



**Australian Government**

**Department of Health**

# **Application Form**

**(New and Amended Requests for Public Funding)**

(Version 2.5)

This application form is to be completed for new and amended requests for public funding (including but not limited to the Medicare Benefits Schedule (MBS)). It describes the detailed information that the Australian Government Department of Health requires in order to determine whether a proposed medical service is suitable.

Please use this template, along with the associated Application Form Guidelines to prepare your application. Please complete all questions that are applicable to the proposed service, providing relevant information only. Applications not completed in full will not be accepted.

The application form will be disseminated to professional bodies / organisations and consumer organisations that have will be identified in Part 5, and any additional groups that the Department deem should be consulted with. The application form, with relevant material can be redacted if requested by the Applicant.

Should you require any further assistance, departmental staff are available through the contact numbers and email below to discuss the application form, or any other component of the Medical Services Advisory Committee process.

Phone: +61 2 6289 7550

Fax: +61 2 6289 5540

Email: [hta@health.gov.au](mailto:hta@health.gov.au)

Website: [www.msac.gov.au](http://www.msac.gov.au)

# PART 1 – APPLICANT DETAILS

## 1. Applicant details (primary and alternative contacts)

Corporation / partnership details (where relevant):

Corporation name:

ABN:

Business trading name:

### Primary contact name:

Primary contact numbers

Business:

Mobile:

Email:

### Alternative contact name:

Alternative contact numbers

Business:

Mobile:

Email:

## 2. (a) Are you a consultant acting on behalf of an Applicant?

- Yes  
 No

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

Insert relevant Applicant(s) name here.

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

- Yes  
 No

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

- Yes  
 No

## PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

### 4. Application title

CAPSULE ENDOSCOPY FOR DIAGNOSIS OF SMALL BOWEL SUSPECTED CROHN'S AND ASSESSMENT OF PATIENTS WITH KNOWN ISOLATED SMALL BOWEL CROHN'S DISEASE

### 5. Provide a succinct description of the medical condition relevant to the proposed service (no more than 150 words – further information will be requested at Part F of the Application Form)

Crohn's disease (CD) is a chronic inflammatory bowel disease that may affect any portion of the gastrointestinal (GI) tract. In cases of small bowel (SB) involvement, CD typically affects the terminal ileum. The condition is becoming more prevalent, severe and complex and in particular is diagnosed in young patients. Approximately 20-30% of all patients with CD present when they are younger than 20 years old. In addition to common Gastrointestinal (GI) symptoms, children with CD often experience growth failure, malnutrition, pubertal delay, and bone demineralization. CD is largely unpredictable with significant variation in the area of the GI tract affected, as well as the degree and pattern of symptoms affecting each patient. The relapsing, unpredictable and chronic nature of CD has broader impacts on a person's emotional, physical and social wellbeing. Hence, early diagnosis and assessment modalities to optimise treatment for tight disease control are crucial. However, existing investigative tools can fail to provide a definitive, timely diagnosis and/or assessment.

Despite the widespread prevalence of CD, it should be noted that the proposed application relates to the diagnosis or assessment of patients with suspected or known isolated small bowel CD with non-diagnostic findings on prior imaging. This population accounts for a small fraction of the total CD population, but has a high clinical need for effective diagnostic and assessment options.

### 6. Provide a succinct description of the proposed medical service (no more than 150 words – further information will be requested at Part 6 of the Application Form)

Capsule endoscopy (CE) is a non-invasive diagnostic test, usually conducted in an outpatient setting, in which the gastrointestinal system is visualised via a camera inside an ingested capsule. The test visualises the gastrointestinal (GI) tract in order to diagnose and assess GI mucosal changes resulting from CD in the small bowel (SB). While the capsule passes through the patient's digestive tract, images are transmitted to a data recorder worn on a waist belt. After the procedure, a colour video taken from the capsule is viewed. This technology is especially useful for visualising the mucosa of the small bowel, which is difficult to access with endoscopic examination.

The proposed application requests the use of capsule endoscopy in two distinct indications:

- 1) The diagnosis of suspected isolated small bowel Crohn's Disease in patients with non-diagnostic findings from prior investigations including colonoscopy with ileoscopy and imaging with MR Enterography
- 2) Assessment of patient with Known Isolated Small Bowel Crohn's disease:
  - Evaluation of exacerbations/suspected complications of known small bowel Crohn's disease patients with non-diagnostic findings from prior investigations
  - Assessment of response to change to therapy in patients with known isolated non stricturing small bowel Crohn's disease patients with non-diagnostic findings from prior investigations

An economic evaluation of the first (diagnostic) indication was previously assessed by MSAC (Applications 1146 and 1146.1), while the second (assessment) indication has not yet been reviewed.

### 7. (a) Is this a request for MBS funding?

- Yes  
 No

**(b) If yes, is the medical service(s) proposed to be covered under an existing MBS item number(s) or is a new MBS item(s) being sought altogether?**

- Amendment to existing MBS item(s)
- New MBS item(s)

**(c) If an amendment to an existing item(s) is being sought, please list the relevant MBS item number(s) that are to be amended to include the proposed medical service:**

N/A

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

- i.  An amendment to the way the service is clinically delivered under the existing item(s)
- ii.  An amendment to the patient population under the existing item(s)
- iii.  An amendment to the schedule fee of the existing item(s)
- iv.  An amendment to the time and complexity of an existing item(s)
- v.  Access to an existing item(s) by a different health practitioner group
- vi.  Minor amendments to the item descriptor that does not affect how the service is delivered
- vii.  An amendment to an existing specific single consultation item
- viii.  An amendment to an existing global consultation item(s)
- ix.  Other (please describe below):

N/A

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

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

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

- Yes
- No

**(g) If yes, please advise:**

N/A

**8. What is the type of service:**

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

**9. For investigative services, advise the specific purpose of performing the service (which could be one or more of the following):**

- i.  To be used as a screening tool in asymptomatic populations
- ii.  Assists in establishing a diagnosis in symptomatic patients
- iii.  Provides information about prognosis
- iv.  Identifies a patient as suitable for therapy by predicting a variation in the effect of the therapy
- v.  Monitors a patient over time to assess treatment response and guide subsequent treatment decisions
- vi.  Is for genetic testing for heritable mutations in clinically affected individuals and, when also appropriate, in family members of those individuals who test positive for one or more relevant mutations (and thus for which the Clinical Utility Card proforma might apply)

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

- Pharmaceutical / Biological
- Prosthesis or device
- No

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

- Yes
- No

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

N/A

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

- Yes (please provide PBAC submission item number below)
- No

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

Trade name: N/A

Generic name: N/A

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

- Yes
- No

**Applicant comment:** Technology required to deliver the proposed service is not implanted –and therefore does not meet current Prostheses List criteria.

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

Billing code(s): N/A

Trade name of prostheses: N/A

Clinical name of prostheses: N/A

Other device components delivered as part of the service: N/A

**(c) If no, is an application in the process of being considered by a Clinical Advisory Group or the Prostheses List Advisory Committee (PLAC)?**

Yes

No

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

Yes

No

**(e) If yes, please provide the name(s) of the sponsor(s) and / or manufacturer(s):**

CapsoCam Plus by CapsoVision (distributed by Device Technologies )

MiRo-Cam by IntroMedic (distributed by C.R. Kennedy)

EndoCapsule by Olympus Australia Pty Ltd

PillCam capsule endoscopy by Medtronic Australasia Pty Ltd

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

Single use consumables: Capsule (camera inside), patency capsule

Multi-use consumables: N/A

## PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

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

Type of therapeutic good:

Manufacturer's name:

Sponsor's name:

- (b) Is the medical device classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?**

- Class III  
 AIMD  
 N/A

- 15. (a) Is the therapeutic good to be used in the service exempt from the regulatory requirements of the *Therapeutic Goods Act 1989*?**

- Yes (If yes, please provide supporting documentation as an attachment to this application form)  
 No

- (b) If no, has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?**

- Yes (if yes, please provide details below)  
 No

ARTG listing, registration or inclusion number:

TGA approved indication(s), if applicable:

TGA approved purpose(s), if applicable:

- 16. If the therapeutic good has not been listed, registered or included in the ARTG, is the therapeutic good in the process of being considered for inclusion by the TGA? N/A**

- Yes (please provide details below)  
 No

Date of submission to TGA: N/A

Estimated date by which TGA approval can be expected: N/A

TGA Application ID: N/A

TGA approved indication(s), if applicable: N/A

TGA approved purpose(s), if applicable: N/A

- 17. If the therapeutic good is not in the process of being considered for listing, registration or inclusion by the TGA, is an application to the TGA being prepared?**

- Yes (please provide details below)  
 No

Estimated date of submission to TGA: N/A

Proposed indication(s), if applicable: N/A

Proposed purpose(s), if applicable: N/A

## PART 4 –SUMMARY OF EVIDENCE

**18. Provide an overview of all key journal articles or research published in the public domain related to the proposed service that is for your application (limiting these to the English language only). Please do not attach full text articles, this is just intended to be a summary.**

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication** *
Studies on Assessment of Patients with Known Small Bowel Crohn’s Disease					
1.	Retrospective multicentre, cross-sectional study.	Small Bowel (SB) Capsule Endoscopy (CE) in the Management of Established Crohn’s Disease: Clinical Impact, Safety, and Correlation with Inflammatory Biomarkers  <i>Kopylov et al.</i>	The study cohort included consecutive 187 patients with established SB CD who underwent Video Capsule Endoscopy (VCE) in 4 tertiary referral centres from January 2008 to October 2013.	<a href="http://www.ncbi.nlm.nih.gov/pubmed/25517597">http://www.ncbi.nlm.nih.gov/pubmed/25517597</a>	2015
2.	Prospective cohort study.	A prospective 52 week mucosal healing assessment of small bowel Crohn's disease as detected by capsule endoscopy.  <i>Hall et al.</i>	108 capsule procedures were performed on 43 patients. Based on the Capsule Endoscopy Crohn's Disease Activity Index (CECDAI), 39 (90%) demonstrated active small bowel CD at baseline with 28 (65%) undergoing 52 week assessment.	<a href="http://ecco-jcc.oxfordjournals.org/content/8/12/1601.long">http://ecco-jcc.oxfordjournals.org/content/8/12/1601.long</a>	2014



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Studies on Assessment of Patients with Known Small Bowel Crohn's Disease					
3.	Sub-study of a prospective, randomized, double blind placebo-controlled study.	Sequential capsule endoscopy of the small bowel for follow-up of patients with known Crohn's disease.  <b>Niv et al.</b>	Consecutive patients with known moderately active CD were prospectively recruited. A control group of 178 non-CD patients was used for comparisons. Thirty-one CD patients were recruited and 19 met the inclusion criteria. A total of 43 CE studies were performed over the time.	<a href="http://ecco-jcc.oxfordjournals.org/content/8/12/1616.long">http://ecco-jcc.oxfordjournals.org/content/8/12/1616.long</a>	2014
4.	Retrospective single centre study.	Tailoring Crohn's disease treatment: The impact of small bowel capsule endoscopy  <b>Cotter et al.</b>	Consecutive patients with known non-stricturing and non-penetrating ileal and/or colonic CD, submitted to Small Bowel Capsule Endoscopy (SBCE) to evaluate disease extension and activity, with ≥ 1 year follow-up. Therapeutic changes were assessed 3 months after SBCE.	<a href="http://ecco-jcc.oxfordjournals.org/content/8/12/1610.long">http://ecco-jcc.oxfordjournals.org/content/8/12/1610.long</a>	2014
5.	Single-centre retrospective study.	Video Capsule Endoscopy Impacts Decision Making in Paediatric IBD: A Single Tertiary Care Centre Experience.  <b>Min et al.</b>	A retrospective chart review was performed in children with established (n = 66) or suspected (n = 17) Inflammatory Bowel Disease (IBD) who underwent Video Capsule Endoscopy (VCE). Diagnostic classifications, treatments, and clinical outcomes before and 1 year after VCE were compared.	<a href="http://journals.lww.com/ibdjournal/pages/articleviewer.aspx?year=2013&amp;issue=09000&amp;article=00013&amp;type=abstract">http://journals.lww.com/ibdjournal/pages/articleviewer.aspx?year=2013&amp;issue=09000&amp;article=00013&amp;type=abstract</a>	2013

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Studies on Assessment of Patients with Known Small Bowel Crohn's Disease					
6.	Retrospective single centre study.	Clinical utility of capsule endoscopy in patients with Crohn's disease and inflammatory bowel disease unclassified.  <b>Kalla et al.</b>	Patients referred routinely from 2003 to 2009 with a diagnosis of Inflammatory Bowel Disease Unclassified (IBDU), suspected or established CD were identified retrospectively. Data were collected for indications and findings at Small Bowel Capsule Endoscopy (SBCE) with subsequent follow-up.	<a href="http://www.ncbi.nlm.nih.gov/pubmed/23325280">http://www.ncbi.nlm.nih.gov/pubmed/23325280</a>	2013
7.	Single-centre retrospective study.	Small bowel capsule endoscopy for management of Crohn's disease: A retrospective tertiary care centre experience.  <b>Dussault et al.</b>	SBCE tests performed in a referral centre from 2008 to 2011; 77 tests were performed in patients with known Crohn's disease. Six patients were excluded due to capsule test retention. Patients were classified into 4 indication groups: unexplained anaemia; discrepancy between clinical symptoms and morphology, full assessment of Crohn's disease location and evaluation of mucosal healing.	<a href="http://www.sciencedirect.com/science/article/pii/S1590865812004227">http://www.sciencedirect.com/science/article/pii/S1590865812004227</a>	2012
8.	Single-centre retrospective study.	Impact of capsule endoscopy on management of inflammatory bowel disease: a single tertiary care centre experience.  <b>Long et al.</b>	86 symptomatic Crohn's patients that underwent CE, 61.6% had therapeutic changes (defined as initiation or discontinuation of any IBD specific medication) in the 3 months after the CE, with 39.5% initiating a new IBD medication.	<a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3116981/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3116981/</a>	2011

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Studies on Assessment of Patients with Known Small Bowel Crohn's Disease					
9.	Single-centre retrospective study.	Impact of capsule endoscopy findings in the management of Crohn's Disease. <b>Lorenzo-Zúñiga et al.</b>	All patients with known CD that underwent CE were identified from IBD and endoscopy databases. Baseline characteristics of the study population, CE findings, changes in therapy, and patient outcome were recorded. Patients were followed for 18 months after CE. CE was performed in 14 CD patients for iron deficiency anaemia (n = 5) or abdominal pain of unknown origin (n = 3), or re-evaluation of disease location (n = 6).	<a href="http://link.springer.com/article/10.1007%2Fs10620-009-0758-8">http://link.springer.com/article/10.1007%2Fs10620-009-0758-8</a>	2010
10.	Retrospective single centre study.	Clinical consequences of video capsule endoscopy in GI bleeding and Crohn's disease. <b>Van Tuyl et al.</b>	VCE was performed in 150 patients - 36 of them with CD. Clinical consequences were evaluated by using a questionnaire and were divided into change of management or unchanged management.	<a href="http://www.sciencedirect.com/science/article/pii/S0016510707015775">http://www.sciencedirect.com/science/article/pii/S0016510707015775</a>	2007
11.	Prospective cohort study.	Capsule endoscopy is safe and effective after small-bowel resection.  <b>De Palma et al.</b>	Ten patients were included in the study. Eight had undergone surgical resection for Crohn's disease, two for malignancy. Indications for capsule endoscopy included suspected relapse of Crohn's disease or of malignancy, with a negative conventional evaluation that included barium contrast radiography, upper endoscopy, colonoscopy, US, CT, and push enteroscopy.	<a href="http://www.sciencedirect.com/science/article/pii/S0016510704015275">http://www.sciencedirect.com/science/article/pii/S0016510704015275</a>	2004

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Studies on Assessment of Patients with Known Small Bowel Crohn's Disease					
12.	Retrospective single centre study.	Capsule Endoscopy's Impact on Clinical Management and Outcomes: A Single-Center Experience With 145 Patients.  <i>Toy et al.</i>	Retrospective chart review was performed on 145 patients who had undergone capsule endoscopy. Demographic characteristics, indication, prior diagnostic tests, capsule findings, interventions, and clinical outcomes up to 8 months following CE were evaluated. Indications included five main categories that were overt gastrointestinal (GI) bleed, occult GI bleed, abdominal pain, Crohn's disease, and iron deficiency anemia. Findings on capsule endoscopy classified into angiodysplasias, ulcers, gastritis and/or duodenitis, ulcers suggestive of Crohn's and normal findings.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/19086954">https://www.ncbi.nlm.nih.gov/pubmed/19086954</a>	2008
13.	Retrospective single centre study.	Usefulness and impact on management of positive and negative capsule endoscopy  <i>Chami et al.</i>	Medical records were reviewed for 70 consecutive CE patients. Based on outcomes from referring physicians, it was determined whether CE was useful, partially useful or not useful.	<a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2657986/pdf/cjg21577.pdf">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2657986/pdf/cjg21577.pdf</a>	2007

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Studies on Assessment of Patients with Known Small Bowel Crohn's Disease					
14.	Retrospective single centre study.	PillCam COLON 2 <sup>®</sup> in Crohn's disease: A new concept of pan-enteric mucosal healing assessment.  <i>Carvalho et al.</i>	Patients with non-stricturing non-penetrating small bowel plus colonic CD in sustained corticosteroid-free remission were included. At diagnosis, patients had undergone ileocolonoscopy to identify active CD lesions, such as ulcers and erosions, and small bowel capsule endoscopy to assess the Lewis Score (LS). After ≥ 1 year of follow-up, patients underwent entire gastrointestinal tract evaluation with PCC2. The primary endpoint was assessment of CD mucosal healing, defined as no active colonic CD lesions and LS < 135.	<a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4476885/pdf/WJG-21-7233.pdf">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4476885/pdf/WJG-21-7233.pdf</a>	2015
15.	Retrospective single centre study.	Initial Experience With Wireless Capsule Enteroscopy in the Diagnosis and Management of Inflammatory Bowel Disease.  <i>Mow et al.</i>	Fifty patients with ongoing symptoms underwent endoscopic capsule examinations to assess the clinical utility of WCE in the evaluation of patients with known or suspected inflammatory bowel disease.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/15017630">https://www.ncbi.nlm.nih.gov/pubmed/15017630</a>	2004

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Studies on Assessment of Patients with Known Small Bowel Crohn's Disease					
16.	Retrospective single centre study.	Capsule Endoscopy Changes Patient Management in Routine Clinical Practice.  <i>Sidhu et al.</i>	Sixty-eight patients were referred for CE to investigate the possibility of small bowel Crohn's disease. Seven patients were known to have Crohn's disease 60 patients were not known to have Crohn's disease prior to CE. A change of management followed in 81% of patients diagnosed with Crohn's disease after CE.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/17357836">https://www.ncbi.nlm.nih.gov/pubmed/17357836</a>	2007
17.	Retrospective single centre study.	Usefulness of wireless capsule endoscopy in paediatric inflammatory bowel disease.  <i>Di Nardo et al.</i>	A prospective paediatric study on the usefulness of wireless capsule endoscopy (WCE) was performed in 117 children (age range: 4-17 years) with established or suspected IBD and compared with non-endoscopic imaging tools. All patients underwent upper and lower gastrointestinal endoscopy. In Crohn's disease patients (CD, n=44), small bowel lesions were revealed by imaging tools in 8 and by WCE in 18 patients, respectively (p<0.01).	<a href="https://www.ncbi.nlm.nih.gov/pubmed/21093392">https://www.ncbi.nlm.nih.gov/pubmed/21093392</a>	2011

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Studies on initial diagnosis of Patients with Suspected Small Bowel Crohn's Disease					
1.	Prospective, consecutive (diagnostic accuracy) single cohort study.	Clinical outcome of patients examined by capsule endoscopy for suspected small bowel Crohn's disease.  <i>Girelli et al.</i>	Examined and enrolled 27 patients with abdominal pain and diarrhea lasting more than 3 months and at least one of the following: anaemia, weight loss, fever, and extra-intestinal manifestation. Eligible subjects were examined by CE, assigned to three groups after CE findings were followed-up median 21, range 15–29 months.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/17196893">https://www.ncbi.nlm.nih.gov/pubmed/17196893</a>	2007
2.	Retrospective single centre study.	Capability of Capsule Endoscopy in Detecting Small Bowel Ulcers.  <i>Ersoy et al.</i>	66 patients who had undergone normal upper and lower endoscopy and small bowel follow-through, CE revealed previously undiagnosed ulcer(s) in the small intestines of 22 patients. Final diagnoses in 22 patients were Crohn's disease for 9 patients. Capsule endoscopy facilitated the detection and assessment of ulcerated mucosal lesions located in the small bowel.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/18536988">https://www.ncbi.nlm.nih.gov/pubmed/18536988</a>	2009
3.	Retrospective single centre (diagnostic accuracy) study.	Small-bowel capsule endoscopy in patients with suspected Crohn's disease-diagnostic value and complications  <i>Figueiredo et al.</i>	Seventy eight patients clinically suspected CD were included. Mean age 37 years, 68% female. C+IL (either negative for CD or failed ileoscopy), blood tests, some patients had SBFT, CT or enteroclysis.	<a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2929590/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2929590/</a>	2010

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Studies on initial diagnosis of Patients with Suspected Small Bowel Crohn's Disease					
4.	Prospective, consecutive (diagnostic accuracy) single centre study.	Diagnosis of small bowel Crohn's disease: a prospective comparison of capsule endoscopy with magnetic resonance imaging and fluoroscopic Enteroclysis  <b>Albert et al.</b>	CE compared with MRI and small bowel enteroclysis. 25 patients with newly suspected CD in which the work-up did not establish a diagnosis other than CD included. Mean age 37 years (m) or 40 years (f), 75% female. Combined diagnostic endpoint of all imaging methods and diagnosis at follow-up.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/16020490">https://www.ncbi.nlm.nih.gov/pubmed/16020490</a>	2005
5.	Prospective single centre study.	MR enterography versus capsule endoscopy in paediatric patients with suspected Crohn's disease.  <b>Casciani et al.</b>	CE compared with MRE. 60 paediatric patients with suspected CD ( $\geq 1$ symptom and one biochemical sign of systemic inflammation) included. Mean age 14 years, 40% female. Prior tests: C+IL (not necessarily negative for CD), EGD, positive blood tests or inflammatory markers.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/20922391">https://www.ncbi.nlm.nih.gov/pubmed/20922391</a>	2011
6.	Retrospective single centre (diagnostic accuracy) study.	The Utility of Capsule Endoscopy in Patients With Suspected Crohn's Disease.  <b>Tukey et al</b>	105 Adult patients evaluated by CE for suspected CD with normal or equivocal prior investigations. Mean age 50 years, 66% female. Prior tests: C+IL, SBFT or CT (all tests negative or equivocal for CD)	<a href="https://www.ncbi.nlm.nih.gov/pubmed/19584828">https://www.ncbi.nlm.nih.gov/pubmed/19584828</a>	2009



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Studies on initial diagnosis of Patients with Suspected Small Bowel Crohn's Disease					
7.	Prospective, non-consecutive blinded diagnostic yield study.	Capsule Endoscopy vs. push enteroscopy and enteroclysis in suspected small bowel Crohn's disease.  <i>Chong et. al.</i>	Twenty-two patients were known to have Crohn's disease, and 21 were suspected to have SB CD. They were prospectively evaluated with push enteroscopy, enteroclysis and capsule endoscopy. Capsule endoscopy had higher yield in patients with known CD. CE changed in management in the majority of these patients.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/15729235">https://www.ncbi.nlm.nih.gov/pubmed/15729235</a>	2005
8.	Prospective, consecutive diagnostic yield study.	Capsule endoscopy findings in patients with suspected Crohn's disease and biochemical markers of inflammation.  <i>De Bona et al.</i>	Thirty-eight suspected CD patients with negative at conventional imaging were examined using CE. CE findings were diagnostic for CD in 13 (34.2%) patients, suspicious in 2 (5.3%), non-specific in 4 (10.5%), normal in 19 (50%), overall detection rate of 39.5%. Specific measures or patient management changes in 39.5% of patients.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/16569524">https://www.ncbi.nlm.nih.gov/pubmed/16569524</a>	2006
9.	Prospective, blinded diagnostic yield study.	Wireless capsule endoscopy (WCE) versus enteroclysis in the diagnosis of small-bowel Crohn's disease  <i>Efthymiou et al.</i>	Twenty-nine patients with known CD (group 1) suspected to have more extensive small-bowel involvement and 26 patients, who were suspected to suffer from CD but didn't have an earlier history of it (group 2) were prospectively evaluated with enteroclysis and WCE.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/19417679">https://www.ncbi.nlm.nih.gov/pubmed/19417679</a>	2009

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
Studies on initial diagnosis of Patients with Suspected Small Bowel Crohn's Disease					
10.	Prospective, consecutive, blinded diagnostic yield study,	Wireless capsule video endoscopy compared to barium follow-through and computerised tomography in patients with suspected Crohn's disease--final report. <b>Eliakim et al.</b>	Thirty-five patients with suspected Crohn's disease underwent the three examinations. The radiologist and gastroenterologist were blinded to each other's results. In cases of discrepancy, colonoscopy and ileoscopy were performed. The diagnostic yield of capsule endoscopy was 77% versus 23% and 20% of barium and computerised tomography examinations, respectively.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/15334771">https://www.ncbi.nlm.nih.gov/pubmed/15334771</a>	2004
11.	Prospective diagnostic yield study.	Capsule endoscopy in diagnosis of small bowel Crohn's disease. <b>Ge et al.</b>	From May 2002 to April 2003, prospectively examined 20 patients with suspected CD. All the patients had normal results in small bowel series and in upper and lower gastrointestinal endoscopy before they were examined. Mean duration of symptoms before diagnosis was 6.5 years.	<a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4622781/">http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4622781/</a>	2004
12.	Prospective, non-consecutive diagnostic yield study.	Wireless capsule endoscopy for obscure small-bowel disorders: final results of the first paediatric controlled trial. <b>Guilhon de Araujo Sant'Anna et al.</b>	Patients (age, 10-18 y) suspected to have either small-bowel Crohn's disease, polyps, or obscure gastrointestinal (GI) bleeding were included. Capsule results were compared with the diagnostic imaging studies normally used in this age group.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/15765446">https://www.ncbi.nlm.nih.gov/pubmed/15765446</a>	2005

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
Studies on initial diagnosis of Patients with Suspected Small Bowel Crohn's Disease					
13.	Prospective diagnostic yield study.	Capsule endoscopy in patients with Suspected Crohn's Disease and Negative Endoscopy. <b>Herrerias et al.</b>	Patients clinical and biochemical suspicion of CD as indicated by symptoms (chronic diarrhoea (>6 months), diffuse abdominal pain, fever or weight loss) included. Crohn's disease not confirmed using traditional techniques.	<a href="http://www.ncbi.nlm.nih.gov/pubmed/12822090">http://www.ncbi.nlm.nih.gov/pubmed/12822090</a>	2003
14.	Prospective diagnostic yield study.	Clinical features of patients with negative results from traditional diagnostic work-up and Crohn's disease findings from capsule endoscopy. <b>Valle et al.</b>	Twenty-three patients (7 men, 16 women; mean age: 40+/-15 y) with negative results from conventional imaging techniques were prospectively included in the study because of suspicion of Crohn's disease. CE diagnosed Crohn's disease in 6 patients (26%).	<a href="http://www.ncbi.nlm.nih.gov/pubmed/16940880">http://www.ncbi.nlm.nih.gov/pubmed/16940880</a>	2006
15.	Retrospective case series study.	The risk of retention of the capsule endoscope in patients with known or suspected Crohn's disease. <b>Cheifetz et al.</b>	Multicentre (3 private gastroenterology practices) December 2000-December 2003 n=102 patients with suspected (n=64) or known (n=38) Crohn's disease. Capsule retention occurred in 13% (95% CI 5.6%-28%) of patients with known CD, but only in 1.6% (95% CI 0.2%-10%) with suspected Crohn's.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/16848804">https://www.ncbi.nlm.nih.gov/pubmed/16848804</a>	2006

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
Studies on initial diagnosis of Patients with Suspected Small Bowel Crohn's Disease					
16.	Prospective diagnostic yield study.	Capsule Endoscopy Is Superior to Small-bowel Follow-through and Equivalent to Ileocolonoscopy in Suspected Crohn's Disease.  <i>Leighton et al.</i>	Eighty patients with signs and/or symptoms of small-bowel Crohn's disease (age, 10-65 years) underwent CE, followed by SBFT and ileocolonoscopy. Readers were blinded to other test results. The primary outcome was the diagnostic yield for inflammatory lesions found with CE before ileocolonoscopy compared with SBFT and ileocolonoscopy. A secondary outcome was the incremental diagnostic yield of CE compared with ileocolonoscopy and CE compared with SBFT.	<a href="https://www.ncbi.nlm.nih.gov/pubmed/24075891">https://www.ncbi.nlm.nih.gov/pubmed/24075891</a>	2014

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
Studies on initial diagnosis of Patients with Suspected Small Bowel Crohn's Disease					
17.	Prospective, blinded single centre study.	Diagnostic Accuracy of Capsule Endoscopy for Small Bowel Crohn's Disease Is Superior to That of MR Enterography or CT Enterography  <i>Jensen et al.</i>	93 patients scheduled to undergo ileocolonoscopy, MRE, and CTE and subsequently CE if stenosis was excluded. Physicians reporting CE, MRE, and CTE results were blinded to patient histories and findings from ileocolonoscopy and other small bowel examinations. Results were compared with those from ileoscopy (n = 70), ileoscopy and surgery (n = 4), or surgery (n = 1). Twenty-one patients had Crohn's disease in the terminal ileum. The sensitivity and specificity for diagnosis of Crohn's disease of the terminal ileum were 100% and 91% by CE, 81% and 86% by MRE, and 76% and 85% by CTE, respectively. Proximal Crohn's disease was detected in 18 patients by using CE, compared with 2 and 6 patients by using MRE or CTE, respectively ( $P < .05$ ).	<a href="https://www.ncbi.nlm.nih.gov/pubmed/21056692">https://www.ncbi.nlm.nih.gov/pubmed/21056692</a>	2011

**Note:** Capsule Endoscopy also named/known as Wireless Capsule Endoscopy or Video Capsule Endoscopy or Small Bowel Capsule Endoscopy.

**Abbreviations:** CD=Crohn's disease; GI=Gastrointestinal; IBD=Inflammatory Bowel Disease; IBDU=Inflammatory Bowel Disease Unclassified; SB=Small Bowel; SBCE= Small Bowel Capsule Endoscopy; CE=Capsule Endoscopy/Endoscope; WCE=Wireless Capsule Endoscopy; CECDAI=Capsule Endoscopy Crohn's Disease Activity Index; US=Ultrasound; CT=Computed/computerised Tomography; LS=Lewis Score; C+IL=Colonoscopy+ileoscopy; SBFT= Small Bowel Follow Through; SBE = small bowel enteroclysis (double contrast small bowel fluoroscopy); MRE=magnetic resonance imaging with enterography; EGD = oesophagogastroduodenoscopy

*\* Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.*

*\*\*Provide high level information including population numbers and whether patients are being recruited or in post-recruitment, including providing the trial registration number to allow for tracking purposes.*

*\*\*\* If the publication is a follow-up to an initial publication, please advise.*

**19. Identify yet to be published research that may have results available in the near future that could be relevant in the consideration of your application by MSAC (limiting these to the English language only). Please do not attach full text articles, this is just intended to be a summary.**

	Type of study design*	Title of research (including any trial identifier if relevant)	Short description of research (max 50 words)**	Website link to research (if available)	Date***
1.	No study to our knowledge to be published in 12 months' time.	N/A	N/A	N/A	N/A
2.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
3.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
4.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
5.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
6.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
7.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
8.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
9.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
10.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
11.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
12.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
13.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date
14.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date

	Type of study design*	Title of research (including any trial identifier if relevant)	Short description of research (max 50 words)**	Website link to research (if available)	Date***
15.	Insert study design	Insert title of research	Insert description	Insert website link	Insert date

\* Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.

\*\*Provide high level information including population numbers and whether patients are being recruited or in post-recruitment.

\*\*\*Date of when results will be made available (to the best of your knowledge).



## PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

- 20. List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the service (please attach a statement of clinical relevance from each group nominated):**

Gastroenterological Society of Australia (GESA)

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

Capsule Endoscopy is used in addition to other investigative services and provided by the same group of clinicians. For diagnosis of suspected CD – it does not replace other investigative services in general. For assessment of known isolated small bowel Crohn’s use, CE may be used in addition to and/or replace alternative investigative services in exceptional situations. Thus we do not expect any significant impact on groups who provide other diagnostic modalities.

- 22. List the relevant consumer organisations relevant to the proposed medical service (please attach a letter of support for each consumer organisation nominated):**

Crohn’s and Colitis Society Australia is the relevant consumer organisation for the proposed medical service. Crohn’s and Colitis Society submitted their letter of support to [hta@health.gov.au](mailto:hta@health.gov.au) on November 8<sup>th</sup>, 2016.

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

EndoCapsule by Olympus Australia Pty Ltd, MiRo-Cam by IntroMedic (distributed by C.R. Kennedy), CapsoCam Plus by CapsoVision (distributed by Device Technologies), PillCam by Medtronic Australasia Pty Ltd.

- 24. Nominate two experts who could be approached about the proposed medical service and the current clinical management of the service(s):**

Name of expert 1:

Telephone number(s):

Email address:

Name of expert 2:

Telephone number(s):

Email address:

Justification of expertise:

*Please note that the Department may also consult with other referrers, proceduralists and disease specialists to obtain their insight.*

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

### **PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION**

#### **25. Define the medical condition, including providing information on the natural history of the condition and a high level summary of associated burden of disease in terms of both morbidity and mortality:**

Crohn's disease (CD) is characterized by recurring episodes of inflammation of any part of the gastrointestinal tract. CD may involve segments of small bowel other than the ileum and isolated small bowel disease can present a diagnostic challenge since it is beyond the reach of colonoscopy with ileoscopy. Imaging modalities with CTE and/or MRE do not provide clear picture of the mucosa or its response to therapies. Isolated small bowel involvement can occur in one third of the patients. These patients can have symptoms such as abdominal pain, diarrhoea, vomiting, or weight loss. They may also experience local small bowel complications (e.g., bleeding, obstruction, fistulae) and complications outside the gastrointestinal tract (e.g., skin rashes, arthritis, inflammation of the eye and fatigue). It is most common in adolescents and young adults, but can occur at any age. There is no single test that can be used to diagnose Crohn's disease, so a combination of tests is usually required. Currently this patient group can remain undiagnosed for years and continue to cycle through rounds of futile diagnostic tests. Early diagnosis to facilitate optimal treatment is a significant consideration in the management of Crohn's disease.

Crohn's disease is a lifelong condition which often requires repeat diagnostic investigations to evaluate and assess disease. Patients may undergo imaging as frequently as several times a year or not at all depending on their progress and disease severity. 50-60% of patients require surgery at some point, to manage their disease. Many require repeat surgery for recurrent disease despite treatment with pharmacotherapy. Management depends on the disease location, disease severity, and disease-associated complications (Zimmermann and Al-Hawary, 2011). Crohn's disease has variable clinical presentation of symptoms and prognosis which all contribute to the challenge of managing the disease. Successful Crohn's disease management begins with an accurate diagnosis and assessment of disease activity, including its precise location in the gastrointestinal tract. Choices for both medical and surgical treatment options will be guided by ongoing clinical and diagnostic assessment of disease activity.

A recent report from PricewaterhouseCoopers (2013) highlights the need for coordination for long-term surveillance to monitor increased cancer risks, management of medications and the broader needs of an IBD sufferer. According to this report, over 74,955 Australians are burdened with a constant and often hidden struggle due to inflammatory bowel diseases including Crohn's disease that affects a sufferer's personal, social and work life. Direct costs resulting from hospitalisation are also increasing, with a significant cost burden related to healthcare utilisation. A comprehensive analysis of total costs for IBD cases including Crohn's disease is difficult due to limited publicly available data and as sufferers of IBD also access hospital services for illnesses potentially unrelated to their chronic condition. This report also states that in 2012 the productivity losses attributable to IBD amounted to over \$380 million. An additional \$2.7 billion of financial and economic costs have been associated with the management of IBD.

Begg et al. (2007) reported that inflammatory bowel disease (which includes Crohn's disease and ulcerative colitis) accounted for 0.5% of the total disease burden in Australia in 2003. Crohn's disease may carry a small increased risk of mortality (Osterman 2006) and a large effect on morbidity due to its negative influence on employment, social life, psychological distress and sexual dysfunction (Morrison et al 2009). Crohn's disease impairs quality of life due to the challenges associated with symptoms such as abdominal pain and diarrhoea. Factors that concern patients include the uncertainty of the disease, adverse effects of medication, having to use an ostomy bag, low energy levels and the possible need for surgery (Pihl-Lesnovska et al 2010). Crohn's disease exerts a significant burden to individuals since it is an incurable chronic condition that manifests most commonly in adolescents and young adults. It substantially impairs quality of life due to the experience of symptoms such as abdominal pain and diarrhoea. Factors that concern patients include the uncertainty of the

disease, adverse effects of medication, incontinence, having to use an ostomy bag, low energy levels and the possible need for surgery.

Two meta-analyses reported standardized mortality ratios for patients with Crohn's disease. A small but statistically significant increase in mortality (standardized mortality ratio 1.39 (95%CI: 1.3-1.49) has been reported (Duricova et al., 2010). The higher number of deaths relative to population norms was explained by increased deaths from gastrointestinal diseases (including Crohn's disease) as well as other diseases (COPD, lung disease and genitourinary disease). In a second study including 13 published studies from 1970, a meta-analysis found an elevated risk of mortality for individuals with Crohn's disease (standardized mortality ratio 1.52 (95%CI: 1.32-1.74),  $p < 0.001$  (Canavan et al., 2007). Many of the studies in the review, however, do not reflect current clinical practice and improved therapies. Access Economics report (2007) states that Crohn's disease is associated with a 47% increase in mortality risk.

In a recent prospective, population-based study of inflammatory bowel disease incidence, the Asia-Pacific Crohn's and Colitis Epidemiology Study, the crude annual overall incidence of Crohn's disease in Australia during 2011-2012 was 14.00 (95%CI: 10.09-18.92) per 100,000 persons (n=49) (Ng et al., 2013). This equates to approximately 3,220 new cases each year in Australia. In this study, there were slightly more females (51%) than males (49%) and all incident cases were Caucasians with a mean age of 40 years. The peak age of diagnosis was 20-24 years with a second smaller peak at 40-44 years. The ratio of Crohn's disease to ulcerative colitis in Australia was 2:1. Median time from the onset of symptoms to diagnosis was 5½ months (interquartile range 1.4 – 15 months) and 25% of patients were diagnosed as an inpatient. (Ng et al., 2013).

**26. Specify any characteristics of patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed medical service, including any details of how a patient would be investigated, managed and referred within the Australian health care system in the lead up to being considered eligible for the service:**

As discussed above, the proposed MSAC submission consists of two distinct indications for Capsule Endoscopy in Small Bowel Crohn's Disease. The first indication is for the diagnosis of patients with suspected small bowel Crohn's Disease, while the second relates to the assessment of patients with known small bowel Crohn's Disease. The Capsule Endoscopy service would be provided by the Specialist Gastroenterologist managing the patients with Known/Suspected Small Bowel Crohn's Disease. Initially patients would generally be referred by General Practitioners other specialists to a Gastroenterologist based on a combination of medical history, physical examination, laboratory findings and possibly initial imaging investigations suggesting the possibility of Small Bowel Crohn's disease.

**Diagnosis of Suspected Small Bowel Crohn's Disease**

Patients eligible to receive capsule endoscopy should have objective evidence of inflammation (elevated CRP, ESR or Faecal Calprotectin) and Gastrointestinal (GI) symptoms such as abdominal pain and diarrhoea. They should have undergone prior colonoscopy with ileoscopy, prior radiographic imaging with CTE or MRE and still remain with a non-diagnostic result. These patients will typically have failed to achieve a diagnosis by ileoscopy due to inaccessibility of most of the small bowel using this modality and inability of imaging modalities to discern subtle mucosal lesions.

**Assessment of Patients with Known Small Bowel Crohn's Disease**

Crohn's disease is a heterogeneous disease showing a wide spectrum of symptoms, severity, anatomical distribution and response to treatment. This necessitates the need for patient specific tailoring of investigative pathways when evaluating the disease.

Patients eligible to receive capsule endoscopy for the assessment of Known isolated small bowel Crohn's disease should have had prior colonoscopy with ileoscopy and demonstration of non stricturing small bowel disease involvement with either MRE or prior capsule endoscopy. Capsule Endoscopy can be used in this patient population to assess mucosal healing response after various treatments and inform medical decisions

regarding cessation, modification or escalation of therapy. It can also be used to evaluate mucosa during suspected complications or exacerbations of known isolated non stricturing small bowel Crohn's disease.

Assessment of Known Isolated Small Bowel Crohn's disease with Capsule Endoscopy will be of particular value in the following sub-populations of patients:

- In the assessment of suspected post-operative recurrence of small bowel Crohn's disease where colonoscopy with ileoscopy is contraindicated or cannot access remaining proximal small bowel and MRE can underestimate superficial lesions. Disease recurs in most Crohn's disease patients after intestinal resection, with endoscopic recurrence preceding clinical recurrence. We consider that capsule endoscopy is a potential alternative in selected patients who have had surgical resections that are not accessible by ileoscopy.
- Assessment of paediatric patients where ileoscopy is contraindicated and MRE might underestimate superficial mucosal lesions: Given the serious consequences of Crohn's on growth and development, early and accurate assessment of paediatric patients is essential. Although diagnostic evaluation in children and adolescents is recommended as soon as IBD is suspected, delayed diagnosis remains a significant problem in this population. The mean delay in diagnosis is 7–11 months for paediatric Crohn's disease (Cuffari 2009). Diagnosis may be particularly difficult in children and adolescents who present with less than typical symptoms and/or extra intestinal manifestations (e.g., short stature, chronic anaemia, unexplained fever, arthritis, mouth ulcers)

**27. Define and summarise the current clinical management pathway *before* patients would be eligible for the proposed medical service (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway up to this point):**

**Diagnosis of Suspected Small Bowel Crohn's Disease (Please refer to Appendix for flowcharts Figure 1 and Figure 3)**

Diagnosis of small bowel Crohn's disease can be difficult as the symptoms for Crohn's disease mimic those of ulcerative colitis and other gastrointestinal conditions. Currently, there is no single test to diagnose all patients with Suspected Small Bowel Crohn's disease. In the absence of an agreed 'gold standard' test, diagnosis of Crohn's disease is based on patient history, physical examination, radiographic imaging, endoscopic evidence, specimen histopathology and laboratory findings. Ileocolonoscopy is commonly used to diagnose Crohn's disease as first-line testing. In most cases, a definitive diagnosis of Crohn's can be made but sometimes the results of ileocolonoscopy are inconclusive due to the inability of ileocolonoscopy to view small bowel. In this case radiological imaging (MRE) is often undertaken as a second line test to confirm the diagnosis of Crohn's disease. This can provide useful information such as the presence of small bowel stricturing. However it does not provide direct visualisation of mucosal inflammation and there are cases where after imaging does not provide diagnostic information. In this case, Capsule Endoscopy with a high negative predictive value can exclude Crohn's disease and prevent further exams in the absence of obstructive symptoms or known stenosis.

In the absence of CE, patients without diagnostic information of Crohn's disease after testing with ileocolonoscopy and imaging, can cycle through repeated futile investigations until their disease substantially progresses. In contrast to earlier applications (MSAC application 1146 and 1146.1), this submission does not assume patients who do not have a definitive diagnosis of CD would be treated empirically (e.g. with immunosuppressants such as azathioprine, 6-mercaptopurine or methotrexate and tapering doses of corticosteroids) based on recent discussions with clinical experts. Alternatively, a small number of patients may undergo bidirectional double balloon enteroscopy which is more invasive and associated with its own risk profile and of limited use in Australia.

**Assessment of Patients with Known Small Bowel Crohn’s Disease (Please refer to Appendix for flowcharts Figure 2 and Figure 3)**

Following diagnosis for patients with isolated small bowel known Crohn’s disease in the absence of obstructive symptoms or known stenosis, the assessment of their disease activity to drive treatment decisions and guide changes in therapy for this patient population utilizes Capsule Endoscopy. A small number of patients may experience recurrent or continued symptoms, requiring subsequent assessment with ileocolonoscopy and MRE. This group includes post-operative patients with non-diagnostic findings from prior imaging, who may require confirmation of recurrent CD in order to be eligible for treatment with biologic therapies.

**PART 6b – INFORMATION ABOUT THE INTERVENTION**

**28. Describe the key components and clinical steps involved in delivering the proposed medical service:**

Clinician consultation: preliminary discussion/communication with patient to guide patient before the procedure with specific instructions. These instructions may include food/drink requirement, medications and medical history. An empty stomach is optimal for viewing, so patients may be required to follow a clear liquid diet after lunch the day prior to the procedure and to begin fasting at midnight. The clinician will also discuss medication the patient regularly takes that might need dose adjustment prior to the Capsule Endoscopy procedure. The clinician also discusses the medical history of the patient, including whether the patient has a pacemaker or other implantable electronic device, any previous abdominal surgery, swallowing problems or previous history of obstructions in the gastrointestinal tract.

Time is taken to prepare the patient and instruct the patient to swallow the capsule. The sensor or sensor belt is applied to the patient and connected to the recorder. The patient then swallows capsule. At the end of this part of the procedure, the patient can leave the healthcare setting and go about normal daily activities. After the test, the patient comes back to the healthcare setting and the test equipment is removed. After this the clinician downloads the images to a computer and will read and analyse these images to provide a full report.

In diagnosis of suspected Crohn’s and assessment of known Crohn’s clinicians looks for images of mucosal fissuring, linear ulcers, round ulcers, irregular ulcers, cobble stoning mucosa, aphthous lesions, or strictured and ulcerated areas of mucosa scarring. Additionally clinicians also observe bleeding lesions, polyps, and pseudo polyps suggestive of Crohn’s Disease. Other minor lesions, such as erythema, oedema, loss of villi, denudated area, or aphthous ulcer, not visualized by conventional radiological techniques, can be detected by the clinician while evaluating suspected and/or known Crohn’s disease cases. According to the Capsule Endoscopy scoring index, 3 parameters are utilised by the clinician: Villous appearance: normal/oedematous (longitudinal extent); Ulceration: number, size (longitudinal extent); Stenosis: Number and associated ulceration (which are weighted based on extent and severity).

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

**30. If the proposed medical service has a prosthesis or device component to it, does it involve a new approach towards managing a particular sub-group of the population with the specific medical condition?**

Yes. Capsule Endoscopy is a minimally invasive and well tolerated test with a high diagnostic yield.

30% of patients will have Crohn’s disease restricted to the small bowel that will be beyond the reach of the ileocolonoscopy. Capsule Endoscopy is also able to detect subtle mucosal lesions that may not be detected on small bowel radiological examinations. As previously outlined this potentially would enable patients who have not had a conclusive diagnosis in Suspected Small Bowel Crohn’s Disease to avoid repeated rounds of potentially futile testing whilst awaiting for disease progression. This is particularly important in the paediatric sub-population where delays in diagnosis can have developmental consequences. In patient with known

Isolated Proximal Small Bowel Crohn's Disease the post-surgical subpopulation with disease distribution not readily accessible for direct visualisation by ileoscopy could be monitored for evidence of mucosal recurrence including subtle lesions not easily identified by imaging.

**31. If applicable, are there any limitations on the provision of the proposed medical service delivered to the patient (i.e. accessibility, dosage, quantity, duration or frequency):**

For diagnosis of Suspected Crohn's capsule endoscopy should be performed to the same patient on not more than 1 occasion in any 12 month period.

Evaluation of exacerbation/suspected complications of patients with known small bowel Crohn's disease should be performed to the same patient on not more than 1 occasion in any 12 month period.

Assessment of change to therapy in patients with known small bowel Crohn's disease should be not more than 1 occasion in any 12 month period.

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

Not applicable.

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

Gastroenterologists will deliver the service.

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

Not applicable.

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

Specialists or consultant physicians performing this procedure must have endoscopic training recognized by The Conjoint Committee for the Recognition of Training in Gastrointestinal Endoscopy, and Medicare Australia notified of that recognition. Referral group consists of GPs, surgeons or Gastroenterologists who do not have the qualifications required to perform a Capsule Endoscopy.

**36. If applicable, advise what type of training or qualifications would be required to perform the proposed service as well as any accreditation requirements to support service delivery:**

Specialists or consultant physicians performing this procedure must have endoscopic training recognised by The Conjoint Committee for the Recognition of Training in Gastrointestinal Endoscopy, and Medicare Australia notified of that recognition.

**37. (a) Indicate the proposed setting(s) in which the proposed medical service will be delivered (select all relevant settings):**

- Inpatient private hospital
- Inpatient public hospital
- Outpatient clinic
- Emergency Department
- Consulting rooms
- Day surgery centre
- Residential aged care facility
- Patient's home
- Laboratory
- Other – please specify below

N/A

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

**Consulting rooms** – This setting is required for patients which consults directly for procedure.

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

- Yes  
 No – please specify below  
N/A

**PART 6c – INFORMATION ABOUT THE COMPARATOR(S)**

**39. 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 (including identifying health care resources that are needed to be delivered at the same time as the comparator service):**

The course of Crohn’s disease is heterogeneous which requires case by case approach. Hence, availability of different diagnostic tools is critical to assess small bowel mucosal inflammation. Despite this heterogeneous nature of patient population, from a general clinical perspective the comparators can be stated as follows:

**Diagnosis of Suspected Small Bowel Crohn’s Disease:**

In the absence of Capsule Endoscopy after failure to make a definite diagnosis of Crohn disease after endoscopy and radiographic imaging, the comparator is “usual care” mainly consisting of repeat endoscopic and radiological investigations until such time as CD is definitively diagnosed. It should be noted these tests are often futile unless the disease has had sufficient time to progress substantially. In patients whose underlying diagnosis is actually IBD, testing can continue until disease symptoms subside. Discussions with clinicians suggest empiric treatment is NOT used in patients do not have a definitive diagnosis of CD, as these are chronic therapies with a serious adverse event profile. This is in contrast to previous submissions for the diagnostic indication (Application 1146 and 1146.1), where empiric therapy was nominated as the main comparator. Another potential comparator is bidirectional double balloon enteroscopy. This technology is most analogous to CE in terms of the type of imaging provided (i.e. can visualise small bowel mucosa); however as it is an invasive procedure that involves its own risk profile including anaesthetic exposure. It is infrequently performed in Australia. Furthermore, the current MBS item does not include its use in Crohn’s disease.

**Assessment of Patients with Known Small Bowel Crohn’s Disease:**

In patients who require assessment of mucosal response to therapy to guide decision making and patients who require evaluation of exacerbation/suspected complications in non stricturing isolated small bowel Crohn’s disease, the comparators are variable on a case by case basis. They include ‘watchful waiting’ with monitoring of blood tests and inflammatory biomarkers as well as imaging usually in the setting of acute exacerbation.

**40. Does the medical service that has been nominated as the comparator have an existing MBS item number(s)?**

- Yes (please provide all relevant MBS item numbers below)  
 No

In general, Capsule Endoscopy will not replace ileocolonoscopy or radio imaging. However for special situations stated in previous sections, it can replace radio imaging modalities particularly Item 63740: MRI Enterography to evaluate small bowel Crohn’s disease.

**41. Define and summarise the current clinical management pathways that patients may follow *after* they receive the medical service that has been nominated as the comparator (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway that patients may follow from the point of receiving the comparator onwards including health care resources):**

**Diagnosis of Patients with Suspected Small Bowel Crohn’s Disease (Please refer to Appendix for flowcharts Figure 1 and Figure 3)**

Currently, patients with suspected Small Bowel Crohn’s Disease continue through cycles of endoscopic and radiologic imaging. A small proportion may eventually receive a confirmed diagnosis of CD if the disease progresses to the point that it can be visualised using these other modalities. Others, including those patients with an underlying diagnosis of IBD will continue to be tested and may receive inappropriate treatment.

Generally, after a positive diagnosis of Crohn’s with previous ileocolonoscopy or MRE, a treatment plan is organized according to patient’s disease activity, behaviour and localization of disease, and associated complications. Present therapeutic approaches is considered sequential to treat “acute disease” or “induce clinical remission,” and then to “maintain response/remission”, minimise side effects of treatment and improve quality of life. Non-surgical treatment includes dietary measures and drug therapy. Corticosteroids, antibiotics and anti TNF agents are used to induce remission, and immunosuppressive agents or maintenance anti TNF therapy to maintain remission. Surgical removal of the affected bowel is sometimes necessary but this is not curative as the disease can recur in other sites. Some people with Crohn’s disease however have long periods of symptom-free remission. The patients’ response to initial therapy should be evaluated within several weeks, whereas adverse events should be monitored closely throughout the period of therapy. Treatment for active disease should be continued to the point of symptomatic remission or failure to continue improvement. In general, clinical evidence of improvement should be evident within 2–4 weeks and the maximal improvement should occur with 12–16 weeks. Patients achieving remission should be considered for maintenance therapy. Those with continued symptoms should be treated with an alternative therapy for mild to moderate disease or advanced to treatment for moderate to severe disease according to their clinical status (Lichtenstein et al. 2009).

**Assessment of Patients with Known Small Bowel Crohn’s Disease (Please refer to Appendix for flowcharts Figure 2 and Figure 3)**

When patient symptoms are not resolved or getting worse in spite of treatment; there is a discrepancy between symptoms and blood or faecal tests or a decision has to be made as to whether to proceed with different medical management or to pursue surgery. This type of investigation may be required on more than one occasion during a patient’s life.

Currently, patients with known CD who are symptomatic and/or with objective evidence of inflammation who have non-diagnostic results on imaging, will have their management determined by clinical judgement. In the absence of a confirmatory diagnosis they may be subject to watchful wait without and adjustment to their therapy or cycle through repeated testing and acute presentations to healthcare services. In case of diagnostic information through investigations, they may be subject to escalation in their therapy or de-escalation depending on their disease state.

**42. (a) Will the proposed medical service be used in addition to, or instead of, the nominated comparator(s)?**

For diagnosis of suspected CD – it replaces repeated investigations in case of non-diagnostic findings from previous modalities.

For Assessment of Known isolated small bowel Crohn’s disease, CE may be used in addition to and/or replace alternative investigative services in sub populations such as post-operative recurrence and paediatrics where other modalities are contraindicated.

- Yes
- No

**(b) If yes, please outline the extent of which the current service/comparator is expected to be substituted:**

- Yes
- No



**If yes, please outline the extent of which the current service/comparator is expected to be substituted:**

For the diagnosis of suspected CD, the proposed service is anticipated to substitute for the comparator where there is no evidence of strictures.

Only for special situations such as post-operative recurrence of isolated proximal small Crohn's disease and paediatric population where ileoscopy contraindicated/failed to provide diagnostic information, suspicion of MRE might underestimate superficial mucosal lesions; Capsule Endoscopy can be used instead of the comparators. Thus the extent of the use is expected to be minimal.

**43. Define and summarise how current clinical management pathways (from the point of service delivery onwards) are expected to change as a consequence of introducing the proposed medical service including variation in health care resources (Refer to Question 39 as baseline):**

**Diagnosis of Patients with Suspected Crohn's Disease**

CE will prevent patients with suspected Small Bowel Crohn's Disease from cycling through repeated investigations including colonoscopy and imaging. Those who do have Small Bowel Crohn's Disease will have their diagnosis confirmed and commence therapy for Crohn's Disease. Others will have Small Bowel Crohn's Disease ruled out definitively, and can avoid repeated diagnostic procedures or exposure to the serious risks of empiric treatment without diagnosis. Therefore, there will be increased use of therapies for CD, but decreased use of endoscopic and radiologic services.

In a recent multicentre prospective cohort study of French CD patients, a long diagnostic delay (>13 months) increased the risk of early surgery (Nahon 2016). A Swiss IBD cohort study reported that a long diagnostic delay was associated with the further development of bowel stenosis and intestinal surgery (Schoepfer 2013). A Korean study demonstrated that a long diagnostic delay is significantly associated with an increased risk of CD-related complications such as intestinal stenosis, internal fistulas, and perianal fistulas. Moreover, older age at diagnosis ( $\geq 40$  years), concomitant upper gastrointestinal involvement, and penetrating disease behaviour are closely associated with diagnostic delay in CD patients (Moon 2015). A retrospective study in Chinese patients also demonstrated that diagnostic delay of Crohn's disease was significantly associated with increased rates of intestinal surgery (Yi 2015). Delayed diagnosis of Crohn's Disease especially in adolescents has psychiatric implications as well (Gabel 2010). On the basis of these results, reducing the diagnostic delay of CD may reduce the occurrence of many disabling complications associated with CD. Hence healthcare expenditures associated with delayed diagnosis will be prevented as Capsule Endoscopy is included in the diagnostic algorithm.

**Assessment of Known Small Bowel Crohn's Disease**

In the current clinical management there can be uncertainties in the assessment of patients who have a suspected post-operative recurrence of disease or known disease where assessment is required to evaluate response to therapy or a potential exacerbation. Current investigations with ileocolonoscopy, and/or MRE may not provide diagnostic information or can be contraindicated.

In this case, capsule endoscopy can remove uncertainty and repeat investigations in the face of a mismatch between objective inflammation evidence and symptoms due its higher diagnostic yield and ability to visualise subtle mucosal lesions in the isolated small bowel Crohn's disease. Capsule Endoscopy can assess the inflammatory state of mucosa after various treatments, or as a prognostic tool, guide treatment (escalation or de-escalation of treatment) thus will reduce any clinical and economic inefficiencies during the course of therapy. CE offers a non-invasive approach to evaluate areas of the small bowel that are difficult to reach with traditional endoscopy. It can guide patient management where symptoms or objective evidence of inflammation escalate or de-escalate and prior investigations remain negative or non-diagnostic.

**PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME**

- 44. Summarise the clinical claims for the proposed medical service against the appropriate comparator(s), in terms of consequences for health outcomes (comparative benefits and harms):**

**Diagnosis of Patients with Suspected Crohn’s Disease**

Capsule endoscopy relative to repeat endoscopic radiologic imaging will provide: Improved quality of life (QALY) in those patients who receive a confirmed diagnosis of CD, and are able to receive appropriate treatment. Patients in whom CD is excluded will also have QALY gains due to cessation of diagnostic investigations and the commencement of appropriate care (e.g. for IBD).

**Assessment of Known Crohn’s Disease**

Capsule endoscopy relative to “watch and wait” will provide improved quality of life in those patients who receive a confirmed diagnosis of recurrent or continuing small bowel Crohn’s disease, and enable access to appropriate therapies.

- 45. Please advise if the overall clinical claim is for:**

- Superiority  
 Non-inferiority

- 46. Below, list the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be specifically measured in assessing the clinical claim of the proposed medical service versus the comparator:**

**Safety Outcomes:**

Treatment related Adverse Events

**Clinical Effectiveness Outcomes:**

Sustained clinical remission

Symptom Relief

Time to a definite diagnosis

Diagnostic performance

Diagnostic yield

Impact on patient management i.e. % change in management plans (for example from medical to surgery)

Health Related Quality of Life

Decreased need for surgery

Decreased need for corticosteroids

Decreased hospitalisation

## PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

### 47. Estimate the prevalence and/or incidence of the proposed population:

An Australian study in the regional Victorian city of Geelong found a crude annual incidence of 17.4 (95% CI =13 to 23) per 100,000 in 2008 (Wilson et al 2010). In a recent prospective, population-based study of inflammatory bowel disease incidence, the Asia- Pacific Crohn's and Colitis Epidemiology Study, the crude annual overall incidence of Crohn's disease in Australia during 2011-2012 was 14.00 (95%CI: 10.09-18.92) per 100,000 persons (n=49) (Ng et al., 2013).

### 48. Estimate the number of times the proposed medical service(s) would be delivered to a patient per year:

Estimated number of times the proposed medical service would be delivered to patient per year for Diagnosis of small bowel Suspected Crohn's should not be more than once a year.

Estimated number of times the proposed medical service would be delivered to patient per year for Assessment of Known Crohn's should not be more than once a year.

### 49. How many years would the proposed medical service(s) be required for the patient?

Diagnosis of small bowel Suspected Crohn's: Once after indeterminate colonoscopy with ileoscopy and non-diagnostic negative/non diagnostic result from CTE/MRE.

Assessment of small bowel Crohn's: Since it is not a curable disease and a long term chronic condition, ongoing assessment might be required. Due to heterogeneous disease course, total number of years required for the proposed service may differ from patient to patient.

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

#### Diagnosis of Patients with Suspected Small Bowel Crohn's Disease

##### *Estimates presented in the July 2011 Assessment Report*

The July 2011 Assessment Report (Gilbert et al 2011) suggested that the estimated utilisation of capsule endoscopy for the diagnosis of small bowel Crohn's disease unconfirmed on prior tests lies between 664 and 1,431 per year, as summarised in Table below.

These estimates were based on the incidence of Crohn's disease reported in Australia (Wilson et al 2010) and the test's estimated diagnostic yield as reported by Selby et al (2008) and Tukey et al (2009). Wilson et al (2010) was the only Australian population-based incidence study for Crohn's disease. In addition, the Advisory Panel estimated that approximately 95% of cases would be diagnosed by prior tests, leaving 5% of incident cases diagnosed by capsule endoscopy.

## Usage estimates for capsule endoscopy included in the July 2011 Assessment Report (Gilbert et al 2011, pg 23)

Row	Variable	Estimates	Source
A	Estimated incidence of Crohn's disease	3,719	Gilbert et al 2011, pg 23
	Cases diagnosed using prior tests		
B	- % diagnosed using other tests	95%	Advisory Panel (July 2011 Assessment Report)
C	- Diagnosed cases	3,533	A x B
	Cases diagnosed by capsule endoscopy		
D	- % diagnosed using CE	186	A - C
	Diagnostic yield		
E	- High	28%	Selby et al 2008, Tukey et al 2009
F	- Low	13%	Selby et al 2008, Tukey et al 2009
	Total capsule endoscopy procedures		
G	- Based on high yield rate	664	Calculated, D / E
H	- Based on low yield rate	1,431	Calculated, D / F

Source: Gilbert et al 2011

Note: Wilson et al (2010) remains to be the only population-based epidemiological data for Crohn's disease in Australia; confirmed by a PubMed search ((Crohn OR Inflammatory bowel disease) AND Epidemiology) AND Australia, performed on the 15<sup>th</sup> May 2013.


The Assessment Report estimated that, if the number of Australian cases of Crohn's disease is approximately 3,719 per year, and 5% (expert opinion of the Advisory Panel) of these are diagnosed by capsule endoscopy for the indication of small bowel Crohn's disease, then the estimated number of patients diagnosed with Crohn's disease by capsule endoscopy is approximately 186 per year. When the diagnostic yield of capsule endoscopy is taken into account (i.e., a positive diagnosis between 13% and 28%; Selby et al 2008, Tukey et al 2009), the estimated number of capsule endoscopy procedures performed – including those with a positive and negative result – can be estimated by dividing the anticipated number of patients diagnosed with Crohn's disease by capsule endoscopy (approximately 186 per year) by the estimated yield of the test (between 13% and 28%) and lies between 664 and 1,431 per year.

The Assessment Report noted the possible presence of overlap between the proposed Crohn's disease indication and the existing OGIB indication. The extent of this is uncertain. According to Wilson et al (2010), 5 out of 45 cases were diagnosed by capsule endoscopy to investigate iron deficiency or GI bleeding where the colonoscopy was indeterminate or negative; suggesting there are some diagnoses of Crohn's disease being made under the current OGIB listing.

### Assessment of Patients with Known Crohn's Disease

According to Medicare data, there were 6171 services for item number 63740: Magnetic Resonance Imaging, MRI to evaluate small bowel Crohn's disease for in September 2015 – September 2016. According to this data, we expect Capsule Endoscopy will be a subset of this population. Detailed analysis will be presented in the evaluation phase.

### Requested Medicare items processed from September 2015 to September 2016

 Click on the item hyperlinks below to get the patient age/gender breakdown of that particular item

Item	State					Total
	NSW/ACT	VIC/TAS	QLD	SA/NT	WA	
	Services	Services	Services	Services	Services	Services
<a href="#">63740</a>	2,141	1,938	1,292	539	261	6,171

**51. Estimate the anticipated uptake of the proposed medical service over the next three years factoring in any constraints in the health system in meeting the needs of the proposed population (such as supply and demand factors) as well as provide commentary on risk of 'leakage' to populations not targeted by the service:**

The applicant considers criteria used to define the eligible patient population in this application will minimize the risk of leakage. The uptake will be determined during the evaluation phase.

## PART 8 – COST INFORMATION

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

The current MBS fee for capsule endoscopy (performed for MBS items 11820 and 11823) is \$1,961.95. This includes the cost of capsule endoscopy technology required to deliver the service. The Applicant proposes the same MBS fee for the proposed services in this application form.

**53. Specify how long the proposed medical service typically takes to perform:**

Initial consultation time takes approximately 30-45 minutes. The procedure takes 1.5 hr for diagnosis of suspected Crohn's.

Initial consultation time takes approximately 30-45 minutes. The procedure takes 1.5 hr for assessment of patients with known Crohn's.

**54. If public funding is sought through the MBS, please draft a proposed MBS item descriptor to define the population and medical service usage characteristics that would define eligibility for MBS funding.**

**Diagnosis of Suspected Small Bowel Crohn's Disease**

**Table 1: Proposed MBS item descriptor for capsule endoscopy for small bowel Crohn's disease**

Category 5 – Diagnostic Imaging Services
<p>1) to diagnose suspected small bowel Crohn disease, using a capsule endoscopy device (including administration of the capsule, imaging, image reading and interpretation, and all attendances for providing the service on the day the capsule is administered), if:</p> <p>(a) The patient to whom the service is provided :</p> <p>ii. has not been previously diagnosed with Crohn's disease</p> <p>iii. has suspected Crohn's disease on the basis of objective evidence of inflammation (ESR,CRP, Faecal Calprotectin) and gastrointestinal symptoms; and</p> <p>(b) The service is performed by a specialist or consultant physician with endoscopic training that is recognized by The Conjoint Committee for the Recognition of Training in Gastrointestinal Endoscopy; and</p> <p>(c) Prior negative colonoscopy with attempted ileoscopy has been performed on the patient, and has not produced a diagnostic finding of Crohn's disease; and</p> <p>(d) Prior radiographic imaging has been performed on the patient, and has not produced a diagnostic finding of Crohn's disease or evidence of strictures. Radiographic diagnostic procedures previously used by the patient may include:</p> <p>iv. magnetic resonance enterography (MRE), or</p> <p>v. computed tomography enterography (CTE), or</p> <p>Conjoint committee</p> <p>The Conjoint Committee comprises representatives from the Gastroenterological Society of Australia (GESA), the Royal Australasian College of Physicians (RACP) and the Royal Australasian College of Surgeons (RACS). For the purposes of Item TBD, specialists or consultant physicians performing this procedure must have endoscopic training recognised by The Conjoint Committee for the Recognition of Training in Gastrointestinal Endoscopy, and Medicare Australia notified of that recognition.</p> <p>Fee:\$2,039.20 Benefit: 75% = \$1,529.40 85% = \$1,964.70</p>

## Assessment of Known Small Bowel Crohn's Disease

**Table 2: Proposed MBS item descriptor for capsule endoscopy for isolated small bowel Crohn's disease**

Category 5 – Diagnostic Imaging Services
<p>Capsule Endoscopy to evaluate isolated small bowel Crohn's disease. Medicare benefits are only payable for this item if the service is provided to patients for:</p> <ul style="list-style-type: none"><li>(a) Evaluation of exacerbation/suspected complications of known Crohn's disease</li><li>(b) Assessment of change to therapy in patients with small bowel Crohn's disease</li></ul> <p>To be eligible for the service patients must have had:</p> <ul style="list-style-type: none"><li>i) Non-diagnostic findings on prior MRI, OR</li><li>ii) Non-stricturing disease</li></ul> <p>The service is performed by a specialist or consultant physician with endoscopic training that is recognized by The Conjoint Committee for the Recognition of Training in Gastrointestinal Endoscopy.</p> <p>Conjoint committee</p> <p>The Conjoint Committee comprises representatives from the Gastroenterological Society of Australia (GESA), the Royal Australasian College of Physicians (RACP) and the Royal Australasian College of Surgeons (RACS). For the purposes of Item TBD, specialists or consultant physicians performing this procedure must have endoscopic training recognised by The Conjoint Committee for the Recognition of Training in Gastrointestinal Endoscopy, and Medicare Australia notified of that recognition</p> <p>NOTE 1: Assessment of change to therapy can only be claimed once in a 12 month period.</p> <p>Fee:\$2,039.20 Benefit: 75% = \$1,529.40 85% = \$1,964.70</p>

## PART 9 – FEEDBACK

The Department is interested in your feedback.

### 55. How long did it take to complete the Application Form?

1 month

### 56. (a) Was the Application Form clear and easy to complete?

- Yes  
 No

#### (b) If no, provide areas of concern:

Although the form is reasonably straight forward to complete, it is somewhat repetitive, particularly questions related to the clinical algorithms (Q.26, Q, 27, Q41, Q43).

Question 42 is somewhat ambiguous with reference to “in addition to, or instead”. It is difficult to answer with “Yes” or “No” to this Question. Question 43 refers to Question 39 as baseline. This should probably refer to Question 41.

### 57. (a) Are the associated Guidelines to the Application Form useful?

- Yes  
 No

#### (b) If no, what areas did you find not to be useful?

### 58. (a) Is there any information that the Department should consider in the future relating to the questions within the Application Form that is not contained in the Application Form?

- Yes  
 No

#### (b) If yes, please advise:

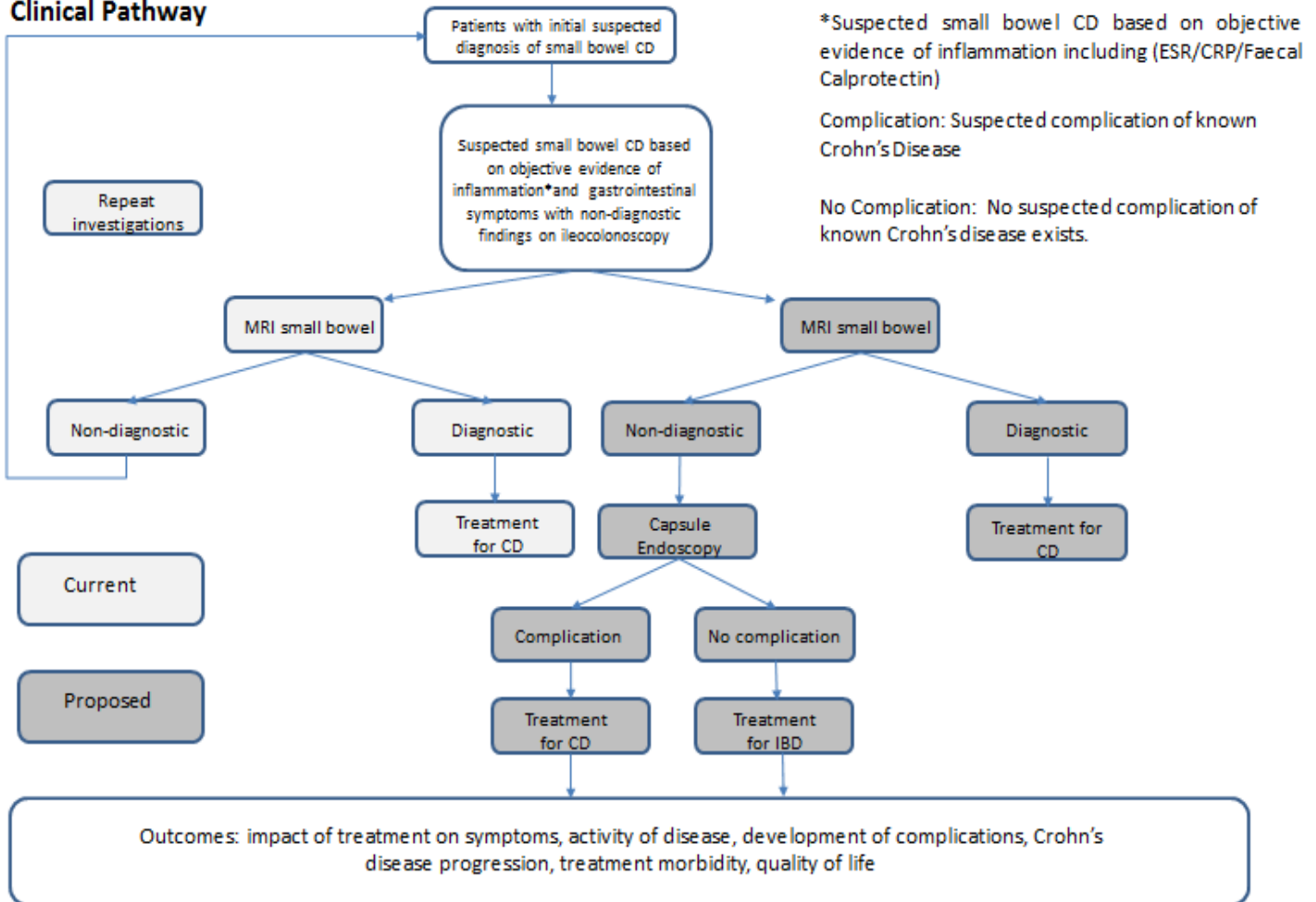
Eligible populations and utilization estimates early in the process of the application can be challenging especially for conditions where publicly available data is scarce. Hence data might be needed from Department of Health to facilitate economic evaluation for instance, the data regarding the indication of Capsule Endoscopy for Diagnosis of Suspected Small Bowel Crohn’s Disease, MBS utilisation data on patients who undergo repeat investigations.



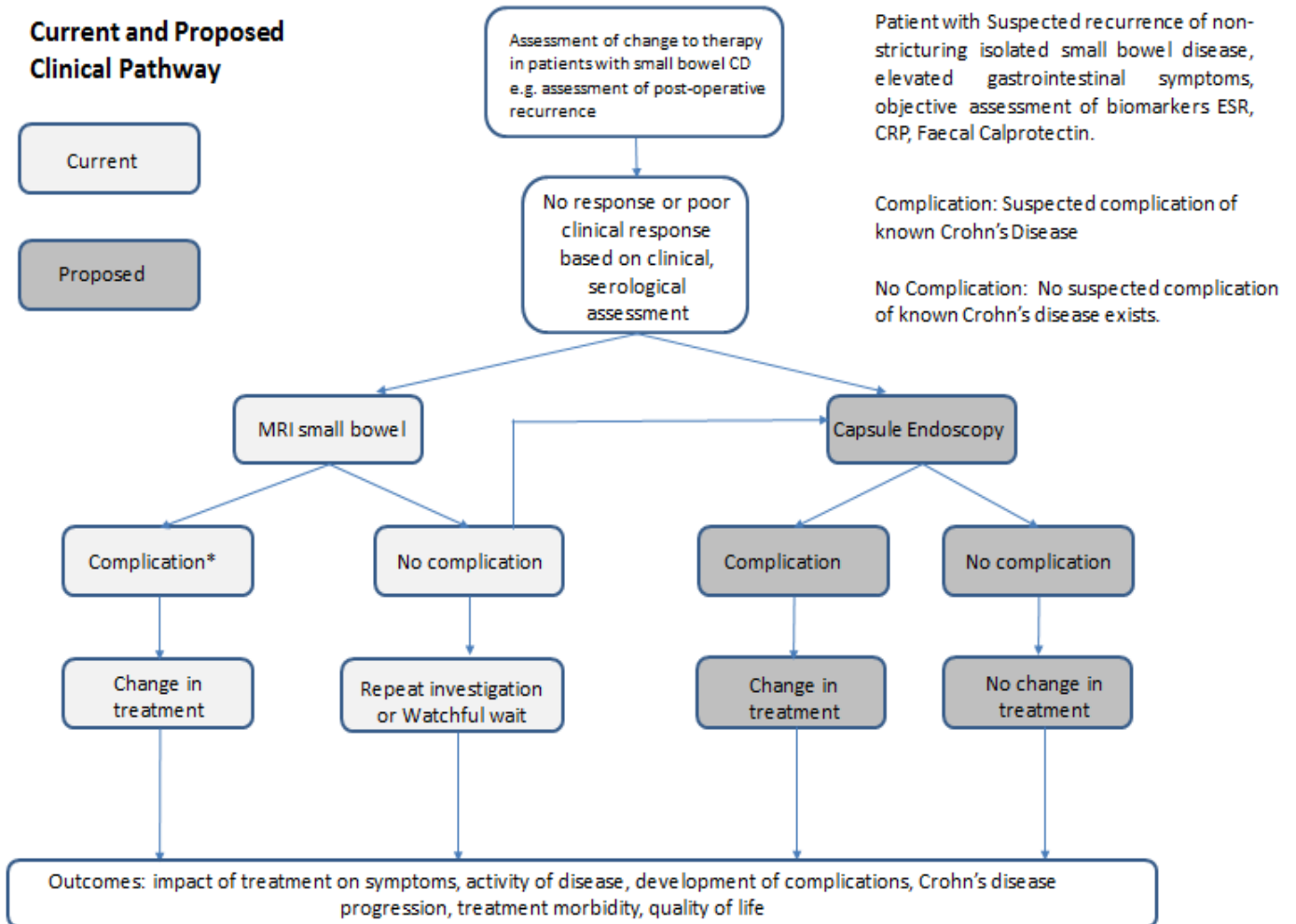
# APPENDIX

Figure 1 Current and Proposed Clinical Pathway before and after patient would be eligible for the current and proposed service

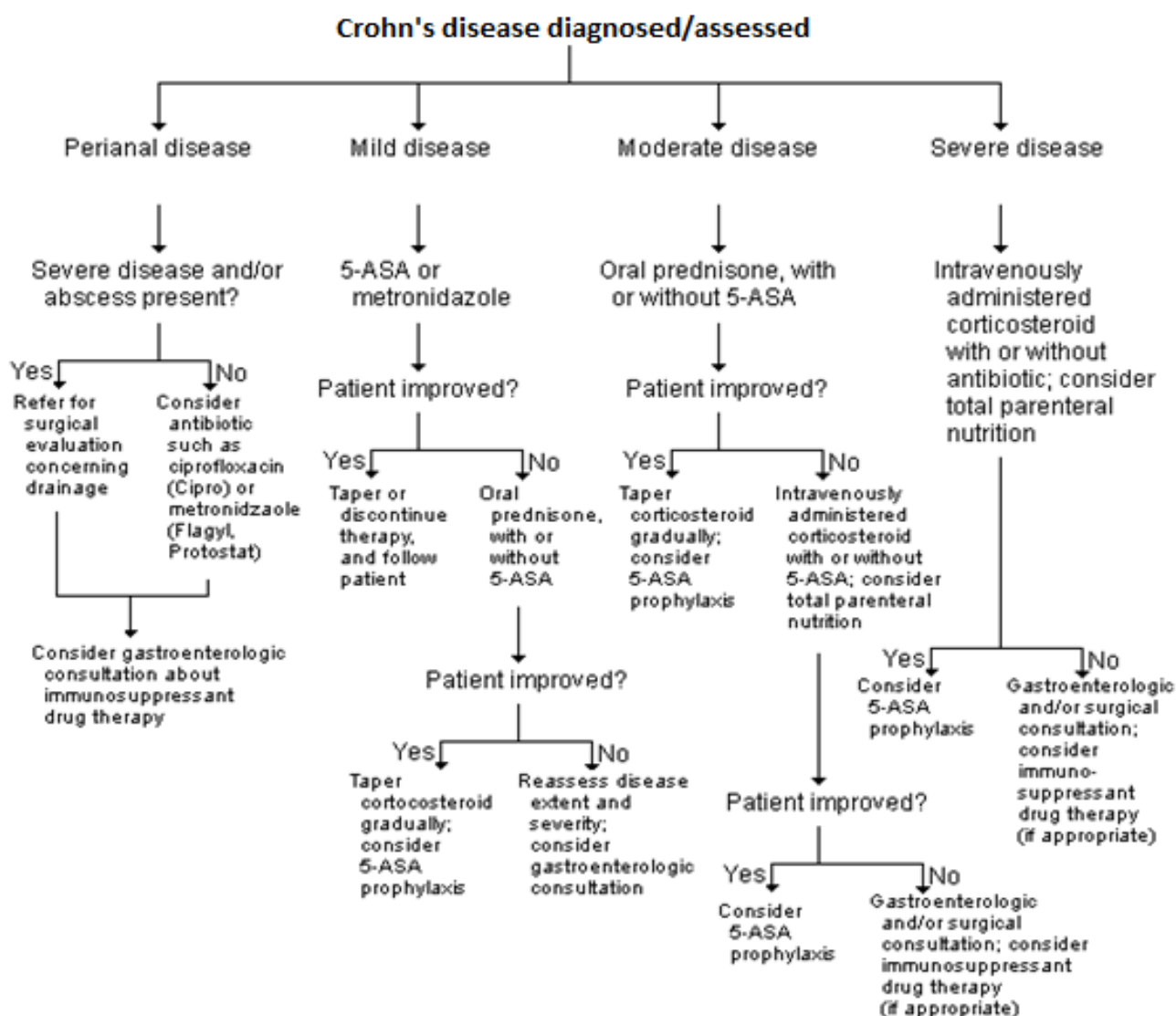
## Current and Proposed Clinical Pathway



**Figure 2 Current and Proposed Clinical Pathway before and after patient would be eligible for the current and proposed service**



**Figure 3 Treatment Pathways for Diagnosed and Assessed Disease**



*Gastroenterologic consultation include introduction of biological therapy as well, if no improvement achieved with above-mentioned medications.*

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