

Feedback Survey

Application 1353- Quantitative measurement of Calprotectin in human stool

The Department of Health is seeking your feedback on the draft protocol for Application 1353 – Quantitative measurement of Calprotectin in human stool. Please note, this protocol has not been ratified by the Protocol Advisory Sub-committee (PASC), a sub-committee of the Medical Services Advisory Committee.

Please reply to the HTA Team

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Email: HTA@health.gov.au

Your feedback is required by **cob 14 November 2014** to enable PASC to consider, when it reviews this protocol, at its meeting of 11-12 December 2014.

PERSONAL AND ORGANISATIONAL INFORMATION

1. What is your name? _____
2. Is the feedback being provided on an individual basis or by a collective group?
 Individual
 Collective group. Specify name of group (if applicable) _____
3. What is the name of the organisation you work for (if applicable)? _____
4. What is your e-mail address? _____
5. Are you a:
 - a. General practitioner
 - b. Specialist
 - c. Researcher
 - d. Consumer
 - e. Care giver
 - f. Other (please specify)

MEDICAL CONDITION (DISEASE)

The symptoms of chronic diarrhoea and abdominal pain can be due to either inflammatory bowel disease (IBD) or irritable bowel syndrome (IBS), a chronic functional gastrointestinal disorder that does not generally require medication or lead to complications. IBS is a syndrome with a diagnosis made on a cluster of symptoms in the absence of structural abnormalities. It does not produce the inflammation found in IBD. It does not result in permanent damage to the intestines, intestinal bleeding, harmful complications and the risk of colon cancer, often associated with IBD. Although there are limited Australian data on the current incidence and prevalence of IBD and IBS (AIHW 2012), IBS in the community is common with a considerable physical and psychological impact on sufferers; it has been estimated to affect about 10% of the Australian population (Gibson 2012). It represents a substantial proportion of the workload of GPs and gastroenterologists (Talley 2006; Quigley et al. 2012). IBS accounts for up to 12% of primary care consultations and 28% of referrals to specialist GI practice (Mitchell and Drossman 1987; Thompson et al. 2000; Dolwani et al. 2004).

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With these symptoms, the crucial diagnostic step is deciding which patients should receive endoscopic and radiological investigations. Differentiating between IBD and IBS often cannot be determined solely on symptoms. A large number of patients are referred for specialist opinion and will undergo endoscopy and colonoscopy for a definitive diagnosis. These investigations carry risks, are costly and require time (1-2 days) to prepare and to undergo. In addition, audits of patients having colonoscopy consistently reveal a large number of inappropriate investigations (Lasson et al. 2008; Chey et al. 2010).

PROPOSED INTERVENTION

Faecal Calprotectin is a marker for intestinal inflammation. Calprotectin concentration in faeces correlates with the severity of inflammation, it is significantly increased in patients with bowel inflammation (IBD), but not elevated in patients with functional disorders like IBS.

There are two proposed interventions:

1. Point-of-care tests- Buhlmann Quantum Blue Calprotectin assay performed and analysed by Gastroenterologists or delegated staff (i.e. nurse) and interpreted by Gastroenterologists. This test has a turnaround time of 20 minutes.
2. Buhlmann Calprotectin ELISA. This is a standard ELISA test to be performed in NATA accredited laboratories and takes 8 hours to complete.

There are two treatment populations proposed:

1. Testing in symptomatic patients to exclude IBS
2. Monitoring of patients with diagnoses IBD.

CLINICAL NEED AND PUBLIC HEALTH SIGNIFICANCE

- 1) Describe your experience with the medical condition (disease) and/or proposed intervention relating to the draft protocol?

- 2) What do you see as the benefits of this proposed intervention for the person involved and/or their family and carers?

- 3) What do you see as the disadvantages of this proposed intervention for the person involved and/or their family and carers?

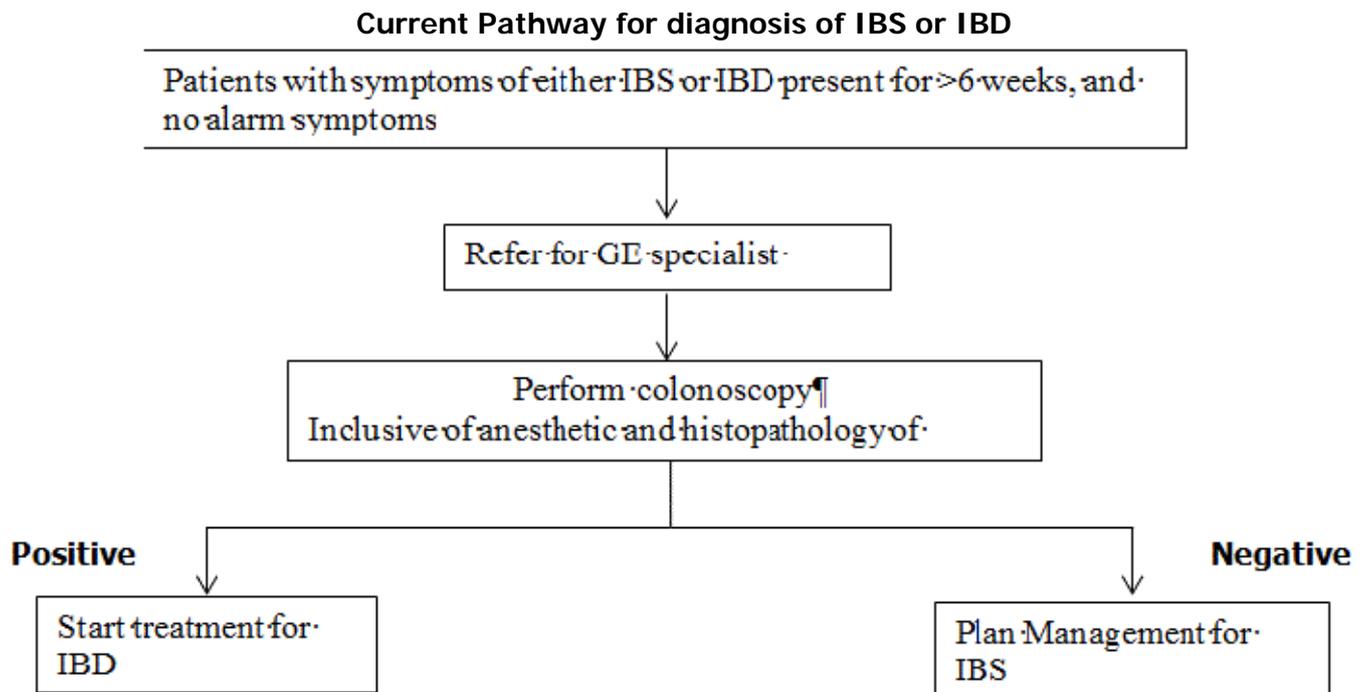
- 4) How do you think a person's life and that of their family and/or carers can be improved by this proposed intervention?

- 5) What other benefits can you see from having this proposed intervention publicly funded on the Medical Benefits Schedule (MBS)?

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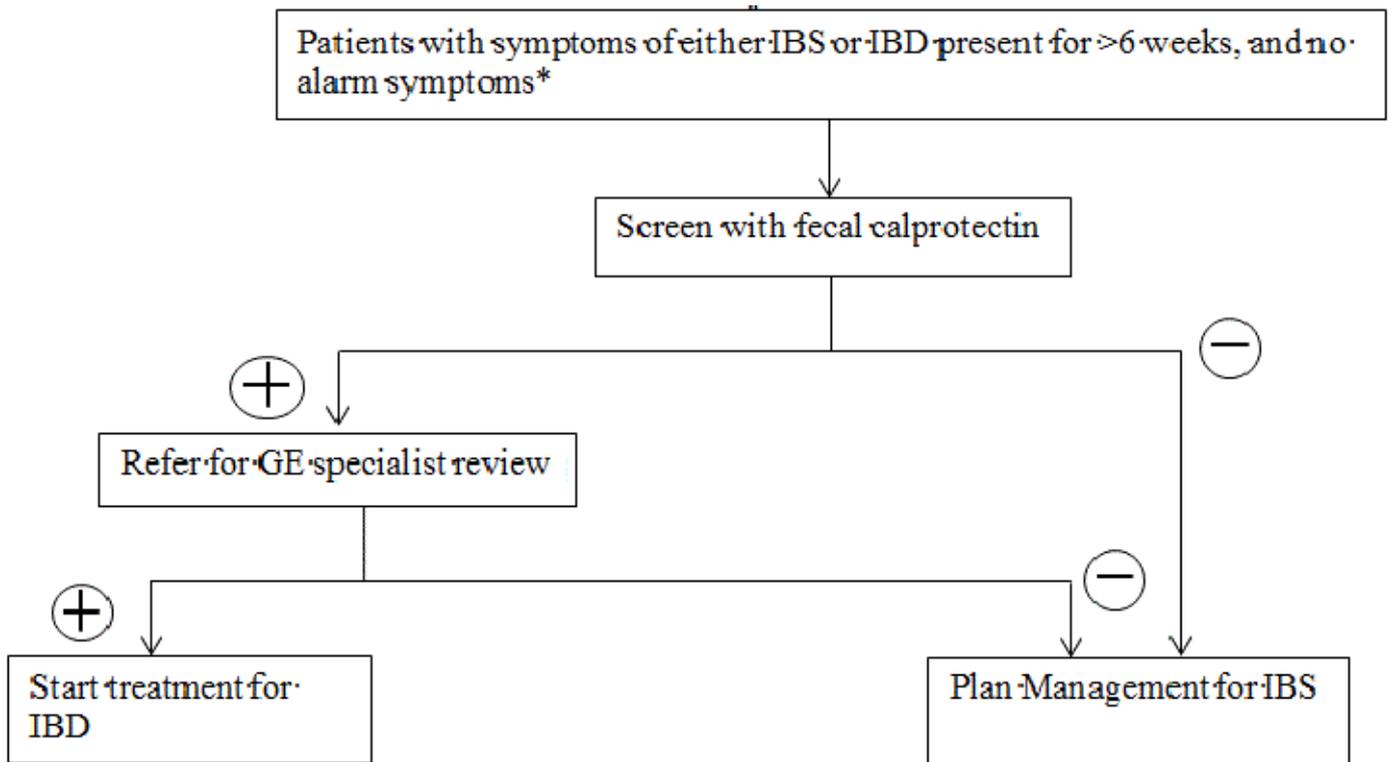
INDICATION(S) FOR THE PROPOSED INTERVENTION AND CLINICAL CLAIM

Flowchart of existing and potential management with the proposed intervention for this medical condition.



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Expected pathway with faecal Calprotectin testing



IBS: Irritable bowel syndrome

IBD: Inflammatory bowel disease

*Alarm symptoms: rectal bleeding, weight loss, nocturnal diarrhoea, high-risk family history for colorectal cancer, anaemia, iron deficiency, elevated inflammatory markers

6) Do you agree or disagree with the eligible population for the proposed intervention as specified in the proposed management flowcharts?

- Strongly agree
- Agree
- Disagree
- Strongly disagree

Why or why not?

7) Do you agree or disagree with the comparator for the proposed intervention as specified in the current management flowchart?

- Strongly agree
- Agree
- Disagree
- Strongly disagree

Why or why not?

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8) Do you agree or disagree with the clinical claim (outcomes) made for the proposed intervention?

- Strongly agree
- Agree
- Disagree
- Strongly disagree

Why or why not?

9) Have all associated interventions been adequately captured in the flowchart?

- Yes
- No

If not, please move any misplaced interventions, remove any superfluous intervention, or suggest any missing interventions to indicate how they should be captured on the flowcharts. Please explain the rationale behind each of your modifications.

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ADDITIONAL COMMENTS

10) Do you have any additional comments on the proposed intervention and/or medical condition (disease) relating to the proposed intervention?

11) Do you have any comments on this feedback form and process? Please provide comments or suggestions on how this process could be improved.

Thank you again for taking the time to provide your valuable feedback.

If you experience any problems completing this on-line survey please contact the HTA Team

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