

MSAC Application 1761

Faecal calprotectin for the monitoring of disease activity in patients with IBD

Application for MBS eligible service or health technology

ID:

HPP200070

Application title:

Faecal calprotectin for the monitoring of disease activity in patients with inflammatory bowel disease

Submitting organisation:

GASTROENTEROLOGICAL SOCIETY OF AUSTRALIA

Submitting organisation ABN:

44001171115

Application description

Succinct description of the medical condition/s:

Inflammatory bowel disease (IBD) is a group of conditions characterised by chronic inflammation of the gastrointestinal tract, comprising both Crohn's disease and ulcerative colitis. The prevalence of IBD in Australia is increasing, with the estimated prevalence of IBD ranging from 414 to 653 per 100,000 patients.

IBD is a chronic relapsing condition and symptoms include diarrhoea, abdominal pain, bleeding, weight loss and fatigue. However, symptoms are a poor marker of gut inflammation (active disease). Uncontrolled disease leads to significant morbidity including hospital admissions, perforation, anaemia, resectional surgery as well as profound effects on the individual's emotional and social wellbeing. Australian and international management guidelines recommend regular assessment of disease activity and tight control of inflammation in an attempt to mitigate against these avoidable outcomes.

Succinct description of the service or health technology:

Faecal calprotectin (hereafter referred to as FC) is a stool protein biomarker that reliably correlates with both clinical and endoscopic disease activity in IBD. Calprotectin is found in the cytosol of human neutrophils and raised levels of calprotectin in the stool (FC) reflects the migration of neutrophils into the gut lumen during active intestinal inflammation. FC provides a non-invasive, accurate and inexpensive (~\$80) method to assess for intestinal inflammation in IBD.

High FC levels indicate active inflammation, allowing for timely adjustments in treatment leading to improved disease management, cessation of ineffective therapies and better outcomes in IBD care including avoidance of irreversible bowel damage, surgery, hospitalisations and morbidity. A low FC is reliable in suggesting no disease activity in IBD, allowing clinicians to avoid unnecessary invasive and expensive investigations such as colonoscopy in many patients.

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?

Organisation

Is the applicant organisation the organisation you are representing in the HPP today?

Yes

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 Prostheses 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
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What is the type of service or health technology?

Investigative

Please select the type of investigative health technology:

Clinical biochemistry

PICO Sets

Application PICO sets

PICO set number	PICO set name
1	Faecal calprotectin for monitoring of disease activity in patients with diagnosed inflammatory bowel disease

Faecal calprotectin for monitoring of disease activity in patients with diagnosed inflammatory bowel disease

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

Purpose category:

Monitoring

Purpose description:

To monitor a condition over time.

What additional purpose(s) could the health technology be used for, other than the purposes listed above for this PICO set?

Purpose category:

Outcome / response assessment

Purpose description:

To assess an outcome or response following an intervention or treatment

Rationale:

The primary benefit of faecal calprotectin testing is for monitoring of disease activity in patients with diagnosed inflammatory bowel disease. It also helps determine response to treatment.

Purpose category:

Prognosis

Purpose description:

To provide information about prognosis (staging/re-staging)

Rationale:

The primary benefit of faecal calprotectin testing is for monitoring of disease activity in patients with diagnosed inflammatory bowel disease. It may also be used to help provide prognostic information about the disease course.

Supporting documentation

Document type	File name(s)
Application PICO set documents	HPP200070_Faecal calprotectin for monitoring of disease activity in patients with diagnosed inflammatory bowel disease.docx
Reference list	References.docx

Population

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

This application is for the use of FC in monitoring of disease activity in patients with known inflammatory bowel disease (IBD) managed by a gastroenterologist.

IBD refers to a group of chronic inflammatory conditions of the gastrointestinal tract, primarily consisting of Crohn's disease (CD) and ulcerative colitis (UC). Crohn's disease can affect any part of the digestive tract, from the mouth to the anus, and involves transmural inflammation with a patchy distribution. Ulcerative colitis primarily affects the colon and rectum, featuring continuous mucosal inflammation starting from the rectum and extending proximally. They are characterised by an influx of inflammatory cells into the gut wall, resulting in various clinical manifestations including

abdominal pain, diarrhoea, rectal bleeding, fatigue and weight loss.

The few epidemiologic studies from Australia show high incidence and prevalence of IBD, and it is estimated that approximately 100,000 Australians are living with IBD (1). While methodology differs across the studies, Australia has amongst the highest reported incidence of IBD worldwide, up to 24.7-32.4 cases per 100,000 people (2). IBD generally occurs with similar frequency in men and women with peak onset of incidence in the second and third decades (3). Although the aetiology of IBD is incompletely understood, it is thought to result from an aberrant immune response to environmental triggers in genetically susceptible individuals (4)

IBD is characterized by periods of active disease interspersed with periods of remission. The disease course varies among individuals and is unpredictable, with some experiencing a more indolent course, while others may have frequent relapses. Gut inflammation over time leads to poor outcomes with complications such as structural damage, strictures, fistulas, and an increased risk of colorectal cancer.

Patients with IBD have an overall similar or slightly increased mortality risk (5,6). Advancements in medical therapies and multidisciplinary care have led to improved outcomes and reduced mortality rates in recent years (6). Subgroups of patients such as males over 40 years of age and those with colonic disease may have a higher mortality rate(6,7). There is also emerging data indicating higher risk of death in elderly patients with IBD, with cardiovascular disease and serious infection major contributors (8,9).

IBD exerts a substantial burden on patients' quality of life. The unpredictable disease course, chronic symptoms, and frequent healthcare interactions impact physical, psychological, and social well-being (10). Fatigue, pain, and impaired functional capacity contribute to limitations in daily activities and work productivity. IBD-related complications, such as strictures and fistulas, can result in hospitalizations, surgeries, and a need for long-term medical management. The disease also places a significant psychological burden on patients, with higher rates of anxiety, depression, and impaired body image (11).

In addition to impacts on patients and their families, IBD imposes a substantial economic burden on the Australian healthcare system. In 2012, direct costs from hospitalizations were estimated to be over \$100 million(1). Productivity losses attributable to IBD were estimated at \$380 million and additional financial and economic costs estimated at over \$2.7 billion.

This application directly supports the findings of the Australian Government's Inflammatory Bowel Disease National Action Plan 2019 (12) which documented the most important short to medium term actions that will impact the improvement of quality of care for people living with IBD in Australia. Priority area 7 promotes the use of faecal calprotectin which "in the IBD clinical management setting...can assist in monitoring relapse and response of current treatment type and as a surrogate marker of mucosal healing or post-operative recurrence" (Page 20).

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

Inflammatory bowel disease

Intervention

Name of the proposed health technology:

Faecal Calprotectin (Quantitative enzyme-linked immunosorbent assay)

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 and biopsy.

The indications and contraindications for both the proposed medical service and the main comparator (colonoscopy and biopsy) are the same. The adverse events that are to be included in the economic evaluation are perforations and bleeding (rate ~1:1000), and anaesthetic risk. Perforations, bleeding and anaesthetic risk occur in colonoscopy. There are no identifiable adverse events occurring from the proposed medical service (FC) itself.

Other healthcare resources that need to be delivered at the same time as the comparator include anaesthetic staff (anaesthetist, anaesthetic nurse) and endoscopy nursing staff as well as use of an appropriately fitted hospital or day centre endoscopy room, recovery area and use of endoscopic equipment (including preparing and cleaning). It should also be considered that patients are required to take time off work for a colonoscopy (~36 hours minimum time, usually 2 working days), hence increasing patient costs.

Outcomes

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

A FC result in a patient with IBD offers gastroenterologists important information on disease activity allowing for timely adjustment to therapy (escalation, continuation or de-escalation). In addition, it can provide valuable insights into prognosis. Figure 2 in the application highlights the potential changes in management based on FC.

Recent meta-analyses demonstrate a high specificity and sensitivity to detect mucosal healing and disease activity in IBD (34–37). Normalisation of FC has also been shown to be associated with reduced risk of disease progression (38). Furthermore, there is a large body of data supporting the utility of faecal calprotectin in predicting relapse (39,40), to assist in de-escalation of therapy (41–43), and monitoring for post-operative recurrence (44)..

Proposed MBS items

Proposed Item AAAAA

MBS item number:

Please search and select the proposed category:

PATHOLOGY SERVICES

Please search and select the proposed group:

CHEMICAL

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:

Faecal Calprotectin test for assessment of disease activity if all the following apply:

- a) the patient has diagnosed inflammatory bowel disease;
- b) the service is requested by a specialist or consultant physician practising as a specialist gastroenterologist.

Proposed MBS fee:

\$80.00

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

\$86.40

Please specify any anticipated out of pocket costs:

\$0.00

Provide details and explain:

See Appendix 1 of PICO application

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

Self-funded by patients.

Please provide a cost break down attachment:

Document type	File name(s)
Cost breakdown attachment	Cost Breakdown.docx

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:

This application makes the following well supported clinical claims: FC testing is cheaper, safer, and clinically non-inferior as the present alternative of performing colonoscopy & biopsy/histopathology for regular assessment of disease activity in patients with established IBD.

Estimated utilisation

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

This application applies to FC testing in patients with previously diagnosed IBD. According to recent studies, the prevalence of IBD in Australia has been steadily increasing with approximately 1.7% growth in the prevalence annually. Estimated prevalence in 2022 has been calculated at between 80,475 and 99,028 people (1).

In terms of incidence, studies have reported varying rates across different regions of Australia. The most recent estimates indicate a crude annual incidence of between 13.23 to 14.7 per 100,000 for CD and between 7.5 to 17.25 per 100,000 for UC (2,49,50). It is important to note that the prevalence and incidence of IBD can vary among different population groups, such as age groups, geographic regions, and ethnic backgrounds. Additionally, improvements in diagnosis and awareness may contribute to increasing incidence rates over time.

Assuming continued growth in the prevalence of IBD at the rate of 1.7% as previously estimated (1), the following provides the IBD prevalence in Australia for years 2022-2026.

2022	2023	2024	2025	2026
99,028	100,711	102,423	104,164	105,935

(Estimated IBD prevalence in Australia 2022-2026 (assuming 1.7% growth in prevalence of IBD)

This prevalence provides a ceiling estimate of the eligible proposed population, although it is important to note that the eligible population for monitoring using the FC test is a subset of the total IBD population. Specifically, this application is limited to FC tests ordered by gastroenterologists to avoid potential leakage. Thus, only those patients with IBD seeing a gastroenterologist would be eligible, which would represent a smaller subset of patients. Estimates of how many patients in Australia with IBD regularly see a gastroenterologist are not readily available. However, a Canadian study found continuous specialist care (defined as having at least one gastroenterologist visit every 12 +/- 3 months for the first five years among patients with at least five years of follow-up) as 31-48% (51). It is unclear how this would translate to an Australian healthcare setting. Furthermore, not all patients will want to submit a stool test. Due to these factors, there is uncertainty in the percentage uptake by the proposed population.

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

Year 1 estimated uptake(%):

60

Year 2 estimated uptake(%):

60

Year 3 estimated uptake(%):

65

Year 3 estimated uptake(%):

65

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

$102,423 \times 0.6 = 59,417$

Optionally, provide details:

2024 estimate of IBD population in Australia: 102,423

Year 1 estimated uptake 60%

$102,423 \times 0.6 = 59,417$

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):

From diagnosis until death.

Optionally, provide details:

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

Up to 4 times per year

Optionally, provide details:

Provide references to support these calculations.

Document type	File name(s)
Estimated utilisation references	Estimated Utilisation References.docx

Consultation

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

Professional body name:

THE ROYAL COLLEGE OF PATHOLOGISTS OF AUSTRALASIA

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

Professional body name:

GASTROENTEROLOGICAL SOCIETY OF AUSTRALIA

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

Professional body name:

ROYAL FLYING DOCTOR SERVICE OF AUSTRALIA (WESTERN OPERATIONS)

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

Number of organisations listed: 1

Professional body name:

AUSTRALIAN CROHN'S AND COLITIS ASSOCIATION (ACCA)

List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed service or health technology:

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