Australian Government

Medical Services Advisory Committee

MSAC Public Summary Document

Application No. 1190 – Magnetic Resonance Imaging for small bowel and pelvis in Crohn disease

Sponsor/Applicant/s: **Australian Inflammatory Bowel Disease Association (Gastroenterology Society of Australia)**

Date of MSAC consideration: **MSAC 61st Meeting, 3-4 April 2014**

1. Purpose of application

The application was submitted in July 2011 by the Gastroenterology Society of Australia (GESA) and requested Medicare Benefits Schedule (MBS) listing for magnetic resonance imaging (MRI) for patients with Crohn disease.

2. Background

MSAC has not previously considered MRI for small bowel and pelvis in Crohn disease and MRI for Crohn disease is not currently funded under the MBS.

3. Prerequisites to implementation of any funding advice

To perform a MRI in patients with Crohn disease, a specialist radiologist with expertise in interpreting MRI scanning and familiarity with Crohn disease would be required.

MRI is currently available in public and private facilities in major centres in each state and territory. There are 170 Medicare-eligible MRI units that can provide services eligible for funding under the MBS.

4. Proposal for public funding

Tables 1 and 2 present the proposed MBS item descriptors for the six indications of the application.

Table 1: Proposed MBS item descriptor for MRI for small bowel Crohn disease with and without contrast agent

Category 5 – Diagnostic Imaging Services
MRI to evaluate small bowel Crohn disease. Medicare benefits are only payable for this item if the service is provided to patients for : (a) Evaluation of disease extent at time of initial diagnosis of Crohn disease (b) Evaluation of exacerbation/suspected complications of known Crohn disease (c) Evaluation of known or suspected Crohn disease in pregnancy (d) Assessment of change to therapy in patients with small bowel Crohn disease NOTE 1: Assessment of change to therapy can only be claimed once in a 12 month period. Fee: $627.50 Benefit: 75% = $470.63 85% = $533.38
MRI enteroclysis for Crohn disease. Medicare benefits are only payable for this item if the service is related to item XXXX Fee: $265.25 Benefit: 75% = $198.94 85% = $225.46

Table 2: Proposed MBS item descriptor for MRI for fistulising perianal Crohn disease

Category 5 – Diagnostic Imaging Services
MRI for fistulising perianal Crohn disease. Medicare benefits are only payable for this item if the service is provided to patients for: (a) Evaluation of pelvic sepsis and fistulas associated with established or suspected Crohn disease (b) Assessment of change to therapy of pelvis sepsis and fistulas from Crohn disease NOTE 1: Assessment of change to therapy can only be claimed once in a 12 month period. Fee: $403.20 75% = $302.40 85% $342.72

5. Summary of Consumer/Consultant Feedback

MSAC's Protocol Advisory Sub-Committee (PASC) noted the responses where positive and supportive and that potential disadvantages are few (only that some patients experience claustrophobia with MRI).

In order to complement the introduction of MRI to diagnose small bowel Crohn disease, survey responses also indicated that funding faecal calprotectin as a non-invasive marker of gut inflammation needs to be considered.

Comments provided by the Royal Australian and New Zealand College of Radiologists support of the proposal, however they are mostly concerned that the DAP did not distinguish between the two MRI techniques. The College agreed with PASC that separate descriptors and fees would be needed to distinguish between MR enterography and MR enteroclysis.

6. Proposed intervention's place in clinical management

It was proposed that MRI will be indicated in six specific situations when evaluating patients with Crohn disease and there are several proposed changes to current practice. These separate places in the clinical management algorithm are summarised in Table 3. In this assessment, the clinical evidence addressed the requirements of the agreed Protocol.

Table 3: Proposed indications of MRI and clinical place in therapy

Proposed Indication	MRI is intended to:
Evaluation of extent of disease at time of diagnosis for suspected or known Crohn disease	Replace CT or SBFT
Evaluation of suspected complications in known Crohn disease	Replace CT or SBFT
Evaluation of suspected Crohn disease in pregnancy	Replace Ultrasound
Assessment of change to therapy in known Crohn disease	Complement CT or SBFT or endoscopy
Evaluation of pelvic sepsis and fistulas suspected or known fistulising perianal Crohn disease	Replace surgical examination or endoanal ultrasound
Assessment of change to therapy in patients with pelvic sepsis and fistulas in known fistulising perianal Crohn disease	Complement surgical examination or endoanal ultrasound

CT = computer tomography, MRI = magnetic resonance imaging, SBFT = small bowel follow through.

7. Comparator

The comparators and their MBS numbers are as follows:

- computer tomography (CT) (56507)
- small bowel follow through (SBFT) (58915)
- ultrasound for the small bowel indications (55700); and
- endoanal ultrasound and surgical examination for the fistulising perianal Crohn disease indications (55014).

The application noted that other MBS items for CT and ultrasound may also be relevant.

MSAC considered these comparators were appropriate.

8. Comparative safety

No studies were identified that report the safety outcomes of MRI compared with the nominated comparators.

Clinical management using MRI is widely viewed as being safer than CT, SBFT and surgical examination. MRI is non-invasive, does not emit ionising-radiation and presents no chemical or bodily harm to the patient. The risks of the use of contrast agents used with the proposed procedures was unable to be specified. The safety aspect of MRI in pregnancy is still unknown.

There is no direct evidence that radiation from imaging procedures in Crohn disease results in increased cancer mortality. Some evidence suggested that cancer incidence is elevated in patients with Crohn disease but this has not been linked to imaging procedures in the study populations (Jess et al., 2005, Pedersen et al., 2010).

9. Comparative effectiveness

The primary sources of evidence were six diagnostic accuracy studies, two 'change of management' studies and three systematic reviews.

The diagnostic performance of MRI small bowel was equivalent to the comparators for sensitivity and specificity. Across the studies, the sensitivity of MRI was high and consistent with the results from the systematic reviews (range 74% to 100%).

A high-quality study by Jensen et al. (2011) found sensitivity and specificity results at the lower end of the overall range across all the studies. Statistical analysis showed that the sensitivity and specificity of MR enterography was not statistically significant from CT enterography (Jensen et al., 2011).

MRI of the pelvis for extent of fistulising perianal Crohn disease was the only proposed service which had superior specificity to its comparator (ie. endoanal ultrasound).

No studies were found comparing the extent of Crohn disease or complications of disease using SBFT as the comparator, as all used CT for small bowel Crohn disease.

No studies reported outcomes for MRI in pregnant women, most likely because the studies included CT and CT is contraindicated in pregnancy.

Overall, there was limited high quality evidence of the clinical effectiveness of the proposed services, but it indicated that MRI appeared to be equivalent compared to the comparators for small bowel Crohn disease and superior to endoanal ultrasound for fistulising perianal Crohn disease.

10. Economic evaluation

A cost-utility analysis was performed for only one of the six proposed indications: pelvis MRI for extent of Crohn disease in fistulising perianal Crohn disease. This was the only indication where a cost-utility analysis was justified based on the superior specificity of MRI to endoanal ultrasound. The evaluation was a simple decision-analytic model with a 12 month time horizon and should be viewed as exploratory due to the absence of key estimates from an evidence base.

In the base case, the mean costs of MRI were lower over 12 months compared to ultrasound (by $806), while the corresponding quality-adjusted life years (QALYs) were slightly higher (0.05). MRI pelvis therefore dominated endoanal ultrasound. Probabilistic sensitivity analyses showed a high likelihood of MRI being cost-effective for this indication and may be cost-saving in most cases, subject to the assumptions of the model.

11. Financial/budgetary impacts

The utilisation and financial estimates were uncertain due to concerns with the population group and size, the frequency of imaging required, and co-claiming of other MBS items.

Estimates of utilisation and financial costs were:

- Likely volume of use of the proposed imaging test per year: 13,597

- Frequency of use per patient per year over 5 years: 1 per year
- Patient numbers per year (prevalence/ incidence mix over time): 13,597
- Total cost of the proposed imaging test to the MBS per year: $8,718,243
- Total cost of the service to the public: unknown
- Net financial cost/year to the MBS (without safety net impacts): $6,256,006

12. Other significant factors

Nil

13. Summary of consideration and rationale for MSAC's advice

MSAC noted that the application was for funding of three new MBS items for magnetic resonance imaging (MRI) - small bowel, pelvis and enteroclysis - in two key populations:

1) patients with small bowel Crohn disease;
2) patients with fistulising perianal Crohn disease

MSAC agreed that there are several comparators depending on the separate indications for MRI. MSAC noted that for the proposed evaluation indications, MRI would replace existing tests, and for the proposed assessment indications MRI would complement existing tests as an additional service.

MRI pelvis for patients with fistulising perianal Crohn disease
MSAC accepted the nominated comparators for MRI of the pelvis for fistulising perianal indications were endoanal ultrasound and surgical examination.

Although endoanal ultrasound is not widely available in Australia, MSAC accepted that MRI of the pelvis for patients with complicated fistulising Crohn disease is superior to other diagnostic modalities including ileocolonoscopy; and more cost effective and safer than surgery, based on the evidence presented.

Based on the superior specificity of MRI to endoanal ultrasound, a cost-utility analysis was performed. Although this analysis was considered largely hypothetical due to the lack of evidence, MSAC noted that the analysis showed that MRI is likely to be cost-effective for perianal disease and may be cost-saving.

MSAC considered that reimbursement for this indication should be limited to one MRI of the pelvis per year per patient and restricted to referrals from Gastroenterologists and Colorectal surgeons as management of this difficult condition requires expert specialist care.

MRI for patients with small bowel Crohn disease
MSAC accepted the nominated comparators for MRI of the small bowel were computed tomography (CT), small bowel follow through (SBFT) and ultrasound.

Based on the evidence presented, MSAC noted that the results for sensitivity and specificity of MRI enterography were not statistically significant compared with CT enterography. MSAC considered that, even with the limitations of small sample sizes and heterogeneity, the evidence indicated that the diagnostic performance of MRI is equivalent to the comparators. However, MSAC noted that no evidence was provided which demonstrated improved patient health outcomes resulting from MRI of the small bowel.

MSAC noted that no studies were identified that reported on comparative safety of MRI to the comparators. However, MRI is generally considered to be safer than CT, SBFT and surgical examinations. MSAC noted that this safety is largely due to non-exposure to ionising radiation, particularly important in a population that could require multiple investigations. Overall, MSAC considered that it remains uncertain what additional benefit patients would receive, apart from a safety advantage, from MRI of the small bowel over the comparator imaging techniques.

MSAC considered that the lack of evidence on the epidemiology and clinical management patterns of Australians with Crohn disease made the economic evaluation and financial estimates very uncertain. Particularly as Crohn disease is most common in adolescents and young adults whom may require repeat diagnostic investigations several times a year or not at all depending on their progress and disease severity. The likelihood of MRI uptake is high and potentially rapid due to the perceived confidence of consumers in the technology.

To address some of the uncertainty associated with the potential population size, MSAC agreed with the applicant's response that the item descriptor should be tightened to more clearly define the patient population who would be eligible under the MBS. MSAC noted that the potential patient population undergoing MR enteroclysis will be small as the majority of patients are likely to undergo the procedure using the oral contrast (MR enterography).

Although MSAC considered that the analytical superiority claim for MRI in small bowel had not been adequately demonstrated, the Committee agreed that it was reasonable to include a small fee advantage over other relevant imaging techniques for improved safety and greater complexity.

14. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to the safety, clinical effectiveness and cost-effectiveness MSAC supported public funding of new MBS items for:

- MRI for evaluation of pelvic sepsis and fistulas in fistulising perianal Crohn disease; and
- MRI for evaluation of known or suspected complications in small bowel Crohn disease.

MSAC recommended that the Department negotiate the proposed fee for the small bowel indication with the radiology craft group, recognising a small fee advantage over other relevant imaging techniques for improved safety and greater complexity, but that the analytical superiority claim for MRI had not been adequately demonstrated.

If no agreement can be reached, then MSAC recommended that a further application with additional data to support the superiority claim of MRI be provided for re-consideration by MSAC via ESC.

MSAC's Proposed descriptors are:

Category 5 – Diagnostic Imaging Services
MRI to evaluate small bowel Crohn disease. Medicare benefits are only payable for this item if the service is provided to patients: (a) Evaluation of disease extent at time of initial diagnosis of Crohn disease (b) Evaluation of exacerbation/suspected complications of known Crohn disease (c) Evaluation of known or suspected Crohn disease in pregnancy (d) Assessment of change to therapy in patients with small bowel Crohn disease NOTE 1: Assessment of change to therapy can only be claimed once in a 12 month period. Fee: Subject to negotiation
MRI enteroclysis for Crohn disease. Medicare benefits are only payable for this item if the service is related to item XXXX Fee: $265.25 75% = $198.94 85% = $225.46
Category 5 – Diagnostic Imaging Services
MRI for fistulising perianal Crohn disease. Medicare benefits are only payable for this item if the service is provided to patients for: - Evaluation of pelvic sepsis and fistulas associated with established or suspected Crohn disease - Assessment of change to therapy of pelvis sepsis and fistulas from Crohn disease Note 1: assessment of change to therapy can only be claimed once in a 12 month period. Fee: $403.20 75% = $302.40 85% = $342.72

15. Applicant's comments on MSAC's Public Summary Document

No comment.

16. Linkages to other documents

Further information is available on the MSAC Website at: www.msac.gov.au.