health technology, describing how a patient would be investigated, managed and referred within the Australian healthcare system in the lead up to being considered eligible for the technology:
If the patient has had a colonoscopy that is incomplete, the GP can refer for a CTC. An incomplete colonoscopy should be clearly documented in the colonoscopy report and should be clearly communicated to the GP. Ideally, a named photographic image of the ileocaecal valve should be provided as a routine part of every colonoscopy report.

If the GP believes that the colonoscopy was incomplete, they should be able to initiate further investigation. This is done by a written referral to a radiology practice for CTC. The patient undergoes bowel prep, faecal tagging and then has the study performed. The result is sent back to the referring GP who then manages the result. Possible results are:

1. No abnormality → reassure the patient
2. Polyp detected → refer for colonoscopy.
3. Cancer detected → stage the patient and refer to oncology or colorectal surgery.

Provide a rationale for the specifics of the eligible population:
This patient population has already been reviewed by MSAC and is currently eligible for CTC but only if referred by an endoscopist. The population does require further evaluation with a definitive test. Currently only two tests are available to investigate patients suspected of having CRC. Barium Enema is no longer appropriate as it has been replaced by CTC which has vastly superior sensitivity, specificity and is supported by a large body of evidence. Colonoscopy is more invasive and has significant wait lists.

Are there any prerequisite tests?
Prior failed colonoscopy.

Are the prerequisite tests MBS funded?
Yes

Intervention

Name of the proposed health technology:
CT Colonography.

Describe the key components and clinical steps involved in delivering the proposed health technology:
CTC is a CT scan of the colon that is performed after a bowel prep and faecal tagging. A small soft tube is positioned in the patients rectum and the colon is inflated with carbon dioxide. The patient then has two low dose CT scan's, once on their back and the second on their front or side. No sedation is necessary and the procedure is well tolerated. Patient are able to drive themselves home and do not need an escort. In addition anaesthetic support is not necessary.

CTC has been proven to be non-inferior to colonoscopy in multiple well conducted randomised trials (see evidence section). In addition, the break-through cancer rate is exceedingly low and is non-inferior to colonoscopy. CTC has an exceedingly high success rate and the Cancer Guidelines state that it should be routinely used for all incomplete colonoscopies.

A significant advantage of CTC over colonoscopy is access with this test being readily available in rural/regional settings and in lower socioeconomic areas. These areas often have high first nation representations.

No sedation is required for the investigation and so it is logistically easier for marginalised and isolated patients.

The studies are reported by radiologists who have been accredited by the RANZCR.

Identify how the proposed technology achieves the intended patient outcomes:
CTC is excellent at detecting CRC and polyps with advanced histology. It is non-inferior to colonoscopy. Patients with incomplete colonoscopy have higher rates of break through cancer which are typically right sided. CTC is required to ensure that the entire colonic mucosa is examined.

Does the proposed health technology include a registered trademark component with characteristics that distinguishes it from other similar health components?
No

Are there any proposed limitations on the provision of the proposed health technology delivered to the patient (For example: accessibility, dosage, quantity, duration or frequency):
No

Provide details and explain:
The test is well tolerated, readily available and has proven to be safe, accurate and cost effective. Sedation is not necessary, it is safer than colonoscopy and incomplete studies are rare. It is excellent for regional/remote areas, isolated patients and patients with co-morbidities.

If applicable, advise which health professionals will be needed to provide the proposed health technology:
The test is performed by radiographers and is interpreted by radiologists who have been credentialed by the RANZCR.

If applicable, advise whether delivery of the proposed health technology can be delegated to another health professional:
Only radiologists have the necessary training to interpret the test.

If applicable, advise if there are any limitations on which health professionals might provide a referral for the proposed health technology:
General Practitioners should be the people requesting the test.

Is there specific training or qualifications required to provide or deliver the proposed service, and/or any accreditation requirements to support delivery of the health technology?
Yes

Provide details and explain:
The radiographers will require a brief training session (many have already done this). The test is routinely performed by radiographers in other countries including New Zealand, the UK, and the USA.

The radiologists require a FRANZCR and to have undergone additional training to be able to report the test. These processes and policies are already in place as the system is necessary as CTC is performed in Australia and to a much larger extent in New Zealand which also falls under the jurisdiction of the RANZCR.

Indicate the proposed setting(s) in which the proposed health technology will be delivered:
☐ Consulting rooms
☐ Day surgery centre
☐ Emergency Department
☐ Inpatient private hospital
☐ Inpatient public hospital
☐ Laboratory
☐ Outpatient clinic
☐ Patient's home
☐ Point of care testing
☐ Residential aged care facility
☒ Other (please specify)

The test is performed in radiology practices. This can be public, private, hospital or community based.

Is the proposed health technology intended to be entirely rendered inside Australia?
Yes

Comparator

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

The comparator is colonoscopy.

Colonoscopy is an excellent test for assessing the colonic mucosa and CT colonography has been shown to be non-inferior. Current issues with colonoscopy include extended wait lists with virtually every state and territory having substantial waiting lists of over 100 days. These delays are more pronounced in regional/rural settings, indigenous populations and in lower socioeconomic regions.

In addition, colonoscopy is an invasive test and CT colonography has a better safety profile.

Colonoscopy has multiple additional costs, beyond the colonoscopy MBS rebate. For example up to 5% are incomplete and then require further investigation with CTC (as per Cancer Council Guidelines). Rates of polypectomy at colonoscopy are high (most are non cancerous hyperplastic polyps). These are sent for histologic analysis at further expense. Anaesthetic fees are often added as the college of anaesthetists states that the proceduralist should not be the person giving sedation.

I am not sure if a physician consultation rebate is frequently co-claimed. No doubt MBS data will be available to answer this.

List any existing MBS item numbers that are relevant for the nominated comparators:
32222

32223

32224

32225

32226

32228

32229

Provide a rationale for why this is a comparator:
Colonoscopy is the only currently funded colonic test that GP's can refer for.

Pattern of substitution – Will the proposed health technology wholly replace the proposed comparator, partially replace the proposed comparator, displace the proposed comparator or be used in combination with the proposed comparator?
☐ None (used with the comparator)

☐ Displaced (comparator will likely be used following the proposed technology in some patients)
☒ Partial (in some cases, the proposed technology will replace the use of the comparator, but not all)
☐ Full (subjects who receive the proposed intervention will not receive the comparator)

Outline and explain the extent to which the current comparator is expected to be substituted:
In many countries that have adopted CTC, 20-30% of colonic examinations are performed with CTC with 70-80% remaining as colonoscopy.

Current waitlists for colonoscopy are longer than recommended and this is expected to worsen with adoption of the national bowel cancer screening program. These issues are greatest in regional and remote areas, as well as in communities with vulnerable, disadvantaged and indigenous people.

As patients comorbidities increase and with the increasing use of anticoagulation, CTC's superior safety profile will result in increased utilisation.

Outcomes

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):

☒ Health benefits

- There are multiple health benefits from adding CTC. A major benefit is reduced anxiety and stress of being told you potentially have a serious medical condition and then getting the answer quickly rather than being left in a state of unknown for months.
- Additionally, by being available in remote and rural areas, CTC improves health equity and will increase compliance with testing in these populations.
- As CTC is more available and does not require and escort, patients and carers need less time of work, which is critical given the cost of living.
- By reducing the number of patients on OC waiting lists, it will benefit high risk patients who will be able to have an OC with less delay.
- Less break through cancers as the entire colonic mucosa is assessed.

☐ Health harms

- by reducing the number of normal OC studies performed, it will reduce waiting lists allowing high risk patients to be examined in appropriate time frames.
- CTC allows the appropriate triaging of patients who require intervention reducing the rates of cancer progression while on extensive waiting lists.

☐ Resources

- The number of normal OC studies will be reduced allowing this more invasive test to be more appropriately used for surveillance in high risk patients and in those requiring polypectomy.
- Not all endoscopists can remove large polyps and so CTC will allow appropriate referral to expert centres for lesions requiring more complex intervention.

As OC lists become more interventional it will become an easier environment for training, credentialing and upskilling with view to having highly skilled interventional endoscopists

☐ Value of knowing

Outcome description – include information about whether a change in patient management, or prognosis, occurs as a result of the test information:
Possible results following CTC are:

1. No abnormality → reassure the patient
2. Polyp detected → refer for colonoscopy.
3. Cancer detected → stage the patient and refer to oncology or colorectal surgery.

By reducing waiting lists CTC will reduce the number of patients upstaged from disease progression while waiting for colonoscopy. Delays with colonoscopy have been shown to result in high morbidity/mortality and greater healthcare costs.

By providing an alternate test, it will increase the number of people who under go a definitive test, again helping to reduce stage progression from waiting or ignoring symptoms.

Proposed MBS items

How is the technology/service funded at present? (e.g., research funding; State-based funding; self-funded by patients; no funding or payments):
Provide your response here

Provide at least one proposed item with their descriptor and associated costs, for each Population/Intervention:

MBS item number (where used as a template for the proposed item)	56553
Category number	Diagnostic Imaging Services
Category description	Insert category description here
Proposed item descriptor	examination of the colon to the caecum by Computed Tomography Colonography, for a patient: (a) for whom a repeat colonic evaluation is required due to inadequate bowel preparation for the patient's previous examination.
Proposed MBS fee	563.35
Indicate the overall cost per patient of providing the proposed health technology	Current rebate covers the cost.
Please specify any anticipated out of pocket expenses	Bulk Bill incentive
Provide any further details and explain	CTC currently has a rebate and the remuneration is not the cause of underutilisation. CTC is not used appropriately due to the current stringent rebatable indications.

Algorithms

PREPARATION FOR USING THE HEALTH TECHNOLOGY

Define and summarise the clinical management algorithm, including any required tests or healthcare resources, before patients would be eligible for the proposed health technology:
Patients will be eligible for the test once they have been reviewed and assessed by the GP. This is identical to the current situation with open access colonoscopy. The only difference is that CTC is requested instead of colonoscopy.

Is there any expectation that the clinical management algorithm before the health technology is used will change due to the introduction of the proposed health technology?

No

USE OF THE HEALTH TECHNOLOGY

Explain what other healthcare resources are used in conjunction with delivering the proposed health technology:
No other health care resources are used.

Explain what other healthcare resources are used in conjunction with the comparator health technology:
Pathology, anaesthetics, nurses, physician consultation are all a routine part of colonoscopy.

Describe and explain any differences in the healthcare resources used in conjunction with the proposed health technology vs. the comparator health technology:
CTC is quick, safe and easy. It can be performed in any radiology practice that has a CT. Consumables are minimal being a rectal catheter, tubing, gas bottle, buscopan. This compares to colonoscopy which is performed in day procedure centres with nurses, anaesthetics, endoscopy equipment, recovery areas, anaesthetic equipment etc.

CLINICAL MANAGEMENT AFTER THE USE OF HEALTH TECHNOLOGY

Define and summarise the clinical management algorithm, including any required tests or healthcare resources, *after* the use of the proposed health technology:
Possible results following CTC are:

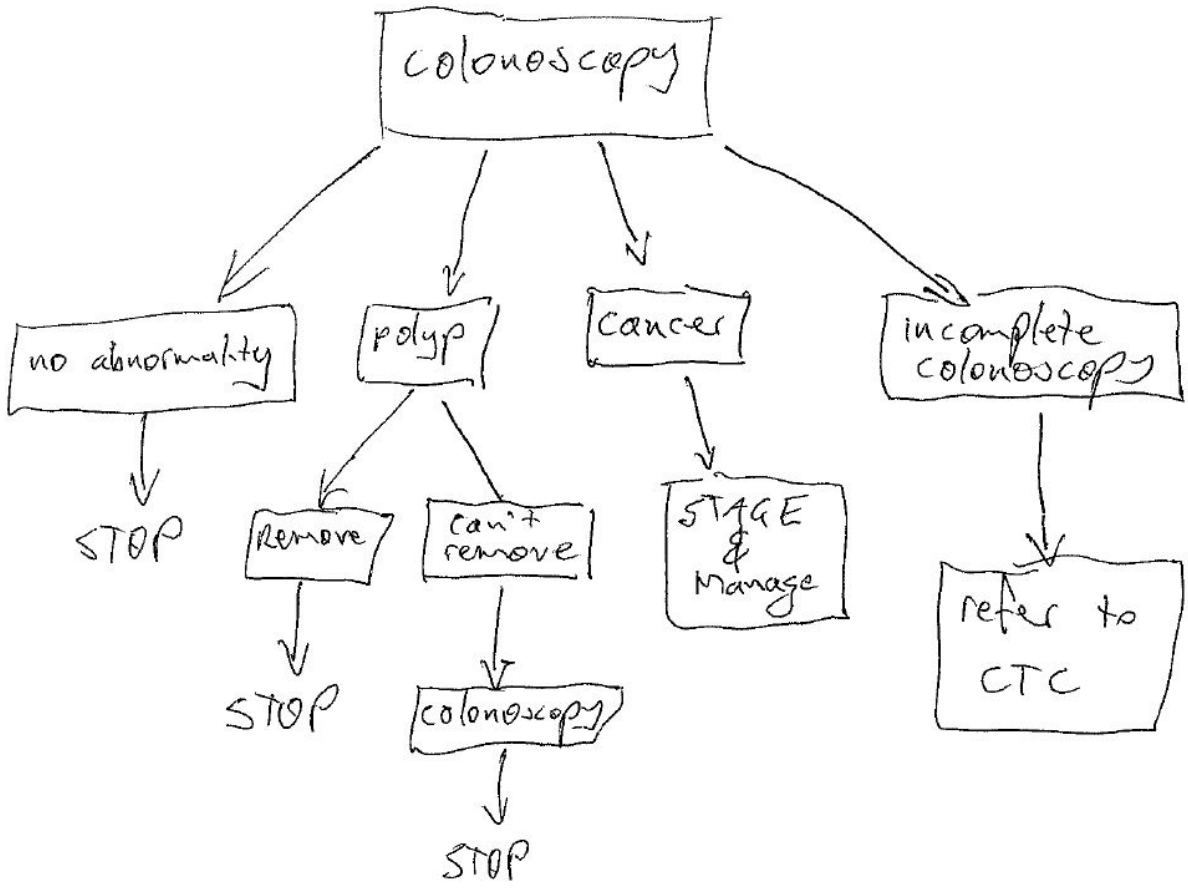
1. No abnormality → reassure the patient. No further test needed.
2. Polyp detected → refer for colonoscopy.
3. Cancer detected → stage the patient (CT CAP +/- rectal MRI) and refer to oncology or colorectal surgery.

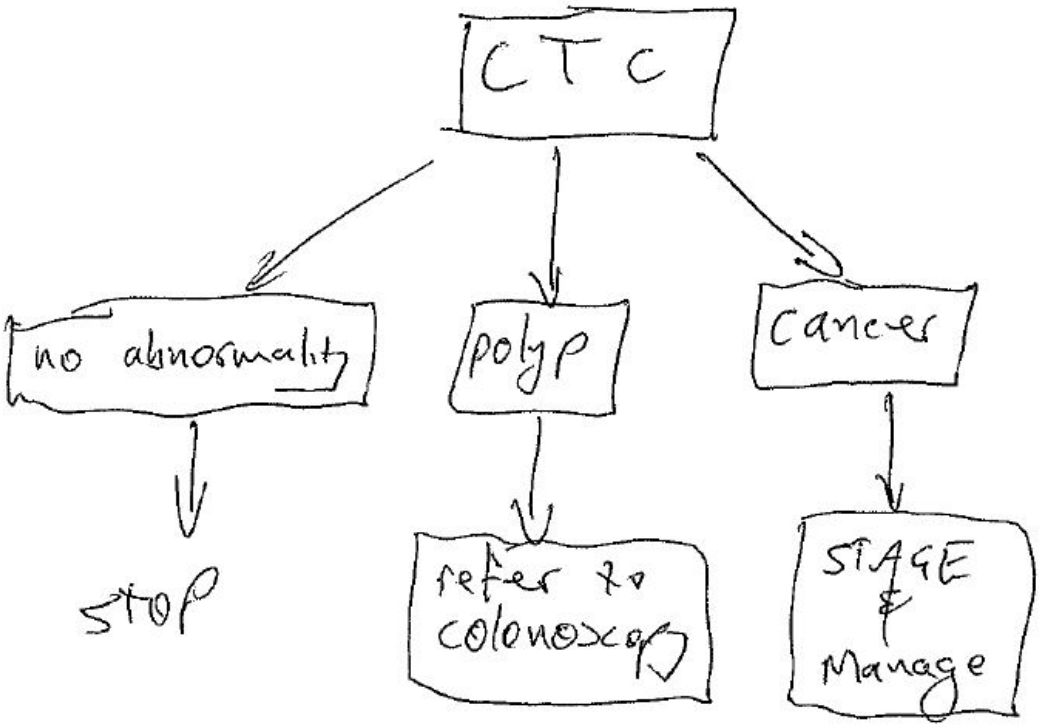
Define and summarise the clinical management algorithm, including any required tests or healthcare resources, *after* the use of the comparator health technology:
Possible results following colonoscopy are:

1. No abnormality → reassure the patient. No further test needed.
2. Polyp detected and removed → no further test needed.
3. Polyp detected and endoscopist unable to remove → refer for colonoscopy.
4. Cancer detected → stage the patient (CT CAP +/- rectal MRI) and refer to oncology or colorectal surgery.
5. Incomplete colonoscopy → refer for CT colonography.

Describe and explain any differences in the healthcare resources used *after* the <u>proposed health technology</u> vs. the <u>comparator health technology</u>:
This is described above.

Insert diagrams demonstrating the clinical management algorithm with and without the proposed health technology:





Claims

In terms of health outcomes (comparative benefits and harms), is the proposed technology claimed to be superior, non-inferior or inferior to the comparator(s)?

☐ Superior
☒ Non-inferior
☐ Inferior

Please state what the overall claim is, and provide a rationale:
There is a substantial body of evidence which shows the test is non-inferior. This will be listed in the appropriate section.

Why would the requestor seek to use the proposed investigative technology rather than the comparator(s)?
The CTC is readily available and so can be used when there is no access to timely colonoscopy. In addition, the test can be used if the patient choses it in preference to colonoscopy, or if they have medical conditions such as anticoagulation.

Colonoscopy wait lists are excessive and this contributes to worse patient outcome and greater healthcare expenditure.

Identify how the proposed technology achieves the intended patient outcomes:
It allows patients and GP's to have control over how quickly a definite test is performed. This reduces patient anxiety and also empowers patients. Patients can also chose the test they prefer which should lead to increased compliance.

For some people, compared with the comparator(s), does the test information result in:

A change in clinical management? No same as colonoscopy

A change in health outcome? Yes

Other benefits? Yes

Please provide a rationale, and information on other benefits if relevant:
The main benefits of the test are quicker performance time leading to less anxiety for the patient. Less chance the patient will have stage migration while waiting for the test. Greater compliance due to patients having choice. Reduced risk to patients with co-morbidities.

In terms of the immediate costs of the proposed technology (and immediate cost consequences, such as procedural costs, testing costs etc.), is the proposed technology claimed to be more costly, the same cost or less costly than the comparator?

☐ More costly
☒ Same cost
☐ Less costly

Provide a brief rationale for the claim:
The current rebate for CTC is greater than the rebate for colonoscopy. However, the vast majority of colonoscopy are co-claimed with polypectomy. This makes the colonoscopy/polypectomy price the same as CTC. In addition, the government then pays for histology to be performed on the polyps. Anaesthetic fees are an additional expense as are any co-claimed consultation fees by the endoscopist.

Summary of Evidence

Provide one or more recent (published) high quality clinical studies that support use of the proposed health service/technology. At 'Application Form lodgement',

	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.	Double blinded head to head	Computed Tomographic Virtual Colonoscopy to Screen for Colorectal Neoplasia in Asymptomatic Adults	CT colonography followed by segmentally unblinded colonoscopy proving CTC is non-inferior.	Computed Tomographic Virtual Colonoscopy to Screen for Colorectal Neoplasia in Asymptomatic Adults | New England Journal of Medicine (nejm.org)	2003
2.	Randomised control trial	CT Colonography versus Colonoscopy for the Detection of Advanced Neoplasia	Patients sent to either CTC or colonoscopy. Same number of cancers found. 4x more polyps removed in OC arm. Cx rate higher OC. Proves non-inferior.	CT Colonography versus Colonoscopy for the Detection of Advanced Neoplasia | New England Journal of Medicine (nejm.org)	2007
3	Retrospective review	Colorectal Findings at Repeat CT Colonography Screening after Initial CT Colonography Screening Negative for Polyps Larger than 5 mm	Retrospective review of patients with a previous normal CTC to determine interval cancer rate. Rates were low and supports accuracy of CTC and non-reporting small lesions (under 6mm).	Colorectal Findings at Repeat CT Colonography Screening after Initial CT Colonography Screening Negative for Polyps Larger than 5 mm | Radiology (rsna.org)	2016

	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	Qualitative review	Wait times for gastroenterology consultation in Canada: The patients' perspective	Long wait times directly impact patients and contribute to anxiety ,lost time from work and social functioning	Wait times for gastroenterology consultation in Canada: The patients' perspective - PMC (nih.gov)	2010
5	Population based analysis	**Diseases of the Colon & Rectum (lww.com)** The Association Between Wait Times for Colorectal Cancer Treatment and Health Care Costs: A Population-Based Analysis	Length of wait time correlates with increasing cost	Diseases of the Colon & Rectum (lww.com)	2020
6	Observational study	An observational study to compare the utilisation of computed tomography colonography with optical colonoscopy as the first diagnostic imaging tool in patients with suspected colorectal cancer	CTC increases colonoscopy capacity and contributes to a functional service.	An observational study to compare the utilisation of computed tomography colonography with optical colonoscopy as the first diagnostic imaging tool in patients with suspected colorectal cancer - PubMed (nih.gov)	2020
7	Waitlist Data	Bowel cancer Australia wait times following positive FOB	Extended wait times.	A Colonoscopy Wait-time and Performance Guarantee - Bowel Cancer Australia	2024