MSAC Application 1789

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

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PICO Confirmation

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

Table 1 PICO for computed tomography colonography (CTC) for diagnostic use in patients requiring colonic investigation for colorectal cancer (CRC): PICO set 1

Component	Description
Population	Patients requiring diagnostic investigation to exclude colorectal cancer (CRC) who fulfil at least one of the following criteria: • have low risk[a] symptoms suggestive of CRC • have a positive faecal occult blood test (FOBT) • for whom diagnostic imaging has shown an abnormality of the colon • have a relative or absolute contraindication for colonoscopy • with a medical history of incomplete colonoscopy (including patients who fall outside of current requirement that incomplete colonoscopy must have occurred within 3 months)
Prior tests	No prior testing
Intervention	Computed tomography colonography (CTC)
Comparator/s	Colonoscopy
Reference standard	Colonoscopy
Outcomes	Efficacy/effectiveness • Polyp detection rates, for adenomas, total serrated polyps, sessile serrated adenomas/polyps (SSA/Ps) and traditional serrated adenomas (TSAs) (where available) • Diagnostic performance (accuracy, sensitivity, specificity) • Subsequent cancer incidence (referred to as post-colonoscopy CRC for the comparator) • Health-related quality of life (HRQOL) • Incomplete colonic examination • Time from first presentation to diagnostic assessment Safety • Bowel perforation • Bleeding post-colonoscopy • Radiation-related events • Allergic reactions to contrast media Healthcare resource use • Extracolonic findings (as a measure of onward costs) • Onward referrals (colonoscopy/biopsy/polypectomy incidence or rate)
Assessment questions	What is the safety, effectiveness and cost-effectiveness of CTC versus colonoscopy in patients requiring colonic investigation for the specified population

[a] "low risk" refers to patients with symptoms suggestive of CRC that do not include symptoms such as rectal bleeding, anaemia or unexplained weight loss that would otherwise warrant urgent referral for colonoscopy.

Table 2 PICO for computed tomography colonography (CTC) for surveillance of patients with previously detected colonic polyps: PICO set 2

Component	Description
Population	Patients with prior diagnosis of colorectal polyps or colorectal cancer (CRC) who require surveillance
Prior tests	No prior testing
Intervention	Computed tomography colonography (CTC)
Comparator/s	Colonoscopy
Reference standard	Colonoscopy
Outcomes	Efficacy/effectiveness • Polyp detection rates, for adenomas, total serrated polyps, sessile serrated adenomas/polyps (SSA/Ps) and traditional serrated adenomas (TSAs) (where available) • Diagnostic performance (accuracy, sensitivity, specificity) • Subsequent cancer incidence (referred to as post-colonoscopy CRC for the comparator) • Health-related quality of life (HRQOL) • Incomplete colonic examination • Time from first presentation to diagnostic assessment Safety • Bowel perforation • Bleeding post-colonoscopy • Radiation-related events • Allergic reactions to contrast media Healthcare resource use • Extracolonic findings (as a measure of onward costs) • Onward referrals (colonoscopy/biopsy/polypectomy incidence or rate)
Assessment questions	What is the safety, effectiveness and cost-effectiveness of CTC versus colonoscopy in patients with prior diagnosis of colorectal polyps or CRC who require surveillance?

Purpose of application

An application requesting MBS listing of computed tomography (CT) colonography (herein referred to as CTC) for the detection of colorectal polyps and colorectal cancer (CRC) was received from a radiologist with a special interest in abdominal radiology by the Department of Health and Aged Care. Through discussions with the department, the applicant, and the evaluation group, an amendment to the existing MBS item was instead proposed for a diagnostic population. Additionally, a second population for those requiring surveillance was also proposed by the applicant.

The applicant's clinical claim was that CTC results in non-inferior health outcomes (efficacy and safety) compared to colonoscopy.

Background

Previous considerations by MSAC

An overview of MBS items listed for CTC and their previous Medical Services Advisory Committee (MSAC) considerations is given in Table 3.

It should be noted that the item descriptor term "high risk" refers to an asymptomatic patient with familial cancer risk (at least three first-degree relatives diagnosed with CRC at any age or at least three first-degree or second-degree relatives with CRC with at least one diagnosed before age 55 years). This is distinct from the use of "high risk" in this PICO confirmation where it refers to clinical symptoms conferring a higher risk of CRC. Familial cancer risk is not otherwise discussed in the current application.

Table 3 CT colonography: MSAC considerations and MBS items

MBS item	MSAC Meeting	Population	MBS Schedule period
56549*	2-year temporary listing, no MSAC application	Patient who has had an incomplete colonoscopy and is referred by the specialist or consultant physician who performed the incomplete procedure	1 May 2005 to 30 June 2007
56551*	2-year temporary listing, no MSAC application	Patient referred by a specialist or consultant physician with either fistula; obstructed colon or megacolon	1 May 2005 to 30 June 2007
56552*	Application 1095, recommended MSAC February 2006	Symptomatic or high risk[a] patients who have had an incomplete colonoscopy (sub-set of requested population)	1 July 2007 to 31 August 2015
56554*	Application 1095, recommended MSAC February 2006	Symptomatic or high risk[a] patients contraindicated for colonoscopy (suspected perforation or high grade obstruction) (sub-set of requested population)	1 July 2007 to 31 August 2015
56553	Application 1269, recommended MSAC November 2014	Items 56552 and 56554 consolidated; 1 CTC per patient per 3 years	1 September 2015 (currently listed)

MBS = Medical Benefits Schedule; MSAC = Medical Services Advisory Committee; * these MBS items have ceased and are no longer listed.
[a] "high risk" refers to an asymptomatic patient with familial cancer risk (at least three first-degree relatives diagnosed with CRC at any age or at least three first-degree or second-degree relatives with CRC with at least one diagnosed before age 55 years).
Source: Compiled from historical MBS Schedules (May 2005; November 2007) and MBS Online (www.mbsonline.gov.au).

MSAC application 1269 from the Abdominal Radiology Group of Australia and New Zealand (ARGANZ)[1] sought amendment of the MBS items then listed for CTC (56552 and 56554). The applicant requested

[1] ARGANZ is a special interest group of the Royal Australian and New Zealand College of Radiologists (RANZCR).

expansion of the indications covered to include additional contraindications to colonoscopy and to remove the three-month time limit restricting its use in patients with incomplete colonoscopy.

At the November 2014 meeting MSAC recommended as follows:

- a new consolidated item for CTC (derived from items 56552 and 56554) for the diagnosis or exclusion of colorectal neoplasia in symptomatic patients or high-risk patients (familial CRC risk) with a history of incomplete colonoscopy or medical and/or technical contraindication(s) to colonoscopy
- the requirement that an incomplete colonoscopy must have occurred no more than three months prior to CTC should be retained
- eligibility for CTC should be widened by extending the list of medical and technical contraindications to colonoscopy (to be included in the associated explanatory notes)
- use of the item should be limited to one CTC scan per patient every three years
- the MBS fee should be commensurate with fees for abdominal CT and double contrast barium enema (DCBE)

In addition to the above recommendations, the assessment report for MSAC 1269 noted that perforation of the colon was a contraindication for both colonoscopy and CTC and as such suggested it be deleted from the eligible indications for CTC (items 56552 and 56554, which no longer exist, indicated that patients contraindicated for colonoscopy due to suspected perforation of the colon are eligible for CTC). Application 1269 had also sought a new MBS item to provide CTC for patients with limited access to colonoscopy but MSAC did not support this use.

The current MBS item for CTC

The descriptor for the currently listed MBS item (56553) for CTC is presented in Table 4.

Table 4 Current MBS item for CTC (56553)

Category 5 - DIAGNOSTIC IMAGING SERVICES
MBS item 56553 Computed tomography—scan of colon for exclusion or diagnosis of colorectal neoplasia in a symptomatic or high risk patient if: (a) one or more of the following applies: (i) the patient has had an incomplete colonoscopy in the 3 months before the scan; (ii) there is a high grade colonic obstruction; (iii) the service is requested by a specialist or consultant physician who performs colonoscopies in the practice of the specialist's or consultant physician's speciality; and (b) the service is not a service to which item 56301, 56307, 56401, 56407, 56409, 56412, 56501, 56507, 56801, 56807 or 57001 applies (R) Bulk bill incentive (Anaes.)
Fee: $571.40 **Benefit:** 75% = $428.55 85% = $485.70

Source: MBS Online (www.mbsonline.gov.au).
MBS = Medical Benefits Schedule

Note that as of the 1 November 2024 explanatory note IN.0.15 was amended, removing reference to high risk, incomplete colonoscopy and any reference to Item 56553 other than that it is for CT colonography.

Under the current item, medical practitioners including GPs, specialists and consultant physicians can request CTC in order to exclude or diagnose CRC if:

- The patient is symptomatic or high-risk patient (familial CRC risk), and,
- Only in the case of an incomplete colonoscopy or a high-grade colonic obstruction.

Specialist colonoscopists may also refer a patient for CTC for any indication for the purposes of excluding or diagnosing colorectal neoplasia in a symptomatic or high risk patient.

The 3 year restriction between services per patient was removed from 1 May 2020. The list of medical and technical contraindications to colonoscopy considered in application 1269 (see Table 9) is not currently reflected in the associated explanatory notes. High grade colonic obstruction is the only contraindication to colonoscopy which is specified in the current item.

PICO criteria: overview

The six PICO sets requested by the applicant are summarised in Table 5.

Table 5 Overview of populations requested for the six PICO sets

PICO set	Proposed population
1	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.
2	Patients for whom diagnostic imaging has shown an abnormality of the colon
3	Patients requiring surveillance following prior diagnosis of colorectal polyps or cancer
4	Patients who have previously had an incomplete colonoscopy or are on anticoagulation
5	Patients with positive FOBT
6	Patients with signs or symptoms potentially from colorectal cancer

FOBT = faecal occult blood test
Source: MSAC 1789 Application Summary

The populations presented by the applicant are likely to inadvertently restrict the evidence that can be used in the assessment given that they were so specific. This was confirmed with preliminary literature searches. The evaluation group proposed two PICO sets for diagnostic use and for surveillance use, based on current clinical guidelines and evidence considering the applicant and department input. An overview of the revised PICO sets is presented in Table 6.

Table 6 Overview of the revised PICO sets proposed by the evaluation group

Revised PICO set	Indication	Applicant's PICO sets	Proposed population
1	Diagnostic use	1,2,4,5,6	Patients with low risk[a] symptoms suggestive of colorectal cancer Patients with positive FOBT Patients for whom diagnostic imaging has shown an abnormality of the colon Patients who have a medical history of incomplete colonoscopy or colonic evaluation (including patients who fall outside of current requirement that incomplete colonoscopy must have occurred within 3 months) Patients in whom colonoscopy is contraindicated (e.g. on anticoagulants)
2	Surveillance & monitoring	3	Patients requiring surveillance following prior diagnosis of colorectal polyps

FOBT = faecal occult blood test

[a] "low risk" refers to patients with symptoms suggestive of CRC that do not include symptoms such as rectal bleeding, anaemia or unexplained weight loss that would otherwise warrant urgent referral for colonoscopy.

Source: Produced during PICO development

The proposed population includes patients with a medical history of incomplete colonoscopy or colonic evaluation falling outside the three-month criterion in the current MBS item 56553 and would include any patients with a previous incomplete colonoscopy documented by an endoscopist in their medical history. The applicant requested that referral of the existing MBS item 56553 be extended to include referral by general practitioners (GPs) (as well as specialist endoscopists), however it is understood that GPs are already eligible to refer patients for two indications (incomplete colonoscopy and high grade colonic obstruction), while specialist referral for CTC is broader and for the purpose of excluding or diagnosing colorectal neoplasia in a symptomatic patient or in a high risk patient (high risk due to familial CRC history) (described above in Background). The applicant's PICO set 1 population (patients with inadequate bowel preparation or with previous incomplete examination) was considered to be covered by the current item.

Further discussion of proposed PICO set elements is given in the following sections.

PICO criteria: PICO set 1 – Diagnostic use

Population

The proposed population for CTC is patients requiring diagnostic investigation for suspected CRC who fulfil at least one of the following criteria:

- have low risk symptoms suggestive of CRC
- have a positive faecal occult blood test (FOBT)
- for whom diagnostic imaging has shown an abnormality of the colon
- contraindicated for colonoscopy (expansion of MBS item 56553 to include GPs as requestors for this indication)
- with a medical history of incomplete colonoscopy (expansion of MBS item 56553 to enable GPs to request CTC for patients who fall outside of the current item requirement that incomplete colonoscopy must have occurred within 3 months)

Colorectal Cancer and polyps

CRC is a disease which often presents at a late (advanced) phase. CRC is the fourth most commonly diagnosed cancer in Australia (Australian Institute of Health and Welfare [AIHW] 2024). It was estimated that in 2024 about 7,265 people aged 50–74 years will be diagnosed with bowel cancer (around 47% of all bowel cancers diagnosed) and 1,793 people in this age group will die from the disease (around 34% of all bowel cancer deaths) (AIHW 2024). The majority of bowel cancers are carcinomas (95% in 2020), of which the most common type of carcinoma is adenocarcinoma (87%) followed by neuroendocrine neoplasms (5.5%) (AIHW 2024).

Symptoms of bowel cancer may be vague or non-specific and patients typically present to their GP (Calazani et al. 2021). Symptoms usually cited as suggestive of CRC (Cancer Council 2023; ACS 2024; McMurrick et al. 2006; the United Kingdom National Institute for Health and Care Excellence [NICE] 2023) are as follows:

- Rectal bleeding
- Anaemia
- Weight loss (unexplained)
- Change in bowel habit (persistent)
- Dark stool / blood in stool
- Abdominal pain
- Abdominal lumps or swelling (palpable mass)
- An unrelieved urge to void the bowels
- Mucous discharge
- Diarrhoea or constipation
- Weakness and fatigue
- Dyspepsia

Patients diagnosed with localised CRC have a 90% five-year relative survival rate compared to the general population, whereas, once the cancer has metastasised, survival rates decrease to 71% for regional metastases and 14% for distal metastases (Siegel et al. 2020).

Colorectal polyps are the precancerous stage of CRC; however, polyps are very common in the large intestine of persons aged over 45 years and the majority will not develop into cancers. Colorectal polyps were previously described as either hyperplastic polyps or adenomas. More recent classification has renamed hyperplastic polyps as serrated polyps, which are divided into true hyperplastic polyps, sessile serrated adenomas/polyps (SSA/Ps) and traditional serrated adenomas (TSAs) (IJspeert et al. 2015).

Current management

Recommendations for CTC and alternatives to colonoscopy for detection of CRC in Australia are captured in guidelines published by Cancer Council Australia and in New Zealand by Health New Zealand and the New Zealand Ministry of Health (NZ MOH). Table 7 presents current recommendations for CTC.

Table 7 Current Guidelines with recommendations for CTC

Region	Guideline title	Recommendations regarding CTC
Australia	Clinical practice guidelines for the prevention, early detection and management of colorectal cancer (Cancer Council 2023)	CTC is recommended as follows: • CRC symptoms with a disease risk threshold below 3% (i.e. lower risk symptoms)[a] • in areas with limited access to colonoscopy services but with access to CT • colonoscopy contraindicated Also: Some patients may have a colon cancer diagnosed by CT scan if they present emergently with obstruction
	Clinical practice guidelines for surveillance colonoscopy (Cancer Council 2022)	CTC is an alternative for patients unable to have colonoscopy Patients with polyp on CTC >10mm should be referred for polypectomy; patients with polyps on CTC 6–9mm should be either referred for polypectomy or repeat colonic examination at three years
New Zealand	Clinical Practice Guidelines for Bowel Screening in New Zealand (Health New Zealand 2023)	CTC may be offered as an alternative to colonoscopy for patients with a positive FOBT (this refers to asymptomatic patients from the NZ bowel screening program) CTC as an alternative to colonoscopy based on referral criteria (below)
	Referral of patients with features suggestive of bowel cancer: Ministry of Health guidance (NZ MOH 2020)	Clinicians in primary care can refer patients for colonoscopy or CTC if they have symptoms and signs suggestive of bowel cancer and meet the referral criteria: CTC may be more appropriate in: • symptomatic patients who do not have altered bowel habit or rectal bleeding as the predominant indication; patients without family history of CRC meeting the referral criteria. • patients aged > 80 years with co-morbidities that would complicate colonoscopy or bowel preparation.

CRC = colorectal cancer; CT = computed tomography; CTC = computed tomography colonography; FOBT = faecal occult blood test.
Source: Cancer Council Australia (2022); Cancer Council Australia (2023); Health New Zealand (2023); NZ MOH (2020).
a See Table 8 for further information regarding symptoms

The Clinical Practice Guidelines for Bowel Screening in New Zealand include recommendations for CTC and colonoscopy for asymptomatic patients identified through the New Zealand's National Bowel Screening Programme, "Time to Screen".[2] This program offers a free FOBT every two years to eligible New Zealanders aged 60 to 74 years of age. Following a positive FOBT, further investigation is typically done through a colonoscopy. Approximately 7% of people who have a colonoscopy as part of the screening program in New Zealand will have cancer[3].

Until quite recently, guidelines only recommended CTC for diagnostic use in Australia in patients with failed/incomplete colonoscopy or contraindications to colonoscopy (Parkin et al. 2018; Moore and Naidoo 2017). The updated Cancer Council Australia guideline recommends CTC in two additional categories, in areas where access to colonoscopy services is limited but where there is access to CT, and in patients with lower risk symptoms (estimated at <3% CRC risk threshold), for the exclusion of cancer, based on the high sensitivity of CTC for colorectal cancer(Cancer Council 2023).

Symptoms considered in the Cancer Council guideline, and their recommended risk status, are presented in Table 8. Disease risk was based on a 3% threshold positive predictive value (PPV). Symptoms with a PPV under the 3% threshold may be considered low risk for this PICO, noting that there is some discordance for

[2] Bowel Cancer Screening - Bowel Cancer New Zealand
[3] https://info.health.nz/keeping-healthy/cancer-screening/bowel-screening/colonoscopy

symptoms and thresholds among different sources. This forms the basis for the proposed description of low risk symptoms for the PICO set 1 subpopulation patients

Table 8 Symptoms suggestive of CRC and their risk status (Cancer Council 2023)

Symptom	Cancer Council 2023[a] (as PPV [95% CI])
Rectal bleeding	**4.8% (3.3 – 6.8)**
Abdominal pain	2.0% (0.5 – 7.6)
Anaemia	**5.8% (2.6 – 12.0)**
Weight loss	**3% (0.3 – 22.9)**
Dyspepsia	0.6% (0.3 – 1.4)
Constipation	(0.4–2.5%)
Change in bowel habit	2.8 – 2.9%

CI = confidence interval; CRC = colorectal cancer; PPV = positive predictive value.
[a] PPV (95% CI) values for potential symptoms of CRC based on a meta-analysis presented in the Australian guideline (Cancer Council 2023), with a disease risk threshold of 3%. Symptoms with a PPV of 3% or above (in bold type) were recommended as criteria for urgent referral for investigation of CRC. The symptoms constipation and change in bowel habit were not included in the meta-analysis but PPV values were presented as a range from other studies.
Note: **Bold** indicates symptoms conferring higher disease risk warranting urgent referral for colonoscopy.
Source: Cancer Council Australia (2023).

It is not clear how the 3% PPV threshold is being interpreted and used in clinical practice. At least one state health service guideline (New South Wales Agency for Clinical Innovation 2020) cites different PPV figures for those symptoms (for example PPV for rectal bleeding of 2.4%; anaemia 9.7%; abdominal pain 3.3% and so on).

The Australian guidelines approach of identifying higher risk symptoms where colonoscopy is preferred versus lower risk symptoms where CTC is a recommended alternative were also found in clinical guidelines for other countries (the United Kingdom [National Institute for Health and care Excellence (NICE) 2023], Europe [European Society of Gastrointestinal Endoscopy (ESGE)/ European Society of Gastrointestinal and Abdominal Radiology (ESGAR) 2023] and New Zealand [NZ MOH 2020]). The PPV values presented in the Australian guideline originated from an update of a meta-analysis undertaken for the NICE guideline on suspected cancer recognition and referral (June 2015 version, chapter on lower gastrointestinal tract cancers).

The ESGE/ESGAR (2023) guideline recommends CTC as an acceptable alternative to colonoscopy for patients with non-alarm symptoms, defined as abdominal symptoms suggestive of colorectal cancer requiring detailed investigation. The guideline defined alarm symptoms as rectal bleeding, anaemia, weight loss, and intestinal subocclusion. The NZ MOH guideline identifies rectal bleeding and persistent change in bowel habits (more than 6 weeks) as key referral criteria where colonoscopy is preferred. Otherwise, in New Zealand, patients with symptoms suggestive of CRC may be offered CTC. Thus, CTC may be recommended as an alternative to colonoscopy in the absence of higher risk symptoms, but there is limited agreement among clinical guidelines as to what constitutes 'higher risk'.

In the United States, colonoscopy remains the mainstay of diagnostic workup (National Comprehensive Cancer Network [NCCN] 2024a; NCCN 2024b) and CTC is only recommended for screening (NCCN 2024c).

Patients with low risk symptoms, incidental findings on diagnostic imaging or with positive FOBT

Patients with low risk symptoms suggestive of CRC, patients for whom diagnostic imaging has shown an abnormality of the colon and patients with positive FOBT would usually be managed similarly and be referred for colonoscopy. The applicant indicated that symptomatic patients will typically present to their GP, who would determine the need for further investigation based on clinical features and medical history. The applicant noted that GPs may order MBS items for either colonoscopy (item 32222) or DCBE (item 58921) as diagnostic investigations of the colon, but not CTC. However, it was noted that GPs may order CTC (item 56553) under limited circumstances which are for the purposes of excluding or diagnosing colorectal neoplasia in a patient who has had an incomplete colonoscopy in the 3 months before the scan or there is high grade colonic obstruction. A preliminary search of the literature indicated these three populations are not frequently studied in relation to CTC and there is likely to be limited evidence to support specific inclusion of patients meeting these criteria.

PASC agreed that out of all proposed populations, patients with low-risk symptoms suggestive of CRC may be most appropriate for CTC but noted that there was no clinical consensus on the definition of low risk versus high-risk symptoms for CRC in this PICO set. PASC was concerned that complexity around current risk definitions could be difficult to interpret at the primary care interface. PASC determined that low risk populations should be more clearly defined

In Australia, eligible individuals aged 50 to 74 years are offered a free kit for a FOBT every two years (with the option for self request of the kit for individuals aged 45-49) under the National Bowel Cancer Screening Program (NBCSP)[4]. The FOBT is an immunochemical test sometimes called a faecal immunochemical test (FIT). The FOBT has a high false positive rate (as high as 40% in Canada [Chowdhury et al. 2023]; reported as 96% for NBCSP participants [Olver and Order, 2017]) thus a positive result requires follow-up investigation. Of patients with a positive FOBT, 58% will have normal colonoscopy, 39% will be diagnosed with a polyp and only 3% will be diagnosed with cancer or suspected cancer (Parkin et al. 2018). A breakdown of onward test findings for FOBT positive NBCSP participants in 2022 has been presented in Appendix 1 (Table 17). A proposed benefit of CTC in these patients would be the potential to rule out the need for a subsequent colonoscopy in the event of a negative result and no symptoms.

Although the patients who are symptomatic, or who have incidental findings on diagnostic imaging or positive FOBT, would most likely present to their GP or specialist for assessment, the current Cancer Council (2023) recommendations are different for patients with a positive FOBT compared to symptomatic patients. The guidelines for Chapter 5 on Summary of recommendations for population screening recommends colonoscopy for patients with a positive FOBT, which is different to the recommendations for low risk symptomatic patients to receive colonoscopy with the option of CTC where colonoscopy is not available but there is access to CT (Guideline chapter 7 on symptomatic patients) (Cancer Council 2023). The studies cited (Aniwan et al. 2017, Chiu et al. 2016, Digby et al. 2015, Njor et al. 2022, Ribbing et al. 2019) to support the Chapter 5 recommendation to follow-up a positive FOBT with colonoscopy however, were mainly investigations of FOBT to examine optimal cut off thresholds, using colonoscopy to confirm the presence of CRC and CRC related pathology and did not investigate alternate modalities such as CTC.

PASC noted that CTC is not recommended for managing positive FOBT patients in the current Australian screening guidelines. The applicant stated that this was because the guidelines had lacked consultation

[4] https://www.health.gov.au/our-work/national-bowel-cancer-screening-program

with wider clinical specialty groups, including radiologists. compared to overseas guidelines. PASC noted NBCSP data for 2020-2021 showed that 3% of patients with a positive FOBT have a cancer detected on colonoscopy (noting that data were incomplete due to limitations on data captured by NBCSP). PASC advised that patients considered high risk for CRC should be excluded from this application as these patients should undergo colonoscopy.

PASC considered the population subset for whom diagnostic imaging has shown an abnormality of the colon (such as bowel thickening) to potentially be appropriate for further investigation by CTC

Overall PASC considered that patients with low-risk symptoms and abnormal abdominal imaging may form the basis of an appropriate population, pending consensus on definition of low risk.

Patients with contraindications for colonoscopy

CTC for patients with contraindications for colonoscopy was considered by MSAC in the previous MSAC application 1269. The list of contraindications for that application was supplied by ARGANZ, which is presented in Table 9.

Although MSAC supported extending the eligibility of CTC to a wider list of contraindications to colonoscopy as part of the associated explanatory notes (MSAC application 1269 Public Summary Document [PSD][5]), the explanatory notes IN.0.15 were not amended during implementation and additionally, as the explanatory notes do not have legislative power, they would not have provided authority to render the MBS service to patients for this reason without that population being included in the final item description itself.

The list of contraindications to colonoscopy provided by ARGANZ to support application 1269 were more specific conditions and differed from the general contraindications cited in the colonoscopy protocols consulted (Canberra Health Services 2022; Western Australia Country Health Service 2019; Alfred Health 2024; Lee and Saltzman 2024). It was unclear whether some or all conditions provided by ARGANZ may fall under the general contraindication “When the risks of the colonoscopy outweigh the expected benefits”. Some of the contraindications for colonoscopy were noted to be contraindications for CTC as well (toxic megacolon, colitis and pregnancy) (Table 9).

[5] http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1269-public

Table 9 Contraindications for colonoscopy

Source	Type of contraindication
Supplied by ARGANZ (MSAC application 1269)	• active colitis • large abdominal aortic aneurysms • recent myocardial infarction or pulmonary embolism • coagulopathies, including patients receiving therapeutic anticoagulation • patients unable to tolerate adequate bowel preparations for colonoscopy • frail patients of advanced age • abdominal large-bowel hernias • splenomegaly
Current clinical practice	• Patient refusal / lack of consent • Known or suspected colonic perforation • When the risks of the colonoscopy outweigh the expected benefits • Active inflammation (toxic megacolon, fulminant colitis, ulcerative colitis, Crohn disease, diverticulitis)

ARGANZ = The Abdominal Radiology Group of Australia and New Zealand; MSAC = Medical Services Advisory Committee
Source: MSAC application 1269; Canberra Health Services (2022); Western Australia Country Health Service (2019); Alfred Health (2024); Lee and Saltzman (2024).

PASC considered that many of the contraindications to colonoscopy which were supplied by ARGANZ during MSAC consideration of Application 1269 would no longer be contraindications, or would now be considered relative contraindications and could be managed clinically, (such as patients on anticoagulant therapy). Some contraindications to colonoscopy could also be considered contraindications to CTC (for example colitis). PASC determined that this list of contraindications needs to be updated. PASC noted the list of contraindications to colonoscopy presented in the PICO (Table 9) as pertaining to current clinical practice and commented that currently, most contraindications are relative, such as very frail patients with multiple co-morbidities and high anaesthetic risk where CTC may be preferred to colonoscopy and clinical judgment is usually required.

PASC noted that although the current item for CTC (item 56553) includes high grade colonic obstruction as an indication, clinically, CTC is contraindicated for patients with high grade colonic obstruction due to the risk of bowel perforation. MSAC may wish to consider whether high grade colonic obstruction should be removed as an indication for CTC.

Patients with incomplete colonoscopy or colonic evaluation

The applicant noted that incomplete colonoscopy or colonic evaluation may be caused by multiple risk factors including increasing age, female gender, or previous abdominal or pelvic surgery (especially hysterectomy). The applicant estimated that 50% of patients with an incomplete colonoscopy will have another incomplete colonoscopy at next attempt. The applicant stated that some patients with a history of incomplete colonoscopy (outside the three-month criterion) had reported from personal experience that they are currently accessing the CTC item by attempting a trial of colonoscopy in order to obtain a referral for CTC.

The previous MSAC application 1269 for CTC also requested the removal of the three-month restriction from the item descriptor for CTC for patients who had an incomplete colonoscopy. Professional body feedback supported the removal of the restriction from the item descriptor given that patients who have had an incomplete colonoscopy are likely to remain unsuitable for an optical colonoscopy. MSAC, however, did not support removal of the restriction from the item descriptor for CTC. Although no detailed rationale

was included, the PSD reported that the Evaluation Sub-committee (ESC) raised removal of the three-month requirement as a key issue due to "considerable potential for use outside the intended patient population".

There have been no changes to guidelines since the previous application that might affect the removal of the three-month restriction. The Cancer Council (2022) recommends, as part of their colonoscopy surveillance guidelines, that same-day CTC is safe to perform following an incomplete colonoscopy, including in patients who have had a biopsy or simple polypectomy. ESGE/ESGAR (2021) also recommends CTC following incomplete colonoscopy, preferably on the same day or next day, with timing dependent on "interdisciplinary decision including endoscopy and radiological factors". However, the Cancer Council (2022) guideline recommends that "CTC should be delayed in patients with complex endoscopic intervention and in patients with high risk of perforation", which may mean that these patients may have a CTC more than 3 months after their initial incomplete colonoscopy.

PASC noted the value of CTC for patients in whom a colonoscopy could not be completed.

Size of the population for testing

For investigative technologies, the incidence and prevalence of the target population (and subgroups) for the test is required. The applicant provided some limited information regarding estimated utilisation for the proposed use of CTC:

- The applicant noted that in other countries where CTC has been recommended for diagnostic use around a third of all colonic examinations are performed with CTC. As a result, the applicant proposed a four year uptake estimate of 20-30% patients requiring investigation would receive CTC instead of colonoscopy.
- For incomplete colonoscopies, the applicant also suggested that the performance indicator of 'no more than 5% of colonoscopies should be incomplete' could provide an estimate for that population.
- The applicant noted that there is little data to support an estimate of patients with an incidental finding on imaging but noted it would be small and under 1000 patients per year.

In addition, NBCSP data was used to derive an estimate of patients with positive FOBT (Appendix 1). Otherwise, a preliminary search conducted during PICO development found that much of the required data to estimate the size of the testing population subgroups in the Australian setting was unavailable (at least publicly).

A summary of the population estimates, and potential basis, developed by the evaluation group is given in Table 10.

Table 10 Population estimates for PICO set 1

Populations	Source	Population estimate (for 2023-2024)
Symptomatic patients	Applicant estimate 20-30% of current colonoscopies (MBS item 32222)	103,805 – 155,708
Patients with positive FOBT	NBCSP data for 2022 calendar year participants (AIHW 2024) (of which 15-25% require biopsy or polypectomy)	~70,000
Patients with incidental finding on imaging	Applicant estimate	<1000
Colonoscopy contraindicated	MSAC 1269 estimated this to be 4,893 in 2014-2015	~4000 – 5000
Patients with incomplete colonoscopy	Applicant estimate 5% of current colonoscopies MBS items 32222-32228, 32230[b] (2023-2024): 683,354 services	34,168

AIHW = Australian Institute for Health and Welfare; CTC = computed tomography colonography; FOBT = faecal occult blood test; MBS = Medical Benefit Schedule; MSAC = Medical Services Advisory Committee; NBCSP = National Bowel Cancer Screening Program.
[a] Only MBS item 32222 has been used as other items (32223-32228) are for patients with specific conditions unlikely to be referred for CTC.
[b] MBS items 32223 – 32228 are lower utilisation items for patients in specific circumstances but if the colonoscopy was incomplete, these patients would all be managed the same way. Item 32230 is for colonoscopy including endoscopic mucosal resection. Item 32229 has not been included as this is co-claimed as a second item where polypectomy is undertaken during the colonoscopy.

The estimate for the symptomatic patient subpopulation is for the group as a whole, no obvious measure is available to permit further estimate for patients with low risk symptoms only.

The applicant has emphasised the importance of CTC as alternative to colonoscopy given colonoscopy wait times and the pressure on existing colonoscopy services. The NBCSP reported that the national median colonoscopy wait times (median time between a positive screen and diagnostic assessment) for participants with a positive FOBT in 2022 was 62 days (AIHW 2024). Wait times were longer for certain sub-groups: 87 days for patients in the public system (versus 51 days for private care); 78 days for those in remote areas, 71 days for people in low socioeconomic areas and 72 days for Indigenous Australians (AIHW 2024).

PASC considered that there is uncertainty regarding the size of the population for testing and further evaluation of the evidence will be needed for development of an assessment report

Intervention

CTC is a radiographic imaging technique for investigating internal structures of the colon and rectum (Cancer Council 2022; Chieng 2023). CTC is sometimes described as 'virtual colonoscopy' or 'CT colonoscopy'. It employs an X-ray source that rotates around the patient, to acquire consecutive tomographic sections of the colon and rectum resembling slices. These two-dimensional images, in turn, can be compiled as a three-dimensional reconstruction of the bowel using imaging software. This may or may not include automated polyp detection software (RANZCR 2013). For the imaging procedure itself, the colon is distended using carbon dioxide insufflation via a catheter placed in the rectum. Perforation of the bowel is a potential complication (0.04%) (Cancer Council 2022) but at a lower rate than from colonoscopy (up to 0.1% for screening colonoscopies; Lee and Saltzman 2024). The patient is not usually offered sedation as opposed to colonoscopy. If a polyp or lesion is detected, the patient is usually referred for colonoscopy.

As with colonoscopy, CTC also requires a cathartic bowel preparation that is used to cleanse and remove faecal material which would obstruct the imaging. This preparation involves dietary restrictions and a

laxative solution for 1-3 days before the procedure. In addition, a contrast agent for faecal tagging (typically Gastrografin which contains iodine) is given orally or as an enema to reduce artefacts from residual material in the bowel (NPS MedicineWise 2021). Unlike CT of abdomen/pelvis, CTC does not usually employ intravenous contrast (RANZCR 2019).

The applicant indicated that no change in the way CTC is performed has occurred since this intervention was considered by MSAC in 2014 (application 1269). The use of CTC for diagnosis or exclusion of CRC would be as an add-on or triage test – that is, a test used to determine which patients require further tests (MSAC Guidelines 2021). The purpose of a triage test is to enrich the test population, thus increasing the proportion of patients likely to benefit from the definitive test. In the case of CTC, patients with clinically significant findings would still require onward referral for colonoscopy (the definitive test), while patients not requiring further investigation may be spared unnecessary colonoscopy (and its associated risks).

Current Australian recommendations for polyps detected are summarised in Table 11 (irrespective of detection method).

Table 11 Recommended steps for different polyps detected, based on size

Polyp size	Action on detection	Action for follow-up
<6mm	Proximal site; and descending colon site: removal depends on characteristics (on colonoscopy); polyps of this size are not reported (on CTC) Rectosigmoid site: No action recommended (unlikely to be clinically significant and polypectomy is associated with complications)	Return to screening population (in occasional cases where diminutive polyps are removed on colonoscopy that show histopathology of concern, the patient would be subject to surveillance intervals in Table 14).
6<9mm	Patient / physician choice to remove (polypectomy)	If non adenomatous return to screening population Clinically significant if adenoma[a] – See surveillance intervals in Table 14
>10mm[a]	Clinically significant – polypectomy recommended. (Also depends on site, invasive characteristics, histology)	See surveillance intervals in Table 14

CTC = computed tomography colonography
[a] an adenoma ≥10mm in size is defined as an advanced adenoma
Source: Cancer Council (2022); ESGE (2024)

The ESGE/ESGAR (2020) guideline notes that in symptomatic patients, small polyps (6–9 mm) and diminutive polyps (≤5 mm) are less relevant since they cannot explain the patient's symptoms. Other recommendations for Europe are captured in the ESGE guidelines on polypectomy and resection (ESGE 2024) which may diverge from practice in Australia. In particular, the ESGE recommends "resection of all polyps with the exception of diminutive (≤5 mm) rectosigmoid polyps that are predicted to be non-adenomatous with high confidence". This would appear to contradict the current Cancer Council recommendation that diminutive polyps detected on CTC are usually not reported as the overwhelming majority of these do not harbour advanced histology (Cancer Council 2022).

PASC noted the main purpose of CTC would be to rule out patients who did not require onward referral for colonoscopy,. PASC noted that all patients with an abnormal CTC still require a colonoscopy, as consultation feedback suggests that patients would be very unlikely to proceed to surgery following detection of lesions on CTC alone due to the need for tissue diagnosis

PASC noted CTC is a diagnostic test only and does not have a therapeutic component (as colonoscopy does).

PASC noted CTC may only be offered in Australia by radiologists with the appropriate accreditation from RANZCR, which the applicant stated is maintained by delivering a minimum number of services per year and meeting the required RANZCR training criteria.

PASC noted the applicant's clinical expert stated that CTC use is widespread in comparable countries such as the United Kingdom and New Zealand.

Most R-type CT diagnostic imaging services (including the current CTC item 56553) may be ordered by medical practitioners, specialists and consultant physicians (MBS explanatory note IN.0.6).

CTC radiation exposure

CTC typically involves a paired scan – one scan with the patient prone (lying on the front) or lateral (lying on the side) and a second scan with the patient supine (lying on the back facing up). According to the International Atomic Energy Agency (IAEA), most multi-slice CTC protocols deliver an effective dose in the range of 2-6 millisievert (mSv) per scan (4-12 mSv for the examination) involving scans in the supine and prone positions (IAEA 2017). The IAEA noted this is comparable with the dose that might be received during a DCBE (7 mSv) and marginally lower than from a CT of pelvis (6-10 mSv) (noting the latter would be typically performed twice – once with and once without contrast, thus doubling the dose). The Cancer Council guideline on surveillance describes this procedure as a "low dose CT" (Cancer Council 2022).

Treatment setting for CTC

CTC is generally performed in a radiology clinic in a similar manner to other diagnostic imaging services. This would be in a public hospital, private hospital or private clinic (all as outpatient services). It was considered unlikely that a patient would receive CTC as an in-patient. Patients hospitalised for acute or high-grade symptoms such as bleeding or severe pain would most likely receive colonoscopy or CT of abdomen/pelvis. The procedure would be performed by a radiography technician under the supervision of a specialist radiologist, both of whom need appropriate credentials and training for this procedure (RANZCR 2013).

Contraindications for CTC

Contraindications for CTC are summarised in Table 12. It was noted that several contraindications are shared with those for colonoscopy (Table 9) (conditions causing acute inflammation such as toxic megacolon also and bowel obstruction).

Table 12 Recommended absolute and relative contraindications for CTC

Type of contraindication	Details
Absolute	Patient refusal Acute abdomen or acute diverticulitis Bowel obstruction Toxic megacolon Recent colonoscopy with biopsy or polypectomy (due to increased risk of perforation. Wait between 2–6 weeks before performing CTC)
Relative	Pregnancy Physical weight limits (based on capacity of the CT scanning table) Inflammatory bowel disease or other patients at high risk for colorectal cancer due to high likelihood of requiring biopsies or endoscopic intervention, such as polypectomy. Young patients (patients younger than 40 years have poorer risk/benefit due to radiation)

CT = computed tomography; CTC = CT colonography.
Source: Moore and Naidoo (2017).

MBS Review Taskforce

In 2016, the Department of Health undertook the MBS Review, which included a consideration of colonoscopy items by the Gastroenterology Clinical Committee (MBS Review Advisory Committee 2023). The Committee recommended changes to colonoscopy items but made no comment regarding CTC. A post-implementation report (MBS Review Advisory Committee 2024, authored by the Colonoscopy Working Group) noted that colonoscopy services remained over-subscribed and that people living in rural and regional areas were not accessing colonoscopy services at a level consistent with their risk of CRC.

The applicant proposed that CTC could offer an alternative to colonoscopy, taking pressure off services and waiting lists. However, the post-implementation report stated that CTC was emerging, but it still required bowel preparation and could not provide histopathology. The working group considered "that the role of CTC in screening assessment has yet to be fully defined".

Comparator(s)

The applicant proposed colonoscopy as the comparator for all requested populations. In current clinical practice, this is recommended for any patients with symptoms or other findings suggestive of CRC (Cancer Council 2023). This is appropriate for symptomatic patients, and patients with incidental findings on imaging or a positive FOBT.

Current standard of care (SOC) was identified as an alternative for patients with contraindications to colonoscopy. Given there is no single alternative recommended in clinical guidelines, SOC could include a range of options:

- CTC (privately funded)
- another test (DCBE, though rarely used)
- a colonoscopy with adjustments such as a pause in oral anticoagulants
- flexible sigmoidoscopy
- a decision to maintain surveillance (no testing) where the risk of CRC was considered unlikely
- a decision to proceed straight to surgery

The option chosen would depend on the patient's clinical situation and the treating physician. However, in terms of the evaluation, colonoscopy would be the most commonly studied intervention. A preliminary search of the peer-reviewed literature indicated that studies of CTC are either uncontrolled (single arm), or compared with colonoscopy, or compared with other interventions not as frequently used for investigation of CRC (i.e., sigmoidoscopy, capsule endoscopy, CTC without bowel preparation). As colonoscopy comprises a large portion of this use in practice it remains the most appropriate choice of comparator for the evaluation.

Description of colonoscopy

Colonoscopy involves endoscopic visualisation of the full length of the colon (anal canal, rectum, sigmoid, descending, transverse and ascending portions of the colon and the caecum) (Lee and Saltzman 2024). The applicant noted that in a procedure where the ileocaecal junction and appendiceal orifice could not be visualised, this would usually be considered a failed colonoscopy. The endoscope is a camera mounted on a thin flexible tube which is passed through the anus, including a light along with equipment for taking biopsy samples and removing polyps (polypectomy). The procedure requires bowel preparation and

sedation and is usually performed as a day patient procedure in an outpatient setting. In comparison with CTC, colonoscopy requires no contrast media and involves no radiographic imaging. When discussed in the context of CTC, colonoscopy is sometimes referred to as optical colonoscopy to distinguish between the two procedures.

Training and credentialling of endoscopists performing this procedure are mandatory in Australia (ACSQHC 2020). Colonoscopy may be performed by a specialist gastroenterologist, consultant surgeon, appropriately credentialled physician or a nurse endoscopist. In country areas, the endoscopist may be a GP. In any case, the qualifications specified by ACSQHC (2020) will apply.

MBS items for colonoscopy may be ordered by GPs and also specialists and consultant physicians (MBS explanatory notes TN.8.152, GN.6.16).

The applicant stated that rates of polypectomy at colonoscopy may be high. A representative breakdown of polyps removed on colonoscopy in FOBT positive patients identified through the NBCSP (Table 13) estimated the rate of polyp detection at 51.5%, of which just over 10% are hyperplastic.

Table 13 Indicative breakdown of polyps removed on colonoscopy – NBCSP data (Bobridge 2013)

Type of polyp	N = 443 colonoscopies	Proportion (%)
Polyp detection rate	223	51.5
Hyperplastic polyps	44	10.2
Adenomas	82	18.9
Advanced adenomas[a]	71	16.4
CRC (pathology confirmed)	14	3.2
Polyps unable to be retrieved / classified	12	2.8

CRC = colorectal cancer; NBCSP = National Bowel Cancer Screening Program.
[a] advanced adenomas defined as a large ≥1 cm adenoma with high grade dysplasia and/or villous changes.
Source: Bobridge 2013

The data in Table 13 are from FOBT positive patients identified through the NBCSP between 2006-2009 in South Australia (Bobridge 2013). Note that hyperplastic polyps are now referred to as serrated polyps according to the Cancer Council (2022), and only a subset are true hyperplastic polyps. A more recent source of information for rates of polyps and their histology similar to Table 13 with the current classification could not be found following a limited search.

The contraindications for colonoscopy are summarised in Table 9**.**

Double contrast barium enema (DCBE)

The applicant has not included DCBE as a comparator, although it was included as a comparator in the previous CTC application (MSAC 1269). Application 1269 was lodged in 2012 and a shift away from use of DCBE has occurred during that time even though its use remains funded on the MBS. The applicant stated that barium enema (that is, DCBE) 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. Although no reference was supplied for this statement, a key randomised trial undertaken for the National Institute for Health Research (NIHR) in the United Kingdom showed CTC was superior to DCBE for both detection rates (7.0%

vs 5.2%; p = 0.0243) and subsequent 3-year cancer incidence (6.7% vs 14.1%, respectively) (Halligan et al. 2015).

MBS utilisation figures were retrieved to investigate the use of DCBE. Over the 12-month period between July 2023 and June 2024, use of the current MBS item for DCBE (MBS item 58921) was 1,365 services, which represented 0.26% of the corresponding utilisation for colonoscopy (MBS item 32222) during the same period (519,026 services). This can be compared to DCBE utilisation in 2001-2002 of 38,330 services.

Guidelines from RANZCR, Cancer Council (2023) and Europe (ESGE/ ESGAR 2020) no longer include recommendations for DCBE for diagnostic use (Moore and Naidoo, 2017; ESGE/ ESGAR 2020). It is understood that DCBE may be considered as a later line option in patients with contraindications for colonoscopy (Moore and Naidoo 2017).

PASC agreed that the appropriate comparator for CTC is colonoscopy, noting that colonoscopy has both diagnostic and therapeutic components.

PASC noted that for patients in whom colonoscopy was contraindicated, SOC is an appropriate secondary comparator. However, PASC noted that SOC could include a range of options as no single alternative was recommended in the clinical guidelines.

Reference standard (for investigative technologies only)

The reference standard would be colonoscopy (for determining accuracy of the test). This is the same for all PICO sets.

PASC agreed that the appropriate reference standard for both PICO set 1 and PICO set 2 is colonoscopy.

Outcomes

The proposed outcomes are summarised in the list below:

Efficacy/effectiveness

- Polyp detection rates, for adenomas, total serrated polyps, SSA/Ps and TSAs (where available)
- Diagnostic performance (accuracy, sensitivity, specificity)
- Subsequent cancer incidence (referred to as post-colonoscopy CRC for the comparator)
- Health-related quality of life (HRQOL)
- Incomplete colonic examination/failed procedure
- Time from first presentation to diagnostic assessment

Safety

- Bowel perforation
- Bleeding post-colonoscopy
- Radiation-related events
- Allergic reactions to contrast media

Healthcare resource use

- Extracolonic findings (as a measure of onward costs)
- Onward referrals (colonoscopy/biopsy/polypectomy incidence or rate)

Outcomes proposed are the same for each PICO sets. These have been based on outcomes used in the previous MSAC application 1269 and those in one of the key studies found in the preliminary literature search (Halligan et al. 2015) which was undertaken to support health technology assessment of diagnostic interventions for NICE, and two relatively recent health technology assessments of CTC versus colonoscopy for the Netherlands (van der Meulen et al. 2018) and Canada (Svystun et al. 2022).

The applicant stated that current issues with colonoscopy include extended wait lists with virtually every state and territory having substantial waiting lists of over 100 days.[6] .

The applicant proposed that CTC services have almost no wait list and that CTC has the potential to reduce over-subscribed colonoscopy services.

A preliminary survey of the peer-reviewed literature suggested that few studies presented wait times separated by intervention – thus no comparative data were available. A registry study presented by the applicant (Delisle et al. 2020) falls into this category. Delisle et al. (2020) presented data from the Manitoba Cancer Registry which included wait times prior to assessments that included CTC and colonoscopy, but it was not possible to distinguish between these. Thus, wait list times are included in the proposed outcomes for this PICO set but may not be able to be assessed depending on availability of clinical evidence.

Any information on onward referral rates (for colonoscopy or requirement for further investigations such as biopsy or polypectomy) will be valuable to inform measures for the evaluation such as colonoscopies avoided. Although this has been included in the proposed outcomes for this PICO set, like wait times, it is unlikely that comparable evidence will be available in the literature.

Extracolonic findings on CTC could be included as a resource use outcome as these are reported in studies of CTC. It was noted that extracolonic pathology outcomes were not considered for MSAC application 1269 as there was no available effectiveness data but that these findings were an outcome reported for the key study (Halligan et al. 2015) published since then.

Any information on onward referral rates (for colonoscopy or requirement for further investigations such as biopsy or polypectomy) will be valuable to inform measures for the evaluation such as colonoscopies avoided. Although this has been included in the proposed outcomes for this PICO set, like wait times, it is unlikely that comparable evidence will be available in the literature.

PASC agreed with the proposed outcomes for this PICO set.

[6] Data on wait time is available from the Bowel Cancer Australia website (https://www.bowelcanceraustralia.org/colonoscopy/colonoscopy-wait-times). The wait time represents the time from colonoscopy following a positive FOBT screen, undertaken as part of the National Bowel Cancer Screening Program.

PASC noted advice from the applicant's clinical expert that CTC offered diagnostic outcomes for lesions extending beyond the lumen of the gastrointestinal tract, which offers an additional benefit in diagnosing patients with unexplained symptoms. However, additional findings may also be incidental and clinically insignificant and incur additional costs when further investigations are undertaken.

PICO criteria: PICO set 2 – surveillance

Population

The applicant has requested CTC as an alternative tool for surveillance and monitoring in patients as follows:

(i) 6-9mm polyp(s) who have not opted for a polypectomy and require surveillance in three years to monitor changes within the polyp(s),
(ii) patients with ≥6mm polyp(s) who have returned a benign biopsy result, and

(iii) patients with previous history of CRC diagnosis.

Current management

Patients who have had a previous adenomatous polyp or polyp with advanced histology require regular colonic surveillance (Cancer Council 2022) (subject to surveillance recommendations described below in Table 14). Not all of the clinical situations described would be suitable for CTC – those patients with a strong possibility of lesions requiring removal (in the high and highest categories) would require colonoscopy.

Table 14 Recommended colonoscopy surveillance intervals (Cancer Council 2022)

Findings on 1st colonoscopy	Surveillance risk category	Surveillance interval (y)	Recommended surveillance colonoscopy interval based on the below findings on 2nd colonoscopy
1-2 adenomas; no risk factors[a]	Low	10	Clear: Return to FOBT screening population Otherwise, risk category as for 1st colonoscopy
1-2 adenomas; plus risk factors	Intermediate	5	Clear: Colonoscopy at 10 y 1-2 adenomas (± risk factors): colonoscopy at 5 y Otherwise, risk category as for 1st colonoscopy
3-4 adenomas; no risk factors	Intermediate	5	As above (intermediate risk at 1st colonoscopy)
1-2 adenomas; ≥10mm[b] plus risk factors	High	3	Clear or 1-2 adenomas (no risk factors): colonoscopy at 5 y 1-2 adenomas (+ risk factors or ≥10mm); 3-4 adenomas (no risk factors); colonoscopy at 3 y Otherwise, risk category as for 1st colonoscopy
3-4 adenomas; risk factors OR ≥10mm 5-9 adenomas; no risk factors	High	3	As above (high risk category at 1st colonoscopy)
1-2 adenomas; ≥10mm ± risk factors	High	3	As above (high risk category at 1st colonoscopy)
3-4 adenomas; ≥10mm plus risk factors 5-9 adenomas; ≥10mm ± risk factors ≥10 adenomas	Highest	1	Clear or 1-2 adenomas (no risk factors): colonoscopy at 5 y 1-2 adenomas (+ risk factors) or 3-4 adenomas (no risk factors): colonoscopy at 3 y Otherwise, 1 y surveillance interval

FOBT = faecal occult blood test

[a] Presence of at least one risk factor confers a higher risk classification. Risk factors based on histopathology findings are high-grade dysplasia and villosity (defined as 25% villous component on histology) – these are recognised indicators of advanced histology, or that the lesion is starting to show dysplastic or neoplastic characteristics.

[b] adenomas of ≥10mm size are defined as advanced.

Source: Cancer Council (2022) (Tables 3, 14, 15 and 16)

Surveillance recommendations are different if the previously identified polyps were small (in size and number) and the patient is returning for a follow-up visit at 12 or 24 months to determine if there is any change to the status of the polyps. These patients are currently managed within the screening framework (Table 14). See current management recommendations for polyps of different sizes summarised in the section Current management algorithm.

Patients with a diagnosis of cancer (CRC) are subject to different requirements for follow-up and monitoring and also a higher baseline risk of disease. Patients who have previously been treated for cancer may be subject to more intense surveillance either receiving colonoscopy or CT chest abdomen and pelvis (C/A/P) (and likely other tests) and the intervals would be more frequent such as three or six months depending on disease staging.

Patients with a diagnosis of CRC who have undergone curative resection are recommended to receive regular tests for tumour antigen (carcinoembryonic antigen; CEA) and CT Chest/Abdomen/Pelvis (Cancer Council 2023). This CT scan is a higher dose broader scan compared to CTC. None of the guidelines identified recommended CTC for this patient population. Furthermore, preliminary literature searches revealed no studies of CTC for this type of monitoring.

No comparative studies were identified in the preliminary literature scan that considered use of CTC for surveillance (monitoring) of CRC patients for recurrence of their disease.

None of the studies reported on patient-relevant direct disease outcomes of CRC such as overall survival, progression-free survival or disease progression.

There was a lack of robust clinical evidence to support the population regarding polyp surveillance. Guidelines from the British Society of Gastroenterology (BSG) state that CTC for patients requiring polyp surveillance should be restricted to those who have undergone polypectomy and who have contraindications to colonoscopy or have had an incomplete colonoscopy (Rutter et al. 2020),

Size of the population

The applicant provided no estimate of utilisation for CTC in patients requiring surveillance for CRC. A limited search of the literature found two recent publications which suggested approximately 15% of colonoscopies undertaken in Australia were for polyp surveillance (Haga et al. 2022; Watson et al. 2023). This would have corresponded to 77,854 services in 2023-2024 based on utilisation in the same period of the main colonoscopy item (MBS item 32222). The two articles found were based on data from regional hospitals and it was not known if figures for metropolitan centres would have been different.

PASC noted that the current Cancer Council guidelines do not include the use of CTC in polyp surveillance and noted the limited evidence to support CTC use in both CRC and polyp surveillance. PASC noted that patients who have had a previous adenomatous polyp or polyp with advanced histology require regular colonic surveillance, and some clinical situations may not be suitable for CTC (e.g. patients with a high likelihood that they would require colonoscopy for lesion/polyp removal, biopsy and histology based on their previous history of polyps).

PASC considered that CRC follow up and surveillance is complex, stratified by risk and involves multiple surveillance modalities, noting that recommendations for polyp surveillance would be highly complex and could be difficult to interpret and manage from a primary care perspective without oversight from a specialist.

Intervention

The intervention is the same as described in PICO set 1.

Comparator(s)

The applicant proposed colonoscopy as the comparator described above for PICO set 1.

PASC agreed the appropriate comparator for CTC is colonoscopy, as per PICO set 1.

Reference standard (for investigative technologies only)

The reference standard would be colonoscopy (for determining accuracy of the test) as described for PICO set 1.

PASC agreed that the appropriate reference standard for both PICO set 1 and PICO set 2 is colonoscopy.

Outcomes

Outcomes are the same as described in PICO set 1.

Assessment framework (for investigative technologies)

Comments on the clinical evidence

The studies cited by the applicant as clinical evidence are summarised in Appendix 2, Table 18 (comparative evidence) and in Table 19 (other, non-comparative evidence). The applicant has cited the same studies for all PICO sets requested. Only three of the studies were comparative (Pickhardt 2003; Kim 2007; Rua 2020), the first two of which were considered in the last submission to MSAC (application 1269). The remaining studies cited were not comparative and represent a very low level of evidence for an indication where there are already funded interventions available.

A preliminary search of the peer-reviewed literature was undertaken that focused on evidence published in the last 10 years. Few articles were returned that evaluated CTC versus colonoscopy and presented either diagnostic or disease outcomes. Many studies were non-comparative and presented specific outcomes only (interval cancers; perforations). Others explored different comparators (sigmoidoscopy, capsule endoscopy, guaiac or immunochemical stool testing), modified interventions (in terms of computer aided detection methods, bowel preparations), or experimental populations (for example Lynch Syndrome). One randomised study was identified in the preliminary search which presents high quality evidence of CTC versus colonoscopy for diagnosis of CRC in symptomatic patients (Atkin et al. 2013; Halligan et al. 2015). This was a trial undertaken for the NIHR (United Kingdom) to inform Health Technology Assessment (HTA) and funding decision-making. It was noted further that the current Australian guideline (Cancer Council 2023) undertook an updated systematic review and meta-analysis of evidence for CTC which is also likely to be relevant. Although the literature search will be a matter for the assessment, it was considered unlikely that there will be more than 10 or so studies with directly relevant comparative diagnostic or disease outcomes for any of the requested PICO sets.

As previously mentioned in the population section for PICO Set 2, no comparative studies were found examining the use of CTC for surveillance (monitoring) of CRC patients for recurrence of their disease and no data could be found on patient-relevant direct disease outcomes. In the absence of direct disease outcomes, the assessment would have to employ a linked evidence approach.

A truncated assessment framework for triage testing (see Figure 1) is proposed based on the claim of non-inferiority and the proposal that CTC is an alternative to colonoscopy. The applicant claims that CTC will provide the same diagnostic information for CRC as colonoscopy. It is therefore assumed that there would be no difference in health outcomes if a patient from either population (diagnostic or surveillance) were to undergo CTC or colonoscopy for the detection of CRC or colorectal polyps.

In the event that non-inferiority cannot be demonstrated (i.e. CTC does not provide the same information and health outcomes), a full assessment framework may be required.

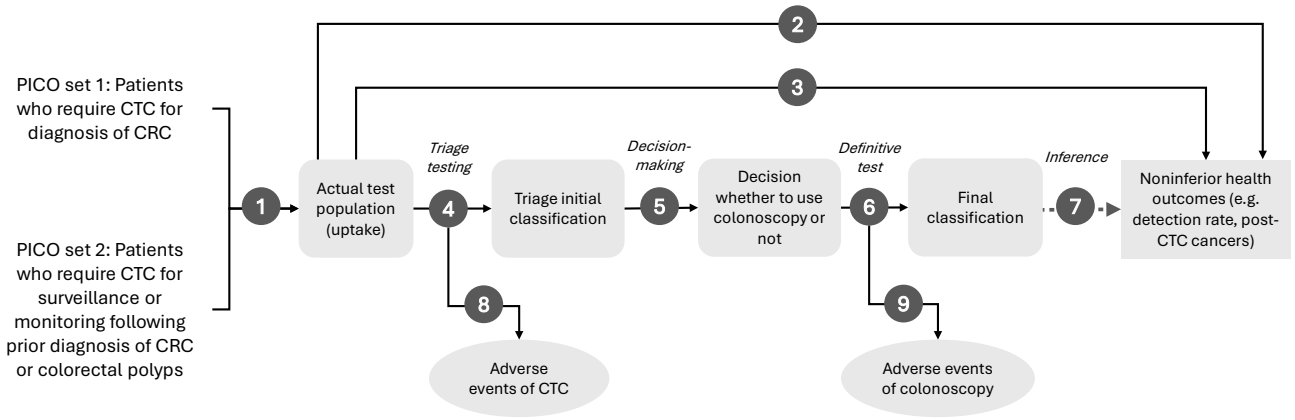

Figure 1 Assessment framework that has been truncated at the final classification of test results (following a triage and definitive test) with the inference that the final classification will result in the same health outcomes

CRC = colorectal cancer; CTC = computed tomography colonography
1: change in uptake rate for testing; 2: direct from test to health outcomes evidence; 3: direct from test to categorisations and clinical decisions; 4: test accuracy; 5: change in investigative thinking; 6: test accuracy in terms of sensitivity and specificity; 7: inference; 8: adverse events due to CTC; 9. adverse events due to colonoscopy

The assessment questions for a claim of non-inferiority for use of a triage test (CTC) compared with the main comparator (definitive test [colonoscopy]) are:

1. Does the use of CTC change the uptake rate for testing compared with the current testing regimen?
2. Does the use of CTC in the diagnostic and surveillance populations in PICO sets 1 and 2 result in the same or better health outcomes (e.g. detection rate, post-CTC cancers) compared with colonoscopy?
3. Does the use of CTC in the diagnostic and surveillance populations in PICO sets 1 and 2 result in the same categorisation (positive/negative, presence/absence, high risk/low risk) or the same clinical decisions compared with colonoscopy?
4. What is the test accuracy of CTC compared with colonoscopy? What is the nature of the incorrect classifications (i.e. ratio of false positives to false negatives) from using CTC? What are the clinical consequences of the false negative CTC result?
5. Does information from CTC result in a change in investigative thinking and change in the individuals who are referred for the definitive test?
6. Inference that the same final classification of patient (all patients classified using colonoscopy are classified similarly if CTC were introduced? will result in the same health outcomes?
7. What are the harms of CTC?
8. What are the harms of colonoscopy?

PASC noted that assessment of CTC would be considered as an add-on service to the existing diagnostic pathway.

Clinical management algorithms

Current management algorithm

The clinical management algorithm showing current practice for detection of CRC using colonoscopy and CTC (under MBS item 56553) is shown in Figure 2. CTC is currently only available as follows:

- For referral by GPs: patients who have undergone an incomplete colonoscopy no more than three months prior, or who have a high-grade colonic obstruction
- For referral by specialist endoscopists or physician qualified to perform colonoscopies: a patient who is symptomatic or high risk (in terms of familial CRC risk), as clinically indicated.

PASC noted that including high grade colonic obstruction as a clinical indication for CTC in the current clinical algorithm is not appropriate. CTC, like colonoscopy, requires bowel preparation which is not safe for patients with high grade colonic obstruction due to the risk of perforation. PASC noted that CTC is not appropriate in the setting of high grade colonic obstruction, due to it being a contraindication for CTC, with other imaging techniques (e.g. CT scan of abdomen and pelvis) being more appropriate than CTC in that setting.

The MBS item for CTC is currently only eligible for use in a diagnostic setting, with little guidance or evidence available on the use of CTC in monitoring and surveillance. The Cancer Council's clinical practice guideline on CRC and colonoscopy surveillance recommends that patients with a detected polyp between 6mm and 9mm can either be offered a polypectomy or "repeat colonic examination "at three years, where "colonic examination" is not explicitly defined as colonoscopy or CTC, but noting that there is no evidence to support to use of CTC as surveillance. This guidance has been incorporated into the current clinical algorithm; however, it is not covered under the current MBS item for CTC.

DCBE has not been included as a comparator in the current clinical algorithm due to its diminishing use in Australian clinical practice, supported by recommendations from the New Zealand Clinical Practice Guidelines for Bowel Screening and the European ESGE/ESGAR Guideline which state that DCBE should not be performed in the diagnosis of colorectal neoplasia or as an alternative to colonoscopy.

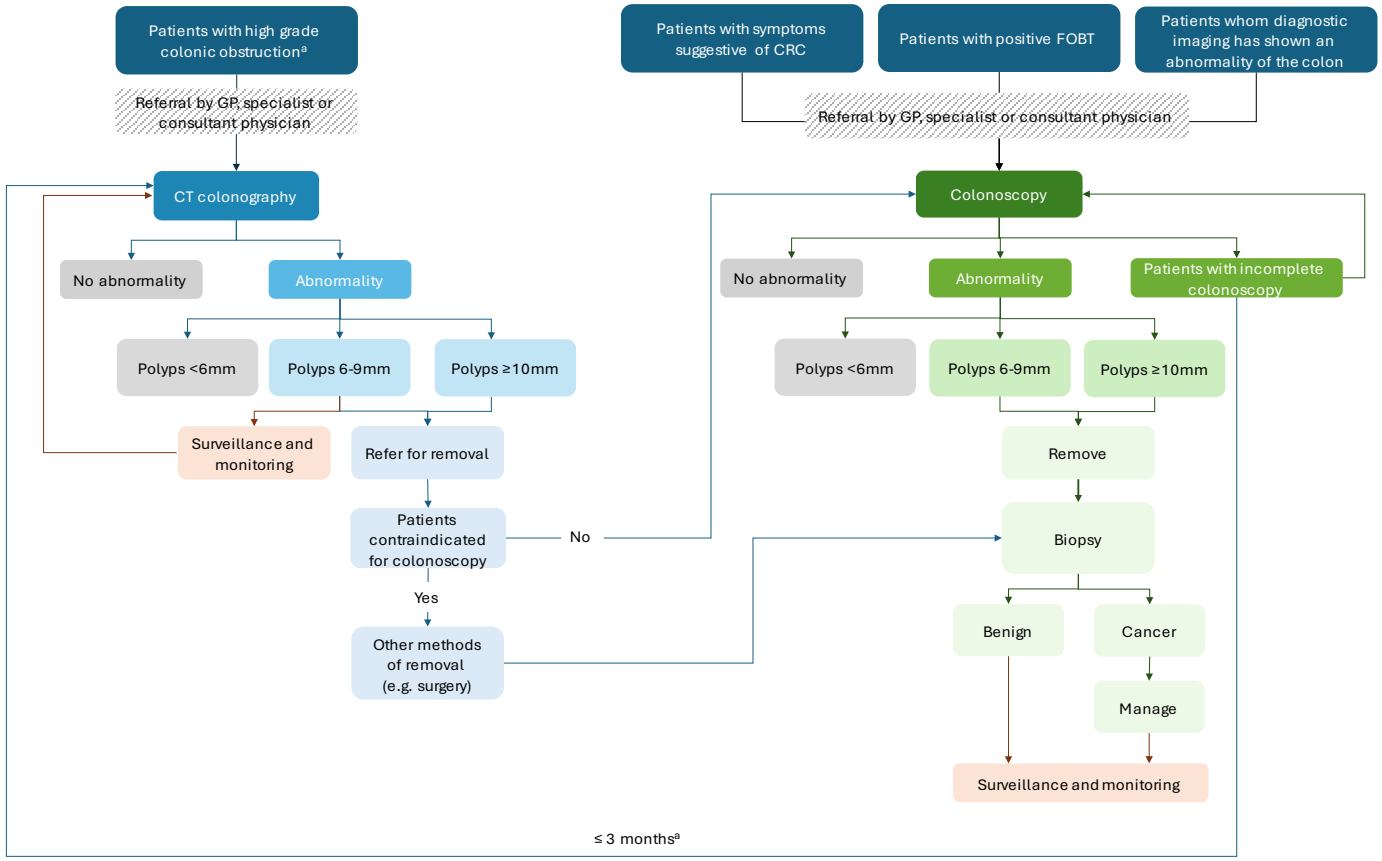

Figure 2 Current clinical diagnostic and monitoring pathway for CRC detection using CTC and colonoscopy.

CRC = colorectal cancer; CT = computed tomography; FOBT = faecal occult blood test
[a] As per MBS item 56553: patients must be symptomatic or high risk (in terms of familial CRC history), and had a scan to exclude of diagnose colorectal neoplasm.
Note: Grey boxes indicate no further action required.
Source: adapted from clinical algorithm provided in application; Cancer Council (2022); Cancer Council (2023)

Proposed clinical algorithm

The application proposes the use of CTC as an alternative to colonoscopy for an expanded population of patients that are currently eligible for colonoscopy. Figure 3 shows the proposed clinical algorithm, which includes the two PICO sets proposed by the evaluation group for diagnostic, and monitoring and surveillance populations.

The proposed clinical management algorithm incorporating the use of CTC for diagnostic and surveillance populations as an alternative to colonoscopy differs from current management (Figure 2) in the following ways:

- Patients with symptoms suggestive of CRC, with a positive FOBT, or in whom diagnostic imaging has shown an abnormality of the colon would be eligible for CTC as a diagnostic tool for polyp detection.
- Patients contraindicated for colonoscopy would also be eligible for CTC as a diagnostic tool for polyp detection as an alternative to colonoscopy. These patients can currently only be referred by

specialist endoscopists in the setting of excluding or diagnosing colorectal neoplasia in symptomatic or high risk patients and the proposal is to extend this to include GPs as requestors.

- Patients with an incomplete colonoscopy would no longer be required to undergo CTC within 3 months of failure.
- CTC is proposed to be an alternative tool for surveillance and monitoring in patients with (i) 6-9mm polyp(s) who have not opted for a polypectomy and require surveillance in three years to monitor changes within the polyp(s), (ii) patients with ≥6mm polyp(s) who have returned a benign biopsy result, and (iii) patients with previous history of CRC diagnosis.

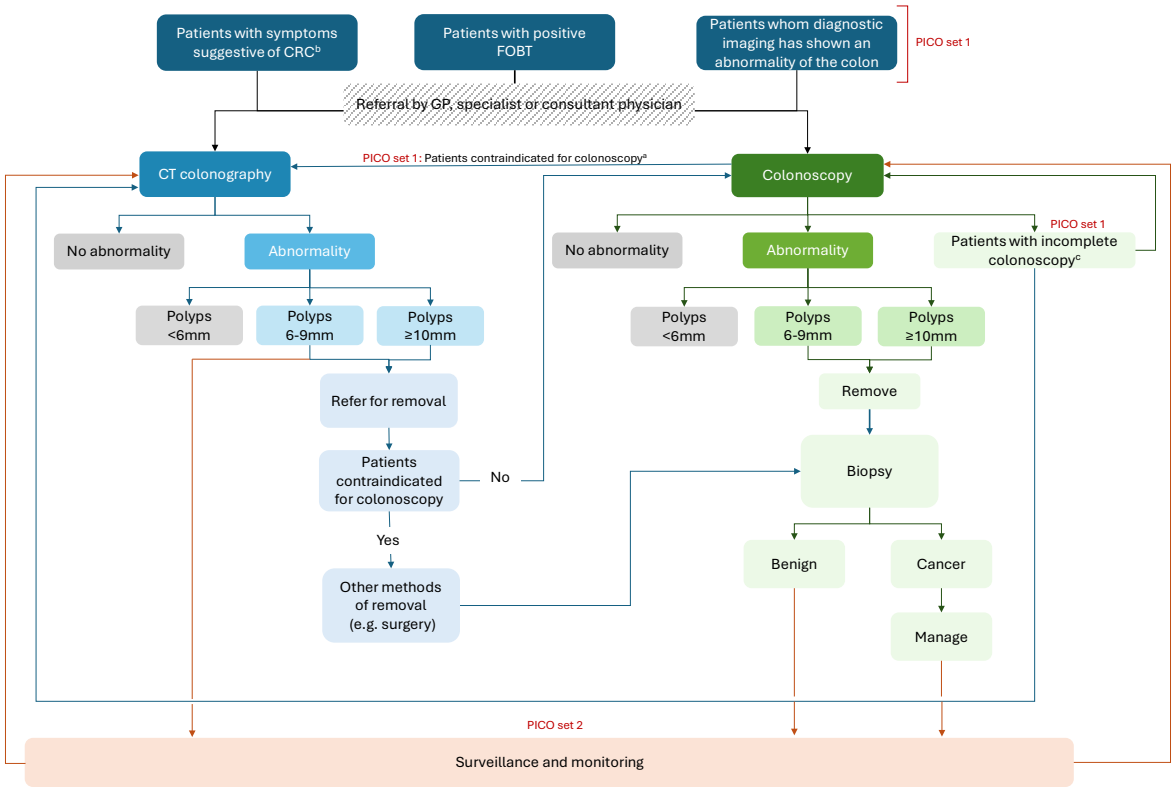

Figure 3 Proposed clinical diagnostic and monitoring pathway for CRC detection using CTC and colonoscopy.

CRC = colorectal cancer; CT = computed tomography; DCBE = double contrast barium enema; FOBT = faecal occult blood test;; SOC = standard of care.
[a] Patients contraindicated for colonoscopy may also be eligible for other alternatives to colonoscopy as part of SOC (e.g. DCBE)
[b] Patients referred for CTC must be low risk symptomatic or without symptoms that would warrant urgent referral (such as rectal bleeding, anaemia or unexplained weight loss)
[c] As per MBS item 56553: patients must be symptomatic or high risk (in terms of familial CRC history), and had a scan to exclude of diagnose colorectal neoplasm
Note: Grey boxes indicate no further action required.
Source: adapted from clinical algorithm provided in application; Cancer Council (2022); Cancer Council (2023).

PASC determined that the clinical algorithms are not currently fit-for-purpose and would need to be revised. The revised algorithms would need to incorporate a symptomatic population that is at low risk for CRC which PASC considered to be likely to be the most appropriate population for the application, rather than including patients who are at high risk for CRC. PASC suggested that patients with low-risk symptoms for CRC and patients with abnormal abdominal imaging may form the basis of an appropriate population when revising the algorithm.

Proposed economic evaluation

The proposed approach for assessment of each PICO set is presented below Table 15. The cells for the noninferiority claim and cost-minimisation analysis are shaded as the appropriate economic evaluation.

Table 15 Classification of comparative effectiveness and safety of the proposed intervention, compared with its main comparator, and guide to the suitable type of economic evaluation

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

CEA=cost-effectiveness analysis; CMA=cost-minimisation analysis; CUA=cost-utility analysis
? = reflect uncertainties and any identified health trade-offs in the economic evaluation, as a minimum in a cost-consequences analysis
[a] 'Uncertainty' covers concepts such as inadequate minimisation of important sources of bias, lack of statistical significance in an underpowered trial, detecting clinically unimportant therapeutic differences, inconsistent results across trials, and trade-offs within the comparative effectiveness and/or the comparative safety considerations
[b] An adequate assessment of 'noninferiority' is the preferred basis for demonstrating equivalence

PASC noted that the proposed cost-minimisation evaluation, comparing CTC to colonoscopy, was based on a non-inferiority claim, with the use of CTC considered an add-on service to the management pathway that currently applies to colonoscopy. Nevertheless, PASC raised concerns that a cost minimisation approach may not be appropriate if the onward management pathways for colonoscopy and CTC differ, and if colonoscopy may be clinically superior given the simultaneous therapeutic ability A CUA should be considered depending on the final subpopulations included in the PICO. PASC noted that the schedule fee for the current CTC MBS item is higher than that of colonoscopy, however the applicant stated that colonoscopy services will include additional MBS costs from associated polypectomy and anaesthesia.

PASC noted there was no clinical consensus for risk stratification between low and high risk categories for CRC and considered that further definition of the target population was needed for an economic evaluation.

PICO set 1 – diagnostic use

The applicant has claimed that CTC for diagnostic use is non-inferior to colonoscopy for detection of lesions suggestive of CRC or significant polyps in terms of both efficacy and safety. This is supported by preliminary literature searches and clinical guidelines for patients with lower disease risk factors for CRC, although direct to health outcomes evidence was not available. Key efficacy outcomes for the linked evidence would be detection rate and cancer incidence during follow-up. For the safety outcome bowel perforation rate, CTC may be superior, but this has not been reflected in the overall claim. Conversely, radiation safety was considered – in principle – inferior for CTC compared to colonoscopy but there was no direct evidence found to inform an assessment of this outcome as actual events are likely to be extremely low frequency and only observed over the long term. A cost-minimisation approach would be appropriate

for the assessment (per procedure) based on a linked evidence approach. Some further outcomes may be of interest, particularly colonoscopies avoided.

PICO set 2 – surveillance

The applicant has claimed that CTC in patients requiring surveillance is non-inferior for detection of lesions suggestive of CRC in terms of both efficacy and safety, compared to colonoscopy. This was not supported by preliminary literature searches and clinical guidelines (as discussed in Comments on the clinical evidence). Clinical evidence for use in this population was very limited and unlikely to be comparative. Should this PICO set be supported for an assessment, a cost-minimisation approach would be appropriate.

Proposal for public funding

The item descriptor and fee proposed by the applicant have been adapted for the revised two PICO sets below.

The applicant has indicated that the bulk billing incentive should be included (as for colonoscopy and the existing CTC item). In recommending the current item, MSAC noted that use should be limited to one CTC scan per patient every three years. It was assumed this would remain unchanged for any new and/or amended items.

PICO set 1 – Diagnostic use

An item for PICO set 1 is presented below as an amendment of the existing item for PASC's consideration.

Category 5 - DIAGNOSTIC IMAGING SERVICES
MBS item 56553 Computed tomography—scan of colon for exclusion or diagnosis of colorectal neoplasia in a symptomatic or high risk patient, if: (a) one or more of the following applies: (i) the patient has had an incomplete colonoscopy ~~in the 3 months before the scan~~, as confirmed by the treating endoscopist, and requires further colonic investigation (ii) there is a high grade colonic obstruction or other contraindication to colonoscopy (iii) the patient has low risk symptoms suggestive of colorectal cancer (iv) for a patient in whom diagnostic imaging has shown an abnormality of the colon (v) for a patient who has received a positive faecal occult blood test (vi) the service is requested by a specialist or consultant physician who performs colonoscopies in the practice of the specialist's or consultant physician's speciality; and (b) the service is not a service to which item 56301, 56307, 56401, 56407, 56409, 56412, 56501, 56507, 56801, 56807 or 57001 applies (R) Bulk bill incentive (Anaes.) (See para IN.0.19 and IN.0.15 of explanatory notes to this Category)
Fee: $583.05 Benefit: 75% = $437.30 85% = $495.60

MBS = Medicare Benefits Schedule
Note: Amended text is indicated either in strikethrough or blue type.

Proposed wording to capture CTC use in the subpopulation with low risk disease symptoms has been included in criterion (iii) in the draft descriptor. A more detailed definition is proposed in the amended explanatory note below. Revised text as it could apply to explanatory note IN.0.15 is suggested below.

Category 5 - DIAGNOSTIC IMAGING SERVICES
IN.0.15 Group I2 - Computed Tomography (CT) (suggested amendment for inclusion) **Computed tomography of the upper abdomen and pelvis** Items 56501 and 56507 are not eligible for benefits if performed for the purpose of performing a virtual colonoscopy (otherwise known as CT colonography and CT colonography). Item 56553 is to be used for a CT colonography. ***Computed tomography of the colon*** Item 56553 is for a scan of the colon for the exclusion or diagnosis of colorectal neoplasia in a symptomatic or high risk patient, who meets defined criteria as listed in the item description. The following list of contraindications for colonoscopy, and 'low risk' definition for colorectal cancer, relate to Item 56553. ***Contraindications for Colonoscopy*** Patients fit into this category if they have any of the following: – Active colitis; – Large abdominal aortic aneurysms; – Recent myocardial infarction or pulmonary embolism; – Coagulopathies, including therapeutic anticoagulation; – Patients unable to tolerate adequate bowel preparation for colonoscopy; – Frail patients of advanced age; – Abdominal large bowel hernias; and – Splenomegaly. ***Definition of 'low risk' for Item 56553*** Patients with symptoms suggestive of colorectal cancer are considered low risk if they do not have symptoms warranting urgent referral such as rectal bleeding, anaemia or unexplained weight loss.

Note: Amended text is indicated in blue type.

Contraindications for colonoscopy could be captured outside the descriptor text in an amendment to the existing MBS explanatory note IN.0.15 for this item (per proposal above), as originally recommended in the PSD for MSAC application 1269.

It has been proposed that this item can be co-claimed with anaesthesia. Although patients undergoing CTC would usually not require anaesthesia, some patients may require sedation and the anaesthetic MBS items can be claimed in conjunction with the service.

PASC advised that the proposed item descriptors would need amendment as follows for PICO set 1:

- *The list of contraindications to colonoscopy should be updated to reflect current clinical practice.*
- *A clear definition of criteria for low risk (and high risk) patients would be necessary once clinical consensus could be reached.*

PASC considered the three-month restriction (maximum time limit between incomplete colonoscopy and CTC) for referrals other than by a specialist or consultant physician was reasonable on the basis that patients with an incomplete colonoscopy were typically scanned on the same day. However, PASC considered it reasonable that some patients with a history of incomplete colonoscopy may be likely to have future incomplete colonoscopy. PASC noted that the three-month restriction should be further considered by PASC following re-development of the PICO.

PASC noted that the current MBS item 56553 includes high grade colonic obstruction as one of the eligibility criteria for CTC however, PASC considered CTC may also be contraindicated for patients with a high grade

colonic obstruction due to the bowel preparation required for CTC. PASC noted that following the assessment, the current MBS item descriptor wording may require further review to reflect clinical practice recommendations from this assessment. MSAC may wish to consider whether high grade colonic obstruction should be removed as an indication for CTC from the current CTC items.

PICO set 2 – Surveillance

An item descriptor for PICO set 2 is presented below using a modification of the item 56553 wording and the wording for the applicant's proposed PICO set 3. The applicant proposed the wording to read "previous adenomatous or cancer" but "cancer" is proposed by the evaluation group to be deleted as patients with a diagnosis of CRC have defined monitoring which currently does not include CTC.

PASC advised that the proposed item descriptors would need amendment as follows for PICO set 2:

- *to remove 'cancer' from the item for the proposed surveillance population.*

As per PASC's advice, PICO set 2 will not progress to the assessment phase due to limited evidence supporting the inclusion of this population.

Category 5 - DIAGNOSTIC IMAGING SERVICES
MBS item *XXXX Computed tomography—surveillance scan of colon for exclusion or diagnosis of colorectal neoplasia, in a patient (a) for whom a repeat colonic evaluation is required due to previous adenomatous colonic polyps~~ or cancer~~; and (b) the service is not a service to which item 56301, 56307, 56401, 56407, 56409, 56412, 56501, 56507, 56801, 56807 or 57001 applies (R) Bulk bill incentive <Explanatory notes as per current item or to be determined as part of implementation>
Fee: $583.05 Benefit: 75% = $437.30 85% = $495.60

MBS = Medicare Benefits Schedule
Note: Amended text is indicated either in strikethrough or blue type.

Proposed fee and out of pocket costs

The proposed fee for both PICO sets was the same as the 1 November 2023 Schedule fee for the existing CTC item 56553. It was assumed that the applicant intended for any new item to have the same fee as the current item. The assessment should use the fee applicable for item 56553 that is current at that time.

The applicant identified the following components as contributing to CTC costs:

- Equipment costs
- Staffing cost (radiographers)
- Reporting costs (radiologists)

- Administrative costs
- Consumables (foley catheter, carbon dioxide, faecal tagging [iodine-containing oral solution such as Gastrografin], buscopan [anticholinergic muscle relaxant])

No numerical values were supplied for these costs, as the proposed fee was based on the fee for the existing CTC item. Further details should be provided for the assessment.

The applicant claims that the proposed fee will cover the costs of the intervention, and the patient should have no out of pocket costs.

In the 2023-2024 financial year, the majority of services for Item 56553 were performed out of hospital (89.1%), and of these services, most were bulk-billed (82.4% bulk-billed), with a smaller number of patients receiving an out-of-pocket amount for the scan.

A smaller number of services for Item 56553 were performed in hospital, however almost all of these services (95.5%) involved an out-of-pocket amount to the patient.

For in and out of hospital services, the average out-of-pocket fee for Item 56553 (after the MBS benefit has been reimbursed) was $163.25 in the 2023-2024 financial year.

Summary of public consultation input

PASC noted and welcomed consultation input from 7 organisations. The 7 organisations that submitted input were:

- Lumus Imaging
- Colorectal Surgical Society of Australia and New Zealand (CSSANZ)
- Australian Diagnostic Imaging Association (ADIA)
- Abdominal Radiology Group of Australia and New Zealand (ARGANZ) a special interest group (SIG) within the Royal Australian and NZ College of Radiologists (RANZCR)
- Gastroenterological Society of Australia (GESA)
- Royal Australian and NZ College of Radiologists (RANZCR)
- Royal Australian College of General Practitioners (RACGP)

The consultation input received was partly supportive of public funding for CTC for the detection of colorectal polyps and colorectal cancer. The consultation input raised a number of concerns, predominately in relation to the proposed populations and number of patients who would require a subsequent colonoscopy following CTC.

Consumer Input

The consultation input included anecdotal experiences from health professionals, stating that extended wait times for colonoscopy caused anxiety for patients and their family, particularly when a patient is waiting to find out if they have cancer.

Benefits and Disadvantages

The main benefits of public funding received in the consultation input included decreased wait times for colonoscopy including, improved access to colon examination for regional and public patients, the

potential to prevent disease progression from benign to malignant, locally advanced or metastatic disease and to diagnose cancer faster. ARGANZ stated that the wait time for public patients to access colonoscopy in Australia is greater than 100 days in all states and territories[7], and that increasing access to CTC would reduce wait times improve access to colon examination for patients unable to afford private colonoscopies. The benefit of expanding the criteria for GPs to request CTC in addition to gastroenterologists included faster access to colon examination for patients leading to faster diagnosis of polyps and cancer and allowing expedition of necessary treatments. RACGP stated that GPs have detailed knowledge of their patients' comorbidities, contraindications to colonoscopy and other factors (e.g. need for travel, carer responsibilities) that may make colonoscopy a less favourable option and CTC more preferable.

Input supporting the application stated CTC was more cost effective for both the healthcare system and patients, less invasive, had a lower risk profile, is clinically non-inferior to colonoscopy and does not require sedation which can pose a logistical challenge for regional and remote patients. Input stated that increased access to CTC would address the current inequity for regional, rural and First Nations populations, as CTC does not require hospital admission that may incur higher out of pocket costs for people required to travel long distances to access hospital.

The main disadvantage of public funding received in the consultation input was that patients with a positive finding on CTC would require colonoscopy for biopsy and removal of polyps to determine diagnosis and potential treatment planning for cancer, with CTC in these cases a waste of resources. RACGP requested further information on CTC including the preparation required and potential harms of radiation exposure. GESA noted that CTC still requires a bowel preparation and colonic gas insufflation.

Population, Comparator (current management) and Delivery

The consultation input mostly agreed with the proposed populations, with all agreeing to the principle of CTC to detect colorectal polyps and colorectal cancer in patients. ADIA proposed expanding the population to include people aged under 45 who do not currently qualify for bowel cancer screening but are being diagnosed at increasing rates. CSSANZ stated CTC is not appropriate for all populations e.g. not suitable to assess inflammatory bowel disease or follow-up for patients with small polyps.

The consultation input mostly agreed with the proposed comparator of colonoscopy.

ARGANZ stated that the technology for providing CTC is already widely in place and that the additional software and insufflation device is cheap to obtain.

MBS Item Descriptor and Fee

The consultation input mostly agreed with the proposed service descriptor. RACGP proposed including 'where colon cancer or colonic polyps are suspected' to avoid use in young or menstruating people as other causes of iron deficiency and anaemia should be considered first. GESA support the current referral

[7] Statement based on data from the Bowel Cancer Australia website (https://www.bowelcanceraustralia.org/colonoscopy/colonoscopy-wait-times/) and the wait time quoted is representative of the 90th percentile (i.e. 90% of people waited less than or equal to that time, while 10% waited longer) in each state and territory in 2022. The wait time represents the time from colonoscopy following a positive FOBT screen, undertaken as part of the National Bowel Cancer Screening Program.

for CTC being limited to specialists, stating that majority of CTCs are ordered by specialists who a perform colonoscopy and the patient had a failed procedure.

The consultation input agreed with the proposed service fee, with ADIA stating the fee could be increased as the current CTC MBS item attracts an average gap of $185 and is a barrier for many patients.

Additional Comments

CSSANZ noted that if the aim is to address challenges in accessing colonoscopy, the most effective and safest solution would be to increase colonoscopy availability rather than expanding access to CTC. GESA noted that there are clear dedicated pathways for referral for endoscopic services with cases triaged based on urgency.

AGANZ stated that the New Zealand referral pathway for bowel investigation includes CTC with up to 30% of colonic investigations being CTC in some areas.

GESA, CSSANZ and RACGP responded to targeted questions including whether a positive result on CTC would require colonoscopy prior to surgery for suspected cancer. All organisations stated that a biopsy or polyp removal, usually via colonoscopy, is best practice to provide histological information for a diagnosis and treatment planning in cases where polyps were detected and particularly if cancer was suspected.

PASC raised concerns about the lack of support from peak body GESA and cautious support from RACGP and CSSANZ for CTC. PASC considered feedback from the Cancer Council to understand their view on CTC in CRC screening and management would be useful for further development of the PICO.

Additionally, PASC noted that clinical advice should be sought from relevant clinical groups to determine consensus around the appropriate target population. PASC considered this to be important to ensure there would be no inadvertent inclusion of groups at high-risk of CRC if the population was restricted to low-risk patients.

Next steps

PASC considered the PICO Confirmation required significant re-development to be feasible for assessment and considered that once the PICO has been further developed, it will require consideration at a future PASC meeting. The PASC considered that the re-development of the PICO set 1 would need clinically supported definitions of low and high risk symptomatic populations in order to be appropriate for assessment. PASC considered that the low and high risk symptomatic populations would likely require differing clinical algorithms, which will need to be revised.

PASC considered that further work and input from relevant stakeholders would be needed to assist defining the target groups who are suitable for a CT colonography instead of colonoscopy, and provide input into defining the low and high risk symptomatic populations given the inconsistency in the literature.

PASC also advised not to proceed with the assessment of PICO Set 2 population due to the lack of evidence (based on preliminary research by the assessment group) and clinical support rendering it not feasible for assessment.

Applicant Comments on Ratified PICO

The department acknowledges that the applicant noted PASC currently does not have a member with a specialty in radiology.

The department notes that the applicant is disappointed that PICO set 2 for the population requiring surveillance had insufficient evidence during the preliminary literature search to proceed to assessment at this point in time. The department has summarised and listed below, the applicant comments on the PICO elements of the application.

- When assessing cost effectiveness of CTC vs colonoscopy, all codes used for colonoscopy including additional codes for polypectomy, anaesthetic codes, pathology codes and specialist consultation should be included.
- Polyp size is important and should be included in the efficacy/effectiveness outcomes, and categorised as >10mm, 6-9mm or <6mm. The safety outcomes should include visceral injury, and sedation complications for colonoscopies.
- Given the current lack of definitions for low and high risk symptomatic populations, there may be difficulty obtaining clinically supported definitions for these populations, even with further input from stakeholders.

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Appendix 1

Patients with positive FOBT

The number of NBCSP participants with a positive FOBT has varied from year to year (due to changes in the number of eligible invitees – which has changed again in 2024) (Table 16). The rate of positive FOBT individuals as a proportion of those invited has been fairly steady, declining slightly as the NBCSP has been expanded.

Table 16 NBCSP participants with a positive FOBT

Year[a]	Participants with positive FOBT	Positivity rate	Estimated number requiring biopsy or polypectomy[b]
2022	64,932	6%	10194 – 17012
2021	76,880	6%	12070 – 20143
2020	85,693	7%	13454 – 22452
2019	89,817	7%	14101 – 23532
2018	78,600	7%	12340 – 20593
2017	69,000	8%	10833 – 18078
2016	69,000	8%	10833 – 18078

FOBT = faecal occult blood test
[a] participant numbers are variable in part due to addition of age groups to the NBCSP as follows: 72 and 64 year olds were added in 2016; 68, 58 and 54 year olds were added in 2017; 66 and 62 year olds added in 2018; and 56 and 52 year olds added in 2019[8].
[b] a range between 15.7 – 26.2% of patients with a positive FOBT requiring a biopsy or polypectomy.
Source: AIHW National Bowel Cancer Screening Program: monitoring reports 2016 – 2022

An approximation of the proportion of patients who would require a colonoscopy following CTC was calculated. It was assumed that any patient in the NBCSP data with histopathology outcomes could be a proxy for this group. Outcomes are published for NBCSP participants with a positive FOBT who have undergone a colonoscopy (AIHW 2024). It was estimated that the proportion of positive participants with a positive FOBT who went on to require tissue sampling and pathology was at least 16% and may be as high as 26% (derivation explained below).

Proportion of positive FOBT patients requiring biopsy or polypectomy

Outcomes were available for less than a third of NBCSP participants recorded as having undergone a colonoscopy following a positive FOBT – this may disproportionately exclude those who returned normal findings in their colonoscopy and required no further investigation. Nevertheless, the data from participants with histology or confirmed diagnosis were considered an approximation of the participants who required a biopsy or polypectomy on colonoscopy. This proxy was used to derive a further estimate of how many of the total participants receiving a colonoscopy (with or without outcomes) required a biopsy/polypectomy – which was 15.7% (figure in bold, Table 17). It was noted that some of the participants who recorded an outcome of "no issue noted" may have had histopathology (note a, Table 17), thus the proportion of colonoscopy cases who required a biopsy or polypectomy could be as high as 26.2%.

[8] www.cancer.org.au/about-us/policy-and-advocacy/early-detection/bowel-cancer/policy-context

Table 17 Colonoscopy assessment outcomes – NBCSP (2022 data)

	Outcome	Number of participants	Percentage (outcomes reported)	*Percentage (with / without outcomes reported)*
A	Assessments without outcome data: reported by Medicare claim reported via NBCSP follow-up (PFUF)	40,591 23,929 16,662	--	*73.8* *43.5* *30.3*
B	Assessments with outcome data	14,390	(100)	*26.2*
C	No issue noted[a]	5,732	39.8	*10.4*
D	Biopsy awaiting histopathology[b]	5,696	39.6	*10.4*
E	Other histopathology diagnosis[c]	307	2.1	*0.6*
F	Confirmed non-advanced adenoma[c]	982	6.8	*1.8*
G	Confirmed advanced adenoma[d]	1,092	7.6	*2.0*
H	Suspected cancer[e]	497	3.5	*0.9*
I	Confirmed cancer[f]	84	0.6	*0.2*
J	*Estimated total colonoscopies (A+B)*	*54,981*	--	*(100)*
K	*Total participants with histopathology or confirmed diagnosis (D+E+F+G+H+I) (as a proxy for biopsy recipients)*	*8,658*	*60.2*	***15.7***

Explanatory notes are reproduced below (a – f). Text in italics represent figures derived by the evaluation group.
NBCSP = National Bowel Cancer Screening Program; NCSR = National Cancer Screening Register (NBCSP and cervical screening); PFUF = Participant Follow Up Function (NBCSP).
[a] 'No issue noted' recorded when no cancers, adenomas, polyps or other diagnoses were noted at colonoscopy and/or histopathology.
[b] Polyps detected at assessment and sent to histopathology for analysis. No histopathology report form received by Register.
[c] A non-cancer, non-adenoma diagnosis was recorded at colonoscopy; for example, hyperplastic polyps.
[d] Confirmed adenoma figures were based on a combination of the assessment and histopathology report forms for a person received by the NCSR.
[e] Cancer suspected at assessment but not yet confirmed by histopathology.
[f] Cancer confirmed by histopathology.
Source: AIHW 2024 Appendix (Table A4.1: Available assessment outcomes of people aged 50–74, by age and sex, Australia, assessed in 2022).

Appendix 2

Clinical evidence presented by the applicant

The studies cited by the applicant as evidence are summarised in Table 18 (comparative evidence) and in Table 19 (other, non-comparative evidence).

Table 18 Comparative clinical evidence presented by the applicant

Ref ID	Citation	Study characteristics	PICO sets
Pickhardt 2003	Computed tomographic virtual colonoscopy to screen for colorectal neoplasia in asymptomatic adults. Pickhardt PJ, Choi JR, Hwang I, Butler JA, Puckett ML, Hildebrandt HA, Wong RK, Nugent PA, Mysliwiec PA, Schindler WR. N Engl J Med. 2003 Dec 4;349(23):2191-200.	Prospective observational cohort (N=1233), received both OC and CTC in sequence (same day) Asymptomatic adults, mean age, 57.8 y (no range or SD reported). Any CRC symptoms or risk factors were exclusion criteria. Non-randomised, consecutive patients Open label, concealed outcomes Outcomes reported: polyps by number, size, site and histology. Also reported: inadequate preparation, incomplete OC, complications.	1,2,3,4,5,6
Kim 2007	CT colonography versus colonoscopy for the detection of advanced neoplasia. Kim DH, Pickhardt PJ, Taylor AJ, Leung WK, Winter TC, Hinshaw JL, Gopal DV, Reichelderfer M, Hsu RH, Pfau PR. N Engl J Med. 2007 Oct 4;357(14):1403-12.	Two retrospective observational cohorts of consecutive patients that received either CTC (N=3120) or OC (N=3163) Screening population of adults (CTC age: 57.0±7.2 y; OC age: 58.1±7.8 y). Exclusion criteria included a history of CRC or other risk factors. Outcomes: polyps by size, number, histology; total harvested polyps; detection of advanced neoplasia (advanced adenomas; carcinomas). Also reported: extracolonic findings detected on CTC; SAEs including perforation; referral rate for subsequent (in CTC group)	1,2,3,4,5,6
Rua 2020	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. Rua T, Watson H, Malhotra B, Turville J, Razavi R, Peacock JL, McCrone P, Goh V, Shearer J, Griffin N. Clin Radiol. 2020 Sep;75(9):712.e23-712.e31.	Prospective observational cost comparison of CTC vs OC (N=180) Non-randomised, single-centre Patients aged >40 y with low-to-intermediate risk of CRC (presenting with constipation or change in bowel habit with differential diagnosis of CRC) but not if high risk symptoms were present (anaemia, diarrhoea >6 weeks, rectal bleeding, colon exam in past 6 months, known history of CRC) Outcomes only as relating to costing comparison: resource use (0-3 mo); PROs including EQ-5D-5L. Also: incidence of cancers diagnosed within 12 mo follow-up; extra-colonic findings (CTC group only); incomplete or suboptimal bowel visualisation. No other diagnostic performance outcomes.	1,2,3,4,5,6

CRC = colorectal cancer; CTC = computed tomography colonography; EQ-5D-5L = 5-level version of the EuroQol 5-domain instrument; OC = optical colonoscopy; PRO = patient reported outcome; Ref ID = reference identification; SAE = serious adverse event; SD = standard deviation.
Source: compiled for this evaluation.

Table 19 Other (non-comparative) evidence presented by the applicant

Ref ID	Citation	Study characteristics	PICO sets
Paterson 2010	Wait times for gastroenterology consultation in Canada: the patients' perspective. Paterson WG, Barkun AN, Hopman WM, Leddin DJ, Paré P, Petrunia DM, Sewitch MJ, Switzer C, van Zanten SV. Can J Gastroenterol. 2010 Jan;24(1):28-32.	Questionnaire of gastroenterology outpatients (N=916) PROs including wait times, QoL Non-comparative, no diagnostic or disease outcomes.	1,2,3,4,5,6
Pickhardt 2017	Colorectal Findings at Repeat CT Colonography Screening after Initial CT Colonography Screening Negative for Polyps Larger than 5 mm. Pickhardt PJ, Pooler BD, Mbah I, Weiss JM, Kim DH. Radiology. 2017 Jan;282(1):139-148.	Retrospective observational cohort (N=1429), patients received repeat CTC screen (time since initial CTC screen: 5.7±0.9 y [range 4.5–10.7 y]) Asymptomatic adult screening population with prior CTC having shown no findings, mean age 61.4 y (no range or SD reported). Positive rates and histologic findings of initial versus repeat screening were reported. Single arm, non-comparative.	1,2,3,4,5,6
Delisle 2020	The Association Between Wait Times for Colorectal Cancer Treatment and Health Care Costs: A Population-Based Analysis. Delisle M, Helewa RM, Ward MAR, Hochman DJ, Park J, McKay A. Dis Colon Rectum. 2020 Feb;63(2):160-171.	Retrospective cohort registry study (N=6936) – Manitoba Cancer Registry. Nonrandomised. All diagnostic interventions grouped together – not possible to distinguish outcomes for CTC vs OC. Outcomes: total wait time from first GI intervention to diagnosis; total inpatient and outpatient health care costs. Overall mortality reported as secondary outcome.	1,2,3,4,5,6
Bowel Cancer Australia (undated)	A Colonoscopy Wait-time and Performance Guarantee: Bowel Cancer Australia advocates for a colonoscopy wait-time and performance guarantee[a]	Summary wait list data from the NBCSP (2014 – 2023). Non-comparative (colonoscopy only).	1,2,3,4,5,6

Source: compiled for this evaluation.

CT = computed tomography; CTC = computed tomography colonography; GI = gastrointestinal; NBCSP = National Bowel Cancer Screening Program; OC = optical colonoscopy; PRO = patient reported outcome; QoL = quality of life; Ref ID = reference identification; SD = standard deviation.

[a] A Colonoscopy Wait-time and Performance Guarantee www.bowelcanceraustralia.org/a-colonoscopy-wait-time-and-performance-guarantee (accessed 16 October 2024)