

MSAC Application 1789

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

Application for MBS eligible service or health technology

ID:

HPP200199

Application title:

CT Colonography

Submitting organisation:

SUTHERLAND, THOMAS ROBERT

Submitting organisation ABN:

80269081682

Application description

Succinct description of the medical condition/s:

Colorectal cancer is a common cancer in Australia and is a frequent cause of cancer death. Australia has invested in a cancer screening program and currently only a single diagnostic test is funded following this. In addition, patients with suspected cancer are referred for this test (colonoscopy). The colonoscopy wait list is long and there are access issues especially in regional/remote areas, first nation peoples and in the socioeconomically disadvantaged community. These leads to health inequality, delayed diagnosis and increased expense as well as poorer health outcomes.

Succinct description of the service or health technology:

CT colonography is an alternative test to colonoscopy that is minimally invasive, safer, readily available and has essentially zero wait list. In multiple excellent international trials, it has been shown to be as accurate as colonoscopy for detecting cancer and precancerous growths. CT colonography has the ability to reduce wait lists, reduce time to diagnosis and will empower patients by giving them a choice of further investigation.

Application contact details

Are you the applicant, or are you a consultant or lobbyist acting on behalf of the applicant?

Applicant

Are you applying on behalf of an organisation, or as an individual?

Individual

Application details

Does the implementation of your service or health technology rely on a new listing on the Pharmaceutical Benefits Scheme (PBS) and/or the Prescribed List?

No

Is the application for a new service or health technology, or an amendment to an existing listed service or health technology?

New

Please select any relevant MBS items.

MBS item number	Selected reason type
32222	Other
56553	Other

What is the type of service or health technology?

Investigative

Please select the type of investigative health technology:

X-rays

PICO Sets

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

PICO Set 1 - Patients with signs or symptoms potentially from colorectal cancer

State the purpose(s) of the health technology for this PICO set and provide a rationale:

Purpose category:

Diagnosis / sub-classification

Purpose description:

To establish a diagnosis or disease (sub)classification in symptomatic or affected patients

Population

Describe the population in which the proposed health technology is intended to be used:

examination of the colon to the caecum by Computed Tomography Colonography, for a patient:

1. who has symptoms consistent with pathology of the colonic mucosa; or
2. with anaemia or iron deficiency;

Search and select the most applicable Medical condition terminology (SNOMED CT):

colorectal cancer

Intervention

Name of the proposed health technology:

CT Colonography

Comparator

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

The comparator is colonoscopy.

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

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

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

There are four potential outcomes following CTC:

1. no polyp or cancer is seen. The patient is reassured and requires no further investigation.
2. a cancer is found and the patient proceeds directly to treatment/surgery.
3. A polyp is found and the patient is referred to colonoscopy for polypectomy
4. A small polyp is found (6-9mm) and the patient is followed with a repeat CTC at 12 months.

Proposed MBS items

Proposed Item AAAAA

MBS item number:

56553

Please search and select the proposed category:

DIAGNOSTIC IMAGING SERVICES

Please search and select the proposed group:

COMPUTED TOMOGRAPHY

Please search and select the proposed item descriptor or draft a proposed item descriptor to define the population and health technology usage characteristics that would define eligibility for funding:

Computed tomography—scan of colon for exclusion or diagnosis of colorectal neoplasia in a symptomatic or high risk patient; 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) (Anaes.)

Proposed MBS fee:

\$563.35

Indicate the overall cost per patient of providing the proposed health technology:

\$563.35

Please specify any anticipated out of pocket costs:

\$0.00

Provide details and explain:

There are enough radiology practices that bulk billing should occur.

How is the technology/service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):

Currently the test is substantially under used. Use is virtually exclusively within the public health system i.e. state funded or with patients paying for the entire test leading to further health inequality.

Claims

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

Non-inferior

Please state what the overall claim is, and provide a rationale:

CTC has been proven to be non-inferior to colonoscopy in multiple well conducted randomised trials (see evidence section). In addition, the break-through cancer rate is exceedingly low and is non-inferior to colonoscopy.

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

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

Estimated utilisation

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

around 1,000,000 colonoscopies are performed each year in Australia. This number will increase with the aging population and with the impact of CRC screening via FOB. Screening results in new patients requiring a diagnostic test as well as an ever growing pool of patients with a diagnosis of a poly who require follow up and surveillance.

The rates of CRC are also increasing in young patients and this cohort will require surveillance over an extended period.

Colonoscopy wait lists are already beyond capacity with extensive data around this in the Australian setting.

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake(%):

5

Year 2 estimated uptake(%):

10

Year 3 estimated uptake(%):

15

Year 3 estimated uptake(%):

20-30

Estimate the number of patients who will utilise the proposed technology for the first full year:

50,000

Optionally, provide details:

Each year in Australia around 1,000,000 colonoscopies are performed. These are performed for multiple indications and the precise number for each indication is difficult to ascertain. In many developed nations that have embraced CTC, around a third of all colonic examinations are performed with CTC. This has led to the 4 year uptake estimate of 20-30% of studies.

Will the technology be needed more than once per patient?

No, once only

PICO Set 2 - Patients with positive FOB

State the purpose(s) of the health technology for this PICO set and provide a rationale:

Purpose category:

Diagnosis / sub-classification

Purpose description:

To establish a diagnosis or disease (sub)classification in symptomatic or affected patients

Population

Describe the population in which the proposed health technology is intended to be used:

The federal government has introduced faecal occult blood testing in recognition of the increasing rates of colorectal carcinoma in Australia and the utility of FOB as a screening test. However, as a screening test, it does have significant false positives, and so patients who return a positive test are recommended to undergo a diagnostic test to confirm or clear them of CRC.

It is known that significant delays occur with performing the diagnostic test (currently only colonoscopy is approved) and that these delays are more likely to occur in rural/regional settings and amongst first nation peoples and those in lower socioeconomic regions.

CTC would help to reduce the delays and would help increase compliance with diagnostic test uptake by empowering patients with a choice of diagnostic test.

Search and select the most applicable Medical condition terminology (SNOMED CT):
colorectal cancer

Intervention

Name of the proposed health technology:
CT Colonography

Comparator

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

The comparator is colonoscopy.

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

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

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

There are four potential outcomes following CTC:

1. no polyp or cancer is seen. The patient is reassured and requires no further investigation.

2. a cancer is found and the patient proceeds directly to treatment/surgery.
3. A polyp is found and the patient is referred to colonoscopy for polypectomy
4. A small polyp is found (6-9mm) and the patient is followed with a repeat CTC at 12 months.

Proposed MBS items

Proposed Item AAAAA

MBS item number:

56553

Please search and select the proposed category:

DIAGNOSTIC IMAGING SERVICES

Please search and select the proposed group:

COMPUTED TOMOGRAPHY

Please search and select the proposed item descriptor or draft a proposed item descriptor to define the population and health technology usage characteristics that would define eligibility for funding:

Computed tomography—scan of colon for exclusion or diagnosis of colorectal neoplasia in a patient following a positive FOB screening test; 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) (Anaes.)

Proposed MBS fee:

\$563.35

Indicate the overall cost per patient of providing the proposed health technology:

\$563.35

Please specify any anticipated out of pocket costs:

\$0.00

Provide details and explain:

CTC is readily available and there are multiple bulk billing radiology practices and health care services.

How is the technology/service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):

CTC currently has an exceedingly narrow MBS rebateable indication and is significantly underutilised compared with other first world nations. The few CTC's that occur are largely in public hospitals i.e. state based funding, or the patient pays or the complete study at significant expense. This contributes to ongoing health inequality and further disadvantages our marginalised and vulnerable community members.

Claims

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

Non-inferior

Please state what the overall claim is, and provide a rationale:

CTC has been proven to be non-inferior to colonoscopy in multiple well conducted randomised trials (see evidence section). In addition, the break-through cancer rate is exceedingly low and is non-inferior to colonoscopy.

Estimated utilisation

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

around 1,000,000 colonoscopies are performed each year in Australia. This number will increase with the aging population and with the impact of CRC screening via FOB. Screening results in new patients requiring a diagnostic test as well as an ever growing pool of patients with a diagnosis of a polyp who require follow up and surveillance.

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake(%):

5

Year 2 estimated uptake(%):

10

Year 3 estimated uptake(%):

15

Year 3 estimated uptake(%):

20-30

Estimate the number of patients who will utilise the proposed technology for the first full year:

50,000

Optionally, provide details:

Each year in Australia around 1,000,000 colonoscopies are performed. These are performed for multiple indications and the precise number for each indication is difficult to ascertain. In many developed nations that have embraced CTC, around a third of all colonic examinations are performed with CTC. This has led to the 4 year uptake estimate of 20-30% of studies.

Will the technology be needed more than once per patient?

No, once only

PICO Set 3 - Patients who have previously had an incomplete colonoscopy or are on anticoagulation

State the purpose(s) of the health technology for this PICO set and provide a rationale:

Purpose category:

Diagnosis / sub-classification

Purpose description:

To establish a diagnosis or disease (sub)classification in symptomatic or affected patients

Population

Describe the population in which the proposed health technology is intended to be used:

Incomplete colonoscopy is common. The GESA conjoint committee mandates that 95% of colonoscopies are complete which is defined as visualisation of the caecum and ileocaecal valve. Colonoscopy complete rates vary and The U.S. Multi-Society Task Force on Colorectal Cancer sets a target of cecal intubation in at least 90% of colonoscopies. Multiple risk factors are associated with incomplete colonoscopy including increasing age, female gender, private vs public practice, previous abdominal or pelvic surgery (especially hysterectomy) and it is also prudent to note that 50% of patients with an incomplete colonoscopy will have another incomplete colonoscopy at next attempt.

These patients should have the option of future surveillance being performed with CTC instead of colonoscopy.

Search and select the most applicable Medical condition terminology (SNOMED CT):

Colorectal cancer

Intervention

Name of the proposed health technology:

CT Colonography

Comparator

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

The comparator is colonoscopy.

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

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

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

The comparator is colonoscopy.

Colonoscopy is an excellent test for assessing the colonic mucosa and CT colonography has been shown to be non-inferior. Current issues with colonoscopy include extended wait lists

with virtually every state and territory having substantial waiting lists of over 100 days. These delays are more pronounced in regional/rural settings, indigenous populations and in lower socioeconomic regions.

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

CT colonography has significantly higher completion rates which is not affected by surgery etc.

Proposed MBS items

Proposed Item AAAAA

MBS item number:

56553

Please search and select the proposed category:

DIAGNOSTIC IMAGING SERVICES

Please search and select the proposed group:

COMPUTED TOMOGRAPHY

Please search and select the proposed item descriptor or draft a proposed item descriptor to define the population and health technology usage characteristics that would define eligibility for funding:

Computed tomography—scan of colon for exclusion or diagnosis of colorectal neoplasia in a patient requiring surveillance or investigation of new symptoms for whom:(a) one or more of the following applies:(i) the patient has a history of an incomplete colonoscopy ;(ii) the patient is being treated with anticoagulation; 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) (Anaes.)

Proposed MBS fee:

\$563.35

Indicate the overall cost per patient of providing the proposed health technology:

\$563.35

Please specify any anticipated out of pocket costs:

\$0.00

Provide details and explain:

CTC is readily available and there are multiple bulk billing radiology practices and health care services.

How is the technology/service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):

CTC currently has an exceedingly narrow MBS rebateable indication and is significantly underutilised compared with other first world nations. The few CTC's that occur are largely in public hospitals i.e. state based funding, or the patient pays or the complete study at significant expense. This contributes to ongoing health inequality and further disadvantages our marginalised and vulnerable community members.

Claims

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

Superior

Please state what the overall claim is, and provide a rationale:

CTC has been proven to be non-inferior to colonoscopy in multiple well conducted randomised trials (see evidence section). In addition, the break-through cancer rate is exceedingly low and is non-inferior to colonoscopy.

For this patient population however, CTC is considered a superior test. This is because;

1. a patient with a previous incomplete colonoscopy is a high risk of another incomplete colonoscopy at next attempt.
2. The incomplete colonoscopy rate is significantly greater than the incomplete CTC rate (5-10 percent for colonoscopy vs less than 1 percent for CTC).
3. Colonoscopy is invasive with a perforation rate of around 1 in 500, as well as complications related to bleeding and visceral injury, which while rare does have fatalities recorded. Anticoagulation is routinely ceased prior to colonoscopy and this exposes the patient to thrombotic complications, morbidity, mortality. Anticoagulation does not need to stop for CTC.

Estimated utilisation

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

The rate of incomplete colonoscopy in Australia is proposed to be 5% however international data with similar populations says that it may be 10-15%. Based upon 1 million colonoscopies per year this is 50,000 incomplete studies per years (based upon the Australian standard of 5%) or up to 150,000 studies based on some international figures. These patients will all require completion CTC and of those who require surveillance studies in the future at least 50% will be expected to have another incomplete study. It would be most cost effective if all incomplete colonoscopy patients were offered CTC as a first line investigation for any future colonic test.

Rates of anticoagulation in the population continue to increase especial with Noval Anticoagulation Therapy (NOAC) and these figures can be obtained via PBS data. Anticoagulation increases the rates of false positive FOB and so these patients should all be offered the choice of CTC as a first line investigation.

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake(%):

5

Year 2 estimated uptake(%):

10

Year 3 estimated uptake(%):

15

Year 3 estimated uptake(%):

20-30

Estimate the number of patients who will utilise the proposed technology for the first full year:

50,000

Optionally, provide details:

see above

Will the technology be needed more than once per patient?

Yes, multiple times

Over what duration will the health technology or service be provided for a patient? (preferably a number of years):

3-5 years

Optionally, provide details:

future follow up should be performed with CTC.

Those patients without polyps may not require follow up.

What frequency will the health technology or service be required by the patient over the duration? (range, preferably on an annual basis):

Once every 3- 5 years

Optionally, provide details:

future follow up should be performed with CTC.

Those patients without polyps may not require follow up.

PICO Set 4 - Patients requiring surveillance following prior diagnosis of colorectal polyps or cancer

State the purpose(s) of the health technology for this PICO set and provide a rationale:

Purpose category:

Diagnosis / sub-classification

Purpose description:

To establish a diagnosis or disease (sub)classification in symptomatic or affected patients

Population

Describe the population in which the proposed health technology is intended to be used:

Colorectal cancer rates are increasing in Australia and usually develop from polyps as precursor lesions. Patients who have a previous diagnosis of colorectal polyps or cancer are advised to undergo regular surveillance colonoscopy. Colonoscopy is recommended as it is currently the only investigation with a rebate for this indication. The purpose is to detect polyps in these patients when they can be treated, before they become invasive cancer. Follow up intervals are either 3 years or 5 years depending upon the patients individual risk factors.

Search and select the most applicable Medical condition terminology (SNOMED CT):

colorectal cancer

Intervention

Name of the proposed health technology:

CT Colonography

Comparator

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

The comparator is colonoscopy.

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

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

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

There are four potential outcomes following CTC:

1. no polyp or cancer is seen. The patient is reassured and requires no further investigation.
2. a cancer is found and the patient proceeds directly to treatment/surgery.
3. A polyp is found and the patient is referred to colonoscopy for polypectomy
4. A small polyp is found (6-9mm) and the patient is followed with a repeat CTC at 12 months.

Proposed MBS items

Proposed Item AAAAA

MBS item number:

56553

Please search and select the proposed category:

DIAGNOSTIC IMAGING SERVICES

Please search and select the proposed group:

COMPUTED TOMOGRAPHY

Please search and select the proposed item descriptor or draft a proposed item descriptor to define the population and health technology usage characteristics that would define eligibility for funding:

Computed tomography—scan of colon for exclusion or diagnosis of colorectal neoplasia in a patient with a previous diagnosis of colonic polyp or cancer who is undergoing surveillance; 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) (Anaes.)

Proposed MBS fee:

\$563.35

Indicate the overall cost per patient of providing the proposed health technology:

\$563.35

Please specify any anticipated out of pocket costs:

\$0.00

Provide details and explain:

CTC is readily available and there are multiple bulk billing radiology practices and health care services.

How is the technology/service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):

CTC currently has an exceedingly narrow MBS rebateable indication and is significantly underutilised compared with other first world nations. The few CTC's that occur are largely in public hospitals i.e. state based funding, or the patient pays or the complete study at significant expense. This contributes to ongoing health inequality and further disadvantages our marginalised and vulnerable community members.

Claims

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

Non-inferior

Please state what the overall claim is, and provide a rationale:

CTC has been proven to be non-inferior to colonoscopy in multiple well conducted randomised trials (see evidence section). In addition, the break-through cancer rate is exceedingly low and is non-inferior to colonoscopy.

CTC also has a better safety profile.

Estimated utilisation

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

around 1,000,000 colonoscopies are performed each year in Australia. This number will increase with the aging population and with the impact of CRC screening via FOB. Screening results in new patients requiring a diagnostic test as well as an ever growing pool of patients with a diagnosis of a polyp who require follow up and surveillance.

The rates of CRC are also increasing in young patients and this cohort will require surveillance over an extended period.

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake(%):

5

Year 2 estimated uptake(%):

10

Year 3 estimated uptake(%):

15

Year 3 estimated uptake(%):

20-30

Estimate the number of patients who will utilise the proposed technology for the first full year:

50,000

Optionally, provide details:

Each year in Australia around 1,000,000 colonoscopies are performed. These are performed for multiple indications and the precise number for each indication is difficult to ascertain. In many developed nations that have embraced CTC, around a third of all colonic examinations are performed with CTC. This has led to the 4 year uptake estimate of 20-30% of studies.

Will the technology be needed more than once per patient?

Yes, multiple times

Over what duration will the health technology or service be provided for a patient? (preferably a number of years):

3-5 years

Optionally, provide details:

Ongoing surveillance is needed at 3-5 year intervals based upon risk factors. The follow up interval is the same as the follow up interval after colonoscopy.

What frequency will the health technology or service be required by the patient over the duration? (range, preferably on an annual basis):

Once every 3- 5 years

Optionally, provide details:

same follow up interval and frequency as colonoscopy.

PICO Set 5 - Patients for whom diagnostic imaging has shown an abnormality of the colon

State the purpose(s) of the health technology for this PICO set and provide a rationale:

Purpose category:

Diagnosis / sub-classification

Purpose description:

To establish a diagnosis or disease (sub)classification in symptomatic or affected patients

Population

Describe the population in which the proposed health technology is intended to be used:

Patients who have undergone imaging of the abdomen will occasionally have incidental findings discovered. These can be in the large bowel, when colorectal carcinoma becomes a diagnostic possibility. These patients are usually referred for colonoscopy to determine if cancer is present. We propose that CTC can be used as an alternate pathway.

Search and select the most applicable Medical condition terminology (SNOMED CT):
colorectal cancer

Intervention

Name of the proposed health technology:

CT Colonography

Comparator

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

The comparator is colonoscopy.

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

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

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

There are four potential outcomes following CTC:

1. no polyp or cancer is seen. The patient is reassured and requires no further investigation.
2. a cancer is found and the patient proceeds directly to treatment/surgery.
3. A polyp is found and the patient is referred to colonoscopy for polypectomy
4. A small polyp is found (6-9mm) and the patient is followed with a repeat CTC at 12 months.

Proposed MBS items

Proposed Item AAAAA

MBS item number:

56553

Please search and select the proposed category:

DIAGNOSTIC IMAGING SERVICES

Please search and select the proposed group:

COMPUTED TOMOGRAPHY

Please search and select the proposed item descriptor or draft a proposed item descriptor to define the population and health technology usage characteristics that would define eligibility for funding:

Computed tomography—scan of colon for exclusion or diagnosis of colorectal neoplasia in patient with a colonic abnormality incidentally detected on imaging; 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) (Anaes.)

Proposed MBS fee:

\$563.35

Indicate the overall cost per patient of providing the proposed health technology:

\$563.35

Please specify any anticipated out of pocket costs:

\$0.00

Provide details and explain:

CTC is readily available and there are multiple bulk billing radiology practices and health care services.

How is the technology/service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):

CTC currently has an exceedingly narrow MBS rebateable indication and is significantly underutilised compared with other first world nations. The few CTC's that occur are largely in public hospitals i.e. state based funding, or the patient pays or the complete study at significant expense. This contributes to ongoing health inequality and further disadvantages our marginalised and vulnerable community members.

Claims

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

Non-inferior

Please state what the overall claim is, and provide a rationale:

CTC has been proven to be non-inferior to colonoscopy in multiple well conducted randomised trials (see evidence section). In addition, the break-through cancer rate is exceedingly low and is non-inferior to colonoscopy.

Estimated utilisation

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

This is a small patient population as colonic incidental findings are relatively uncommon (other than diverticular disease). A diagnosis can usually be made on the initial imaging. In indeterminate cases, further investigation is necessary, but I would suspect that it would be in the order of 1000 patients a year.

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake(%):

1

Year 2 estimated uptake(%):

1

Year 3 estimated uptake(%):

1

Year 3 estimated uptake(%):

1

Estimate the number of patients who will utilise the proposed technology for the first full year:

1000

Optionally, provide details:

relatively uncommon indication and therefore the patient population is only very small.

Will the technology be needed more than once per patient?

No, once only

PICO Set 6 - 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.

State the purpose(s) of the health technology for this PICO set and provide a rationale:

Purpose category:

Diagnosis / sub-classification

Purpose description:

To establish a diagnosis or disease (sub)classification in symptomatic or affected patients

Population

Describe the population in which the proposed health technology is intended to be used:

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

patients with poor prep have non-diagnostic studies that require repeat examinations for.

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

Search and select the most applicable Medical condition terminology (SNOMED CT):

Colorectal cancer

Intervention

Name of the proposed health technology:

CT Colonography

Comparator

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

The comparator is colonoscopy.

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

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

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

There are four potential outcomes following CTC:

1. no polyp or cancer is seen. The patient is reassured and requires no further investigation.
2. a cancer is found and the patient proceeds directly to treatment/surgery.
3. A polyp is found and the patient is referred to colonoscopy for polypectomy
4. A small polyp is found (6-9mm) and the patient is followed with a repeat CTC at 12 months.

Proposed MBS items

Proposed Item AAAAA

MBS item number:

56553

Please search and select the proposed category:

DIAGNOSTIC IMAGING SERVICES

Please search and select the proposed group:

COMPUTED TOMOGRAPHY

Please search and select the proposed item descriptor or draft a proposed item descriptor to define the population and health technology usage characteristics that would define eligibility for funding:

Computed tomography—scan of colon for exclusion or diagnosis of colorectal neoplasia in a patient if:(a) one or more of the following applies:(i) the patient has had an incomplete colonoscopy;(ii) there has been a poor quality colonoscopy due to residual faecal material; 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) (Anaes.)

Proposed MBS fee:

\$563.35

Indicate the overall cost per patient of providing the proposed health technology:

\$563.35

Please specify any anticipated out of pocket costs:

\$0.00

Provide details and explain:

CTC is readily available and there are multiple bulk billing radiology practices and health care services.

How is the technology/service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):

CTC currently has an exceedingly narrow MBS rebateable indication and is significantly underutilised compared with other first world nations. The few CTC's that occur are largely in public hospitals i.e. state-based funding, or the patient pays or the complete study at significant expense. This contributes to ongoing health inequality and further disadvantages our marginalised and vulnerable community members.

Claims

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

Non-inferior

Please state what the overall claim is, and provide a rationale:

CTC has been proven to be non-inferior to colonoscopy in multiple well conducted randomised trials (see evidence section). In addition, the break-through cancer rate is exceedingly low and is non-inferior to colonoscopy.

Estimated utilisation

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

Incomplete colonoscopy is up to 5% of all colonoscopies that are performed based upon GESA accreditation standards and so this equates to around 50,000 patients per annum.

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake(%):

5

Year 2 estimated uptake(%):

10

Year 3 estimated uptake(%):

15

Year 3 estimated uptake(%):

20-30

Estimate the number of patients who will utilise the proposed technology for the first full year:

50,000

Optionally, provide details:

around 1,000,000 colonoscopies are performed each year in Australia. This number will increase with the aging population and with the impact of CRC screening via FOB. Screening results in new patients requiring a diagnostic test as well as an ever growing pool of patients with a diagnosis of a polyp who require follow up and surveillance.

The rates of CRC are also increasing in young patients and this cohort will require surveillance over an extended period.

GESA accepts that 5% of all studies will be incomplete.

Will the technology be needed more than once per patient?

No, once only

Consultation

List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the health technology/service:

- Bowel Cancer Association
- Colorectal Surgical Society of Australia and New Zealand
- Gastroenterology Society of Australia
- Royal Australasian College of General Practitioners
- Royal Australian New Zealand College of Radiology

List all appropriate professional bodies / organisations representing the group(s) of health professionals who request the health technology/service:

- Royal Australasian College of General Practitioners

List all appropriate professional bodies / organisations representing the group(s) of health professionals that may be impacted by the health technology/service:

- Royal Australasian College of Physicians
- Royal Australasian College of Surgeons
- Royal Australian and New Zealand College of Radiologists

List the patient and consumer advocacy organisations or individuals relevant to the proposed health technology:

- Bowel Cancer Association

Regulatory information

Would the proposed health technology involve the use of a medical device, in-vitro diagnostic test, radioactive tracer or any other type of therapeutic good?

No