



Australian Government
Medical Services Advisory Committee

MSAC Public Summary Document

Application No. 1203 – Catheter-free (wireless) ambulatory oesophageal pH monitoring for Gastro Oesophageal Reflux Disease (GORD)

Sponsor/Applicant/s: Given Imaging Pty Ltd

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

1. Purpose of application

The application requested Medicare Benefits Schedule (MBS) listing of catheter-free ambulatory oesophageal pH monitoring for Gastro Oesophageal Reflux Disease (GORD).

2. Background

MSAC has not previously considered catheter-free ambulatory oesophageal pH for GORD.

3. Prerequisites to implementation of any funding advice

The Bravo pH monitoring system (Manufactured by Given Imaging Pty Ltd) for catheter-free ambulatory oesophageal pH monitoring for GORD is registered with the Therapeutic Goods Administration (TGA) on the Australian Register of Therapeutic Goods (ARTG).

The catheter-free procedure requires the Bravo system which incorporates:

- pH capsule with delivery device;
- pH receiver;
- pH software on a computer; and
- calibration stand, datalink, vacuum pump and accessories.

4. Proposal for public funding

The application proposed the following item descriptor:

Category 2– Diagnostic procedures and interventions
MBS [item number] CLINICAL ASSESSMENT of GASTRO-OESOPHAGEAL REFLUX DISEASE that involves 48 hour catheter-free wireless ambulatory oesophageal pH monitoring including administration of the device and any endoscopy associated with this, analysis and interpretation of the data and all attendances for providing the service, if (a) the service is performed by a specialist or consultant physician with endoscopic training that is recognised by The Conjoint Committee for the Recognition of Training in Gastrointestinal Endoscopy; and (b) the patient has previously failed (rather than intolerant of) a catheter-based ambulatory oesophageal pH-monitoring or is anatomically inappropriate for a catheter based system. Fee: \$913.64

The fee listed in the item was provided in the application. It included a \$350 fee for professional time for performing the test, \$430.40 for the capsule, and \$133.25 for the reader system (based on a depreciation of capital investment, 50 patients per year over three years: \$19,990 cost of purchasing the system).

MSAC recommended that this test should be used in patients for whom pH monitoring is clinically indicated. MSAC agreed that a restriction should apply and should only be used for patients for whom a catheter-based test had already failed, or in those for whom it is anatomically inappropriate to undertake.

MSAC considered that the performance of this test and associated endoscopy should only be performed by a specialist or consultant physician with endoscopic training that is recognised by the conjoint committee for the recognition of training in Gastrointestinal Endoscopy.

5. Summary of Consumer/Consultant Feedback

The Gastroenterological Society of Australia (GESA) provided public consultation feedback and were supportive of the proposed listing.

6. Proposed intervention's place in clinical management

The application's proposed intervention (catheter-free) will be used if the patient has previously failed a catheter-based test or is anatomically inappropriate for a catheter-based test.

The clinical pathway proposed in the application indicated that this would be another diagnostic option for patients who have had a failed catheter-based test and for those patients in whom it is anatomically inappropriate to use the currently available catheter-based (i.e. as an alternative to no pH monitoring). Instead of no further testing and continuation of potentially ineffective proton pump inhibitor (PPI) treatment, patients are able to undergo a pH monitoring test using catheter-free which would lead to more treatment options such as surgery or different medication.

7. Comparator

The application proposed that the comparator was no pH monitoring (and empirical therapy) after a failed catheter-based test or for patients in whom a catheter-based test is anatomically inappropriate. MSAC considered these comparators to be appropriate.

MSAC agreed with PASC that to determine the diagnostic sensitivity, specificity and safety of catheter-free pH testing, the appropriate comparator is catheter-based testing.

8. Comparative safety

Catheter-free compared to no pH monitoring

MSAC noted that when compared to “no monitoring”, there was overall a lack of good quality data that could aid the assessment of comparative safety and effectiveness of catheter-free. Only one study (Francis 2012) was identified assessing the safety of catheter-free ambulatory oesophageal pH-monitoring for GORD compared to no pH monitoring. This randomised controlled trial found that chest pain was more likely to occur in those undergoing catheter-free monitoring (66%) than those undergoing no monitoring (28%) although the difference in risk was not statistically significant (RR = 2.33, 95% CI 0.81, 6.76). Chest pain is likely to be attributed to the placement of the capsule. Specifically, this study was examining the ideal placement of the capsule, and examined the insertion of 2 capsules (one at 16 cm and one 6 cm) as opposed to only one capsule at 6 cm proximal to the gastro-oesophageal junction. Less chest pain was reported in those patients in whom only one capsule at 6 cm was inserted.

Catheter-free compared to catheter-based

Twelve comparative studies were identified, reporting on complications of catheter-free vs catheter-based approach. Included were four randomised controlled trials, one pseudo-randomised controlled trial, three cohort studies, two non-randomised controlled trials and two case-control studies.

No deaths or life threatening events caused by pH monitoring were reported in the comparative studies. Chest pain was significantly more prevalent in patients undergoing catheter-free compared to catheter-based, as reported in four out of seven studies. On the other hand, other adverse events, such as nose and throat pain, dysphagia, eating and drinking difficulties and headache were significantly more prevalent in catheter-based compared to catheter-free. Furthermore, catheter-based causes more overall discomfort than catheter-free and has more negative impact on normal daily activities and work attendance.

In addition to the comparative studies, 29 non-comparative level IV studies were included to determine other complications and/or adverse events caused by catheter-free. The most common reported adverse events were chest pain and foreign body sensation. Other complications included diminished appetite, extreme gagging, nausea, epistaxis, pharyngeal irritation, retrosternal discomfort on swallowing, throat pain, back pain, rash, mucosal abrasion with (minor) haemorrhage, capsule dislodgement, capsule detachment failure, laryngospasm, vasovagal reaction, poor capsule tolerance with vomiting, and a dizzy spell during insertion.

In children, two oesophageal tears were reported, at least one due to a capsule release failure. Less severe adverse events in children were overall discomfort, mild chest discomfort, coughing and dysphagia.

Seven case reports were identified that reported some additional (rare) complications resulting from catheter-free, such as capsule dislodgment and/or aspiration, retention of the capsule in a colonic diverticulum and oesophageal perforation. However, some (rare) complications have been reported in case reports, and can become severe when left untreated.

MSAC considered catheter-free to have equivalent safety to catheter based.

9. Comparative effectiveness

Effectiveness of catheter-free testing for GORD in patients who have previously failed a catheter based test or where it is anatomically inappropriate

No studies assessing the direct health impact of catheter-free versus no monitoring in the selected study population were available. However, one matched-pairs study found that slightly more patients who were monitored by the wireless system had an improvement or disappearance of the principal symptom, compared to those monitored by the catheter system (73% in the wireless group versus 69% in the catheter group (n = 51 in each group)). A before-and-after study reported that 9 patients had a good or moderate improvement in symptoms, out of 26 patients who received medical therapy or conservative advice after a catheter-free test.

Catheter-free was found to have over 3 times the risk (RR=3.3, 95% CI 1.63, 6.81) of having technical problems compared to catheter-based in adults. On meta-analysing the available data, a relative risk of 2.87 (95% CI 1.47, 5.62) for adults and children combined was found. Most studies (15/20) reported only minimal day-to-day variability in oesophageal acid exposure across the two days of monitoring suggesting that catheter-free is a reliable means of monitoring pH.

Diagnostic accuracy of catheter-free for GORD compared to catheter based oesophageal pH monitoring

There was no consensus in the literature regarding what cut-offs should be used for pH monitoring to diagnose GORD, leading to difficulties in comparatively assessing the diagnostic accuracy of catheter-free and catheter-based. It is also important to note that the most widely accepted diagnostic “gold standard” is a clinical one - that is, the patient’s response to treatment. Furthermore, catheter-based is in itself an imperfect comparator. However, in the highest quality study available, a diagnosis of GORD was given if patients had a pH <4 for more than or equal to 4.4% of the time. Using these criteria, the catheter-free test had reasonable sensitivity (86.4%) and specificity (77.8%) when catheter-based was used as a reference standard. The two other studies which used this reference standard reported similar accuracy results, with slightly lower sensitivity, and slightly higher specificity.

Five diagnostic case-control studies used clinical diagnosis as a reference standard. The study with the largest patient population reported sensitivity values between 59% and 88% and specificity values between 75% and 96%, depending on which cut-off value was used (between 1.9% and 4.4% of the time that patients had pH <4). The remaining studies used

cut-off values between 4.4% and 5.3% for 'proximal' oesophageal pH monitoring. The sensitivity and specificity in these studies varied from 67% to 100% and from 66% to 100%, respectively. No studies compared the accuracy of catheter-free and catheter-based against the reference standard of clinical diagnosis.

Nine studies reported on the time that the oesophagus was exposed to acid, rather than using diagnostic cut-offs, during monitoring with catheter-free compared to catheter-based in adults. In four of the studies both tests were conducted in the same patient population, and therefore variations in results can be attributed with more certainty to the monitoring method, rather than variability between two different samples of patients. However, the results were mixed, with two studies reporting that catheter based detected more acid exposure time and one study reported that catheter-free detected more acid exposure (Azzam et al. 2012). The remaining five studies reported no significant differences between the two measurement methods. One study reported on oesophageal acid exposure in children, finding significantly more reflux with wireless monitoring compared to catheter-based monitoring ($p = 0.01$). Four studies reported not only on acid exposure time concordance, but also on variation in the number of reflux events. Three of the four studies, two level II studies and one level III-2 study, reported significantly more reflux events with the catheter-based monitoring system.

Two comparative diagnostic yield studies reported that significantly more patients were diagnosed with catheter-free compared to catheter-based ($p < 0.001$). One reported an advantage of catheter-free is that it allows a longer monitoring period than catheter-based (48 hours rather than 24 hours). Six studies reported that the additional day of monitoring increased diagnosed yield with a median of 7.8%.

Clinical management of catheter-free compared to no pH monitoring for patients with symptoms of GORD who have previously failed a catheter-based test or where a catheter-based test is anatomically inappropriate

No studies were available reporting on a change in management based on catheter-free, in the population who would otherwise have had no monitoring (i.e. those who could not tolerate the catheter-based). Five studies reported on change in patient management after catheter-free, in patients who could have potentially tolerated a catheter-based test. One comparative study reported that concordance between the results of the test and treatment of GORD was higher in the catheter-free group (78%) than in the catheter-based group (58%; $p < 0.05$).

As with the comparative study, before-and-after case series also reported that the management received did not always correspond to the results of the test. One study reported that 42.2% of patients (38/90) continued to take anti-reflux medication despite a negative pH test. Only 17 patients recalled being instructed to stop taking PPIs. In another case series, 12/38 of patients underwent surgery for GORD, although only 9 of these had a positive diagnosis based on catheter-free. In a further case series, catheter-free monitoring led to a change in management in 63% of patients referred for testing. In a paediatric study, catheter-free resulted in a change in management in 88% of patients. Patients with an abnormal study result were more likely to have a change in management than patients with a normal study.

Based on the literature, MSAC considered that the results of catheter-free influence subsequent management, although not all patients have management consistent with the results of pH monitoring. It is expected that the key changes based on monitoring with catheter-free, are that patients who are found not to have GORD, have their (mostly

ineffective) PPI treatment suspended, whereas patients who have their GORD confirmed, have an additional option of surgical treatment. However, it is uncertain as to what proportion of patients who are endoscopy negative, catheter-free positive, would be offered or proceed to surgical intervention.

Alterations in clinical management and treatment options impact on the health outcomes of patients with symptoms of GORD who have previously failed a catheter based test or where a catheter based test is anatomically inappropriate

For people initially suspected of having GORD, who are given alternative diagnoses correctly after catheter-free (true negatives), it is assumed that their clinical management would be optimised as a result of obtaining the correct diagnosis. Patients who receive a false positive would likely continue to receive ineffective PPI treatment, and a delay in receiving their correct diagnosis. A false negative would likely result in suspension of PPI treatment, and delay in diagnosis, while an alternative diagnosis is sought. No relevant studies were identified regarding the impact of false negatives, however, two studies on false positives were included. These studies reported that infants with infantile spasms with delayed treatment (as a result of a false GORD diagnosis) had a poorer outcome and worse treatment response than infants without a delay in diagnosis and treatment.

Furthermore, two systematic reviews on true positives were included to answer the question if anti-reflux surgery for GORD leads to better health outcomes compared to medical treatment in patients with GORD (and a positive pH test result). The first, medium quality review reported that improved outcomes were more common after surgical than medical treatment with significant differences in objective outcomes (pH reflux duration, oesophagitis, lower oesophageal sphincter pressure, etc.) in 5/6 included RCTs and 2/3 cohort studies. Subjective outcomes were also more common among surgical patients in 7/8 studies. The second (more recent, high quality) review compared medical management with laparoscopic fundoplication surgery. Four RCTs were included. Significant improvements in QoL were reported at three months and one year after surgery, compared to medical treatment. All studies reported significant increases in GORD-specific QoL postoperatively, compared to medical treatment. Post-operative complications were rare.

Two of the four RCTs included in the latter review published five-year follow up studies after the Cochrane review was conducted. Most patients achieve and remain in remission at five years with anti-reflux surgery, and fundoplication continued to give better pain relief than medical management. It should be noted, however, that these trials consisted solely of PPI responders and their results do not generalise to patients who are refractory to PPI therapy.

The expected treatment changes that may result from having a catheter-free test in patients with symptoms of GORD who have previously failed a catheter based test or where a catheter based test is anatomically inappropriate are likely to benefit quality of life.

MSAC considered the comparative clinical effectiveness of catheter-free to have an equivalent diagnostic accuracy to catheter based.

10. Economic evaluation

The application presented two economic models to determine (i) the cost-effectiveness of catheter-free vs no monitoring (empirical treatment) in an Australian population who cannot tolerate catheter-based monitoring, and (ii) to determine the cost-effectiveness (or not) of catheter-free monitoring vs catheter-based monitoring if use of the proposed listing ‘leaks’ to include patients who are not intolerant of catheter-based monitoring.

Characteristics of the cost-utility models, which assumed a health system perspective (public and private healthcare providers and defined patient contributions), are outlined in Table 1.

Table 1 Summary of the economic evaluation (applies to both models)

Time horizon	Base case analysis of 15 years
Outcomes	Quality-adjusted life years
Methods used to generate results	Markov model (with half-cycle correction)
Cycle length	1 year
Discount rate	5% for both costs and outcomes
Software packages used	TreeAge Pro and Excel (hybrid)

Key structural assumptions were: (i) that a positive pH test result provided patients the option of surgery to treat the GORD symptoms, and (ii) that a negative result would prompt investigation for other diagnoses and reduce the use of ongoing high dose PPIs. When modelling, it was considered that inclusion of the accuracy of catheter-free testing when measured against catheter-based monitoring – an imperfect reference standard – would distort the results, and as such the base case assumes catheter-free, catheter-based monitoring and a trial of empirical treatment (high dose PPIs) to be equally accurate. Sensitivity analyses explore alternative test accuracy values.

The base case analysis found that catheter-free vs no pH testing had an incremental cost-effectiveness ratio of \$14,457 per quality-adjusted life-year (QALY) gained. However, when compared against catheter-based testing, catheter-free was dominated – it had a higher cost and was less effective (with the lesser effectiveness due to an increased technical failure rate). Thus, if catheter-free monitoring were to be MBS listed, leakage of use into patients who could otherwise tolerate catheter-based testing may substantially reduce the assumed cost-effectiveness. The overall cost-effectiveness of an MBS listing is dependent on the predicted extent of leakage, with 30% leakage into cohorts of patients who are able to tolerate (or do not fail) catheter-based testing increasing, the overall ICER increased to \$58,429/QALY.

Other key areas of uncertainty in the cost-utility models related to: (i) the assumed accuracy of the test; where imperfect sensitivity and specificity values are incorporated, sensitivity analyses showed that catheter-free was dominated with sensitivity values $\leq 90\%$; and (ii) the assumption that in the absence of a pH test (which incorporates a follow-up assessment of results) some patients will be trialed on high dose PPIs and inappropriately remain on high dose PPI treatment indefinitely. That this occurs is supported by the literature and expert opinion, but quantification is highly uncertain. If the assumption is removed altogether, then catheter-free is dominated by an empirical trial of high dose medication. The base case assumed that inappropriate ongoing high dose PPI use occurs in 1 in 10 patients diagnosed with non-erosive reflux disease (NERD)-like symptoms but who actually have non-acid

related conditions. Another area of uncertainty in the modelling was, in the absence of catheter-free, the extent to which these patients are investigated for other causes of their symptoms.

The proposed fee per occasion of catheter free, as requested in the application, was \$913.64, based on:

- professional time:
 - performing the procedure (approximately 27 min)
 - downloading and reading of data (approximately 20 min), estimated at 50 mins with a value of \$350.
- equipment costs:
 - consumable pH transmitter capsule (Bravo) \$430.30
 - depreciation of capital – wireless receiver and recording system, including software (Bravo) \$19,990, depreciated fully over 3 years/150 patients; \$133.34/occasion
 - For a total equipment cost of \$563.64.

A significant proportion (62%) of the proposed fee was equipment. The Department noted that even after adjustment for currency exchange, the quoted equipment prices remained considerably higher than the 2006 prices published by the American Society for Gastrointestinal Endoscopy Technology Committee (Chotiprashidi et al. 2005) (\$1125 for a box of 5 capsules), despite a general trend in other medical technology prices to have decreased over this time.

Of note was that the calculated depreciation of capital requires each doctor providing the service to perform 50 services each year to break even with respect to equipment costs. The predicted current patient demand for services – based on the restricted listing – estimated less than 400 tests should be required per annum. This would suggest that the market would only support eight practitioners around Australia to purchase the equipment and provide the service whereas currently, catheter-based is undertaken by at least 56 practitioners (Medicare Local Data 2013). Reduced numbers of practitioners may result in access difficulties, or if most practitioners who currently undertake catheter-based monitoring were to invest in the catheter-free system there would economic pressure to either increase the patient cost beyond the schedule fee (i.e. have a large gap payment) or to over-service ('leakage').

There are no MBS cost offsets to be accounted for in this patient population. Some cost offsets can be expected in those patients who are true positive, and avoid multiple other consultations and/or investigations in looking at their symptoms. Of this MBS expenditure total of \$436,000, patients are expected to pay approximately \$100,000.

MSAC noted the economic evaluation was based on the cost-effectiveness of catheter-free compared to no monitoring in those patients who cannot tolerate catheter based testing. The economic model demonstrated an ICER of \$14,457 per QALY. However, when compared to the catheter based, catheter-free had a higher cost and was less effective (due to increased technical failure rate). In addition, MSAC considered that there may be leakage from patients who would otherwise tolerate catheter-based. Overall, the ICER for catheter based versus catheter-free was \$58,429 per QALY. However, MSAC agreed that the paucity of information in the application around the consumable and equipment costs of the catheter based created some uncertainty around comparative costs and that this information would have better informed the economic evaluation.

11. Financial/budgetary impacts

The expected uptake of catheter-free in the intended catheter-intolerant population was estimated at approximately 400 tests annually. However if catheter-free occurs in a broader population, as many as 4,000 tests could be undertaken annually.

	2012-13	2013-14*	2014-15*	2015-16*	2016-17*
Base Case					
Number of catheter-based tests* *projected to increase at 4%p.a.	3590	3734	3883	4038	4200
Estimated number of wireless tests (10% of catheter-based pH tests)	359	373	388	404	420
Total pH tests	3949	4107	4271	4442	4620

In the majority of patients, it is anticipated that catheter-free testing would only occur once in their lifetime. However, in a minority of patients who continue to have symptoms despite different medication regimens or surgery, repeat testing (e.g. on/off treatment) may be indicated.

The total cost for catheter-free in the intended catheter-intolerant population was estimated to be approximately \$0.5 million annually. This would increase to \$3.6 million if the catheter-free test is used in the broader population requiring pH monitoring.

Other non-MBS costs incurred are private hospital costs which may range from \$275,000 to \$2.5 million, across the population, depending on leakage.

The total cost to the Australian healthcare system including the MBS for catheter-free testing, in the intended catheter-intolerant population, was estimated to be \$0.7 million annually, increasing to over \$6 million if the test is used in the broader population requiring pH monitoring.

	2014-15*	2015-16*	2016-17*
Number of patients eligible for wireless test	388	404	420
MBS costs (see Table 19)	\$419,218	\$435,987	\$453,426
Private insurer/patient costs	\$235,695	\$245,122	\$254,927
Total	\$654,913	\$681,109	\$708,353

12. Other significant factors

Defining the population and the potential for 'leakage'

MSAC noted that it can be difficult to determine whether a person is 'unable' to tolerate a catheter. The catheter-free monitoring test is viewed as more convenient and can lead to a higher diagnostic yield due to prolonged monitoring, compared to catheter-based monitoring. Physicians could be inclined to give more patients catheter-free monitoring to avoid discomfort and embarrassment, especially in children. Furthermore, it is shown that catheter-free monitoring has less impact on normal daily activities, which makes the recording more reliable. Therefore it is possible that the population using catheter-free monitoring may expand beyond those who are currently considered unable to tolerate catheter-based

monitoring (when the alternative is no testing), i.e., the use of the catheter-free could start leaking into the population currently receiving the catheter-based test.

Because of the higher costs of catheter-free monitoring compared to catheter based monitoring this 'leakage' could lead to extra costs. This was examined in the economics section of the report.

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

MSAC considered an application for the listing of a catheter-free ambulatory pH test (catheter-free) for the diagnosis of GORD. The proposed listing is for the catheter-free test to follow the standard catheter based approach (catheter based) as a second line treatment if a patient has failed or is anatomically unsuitable for the existing MBS funded catheter based approach, currently reimbursed via MBS item number 11810.

MSAC agreed with the nominated comparator which includes clinical response to medication such as proton pump inhibitors (PPI) in the absence of pH monitoring. MSAC noted that PPIs and other medications were standard treatment for patients with GORD symptoms and many patients stay on them episodically for life even with a negative pH result. MSAC noted that the relatively low service number of catheter based tests could be due to the introduction of PPIs and the way health professionals treat patients with GORD and that very few patients overall with a diagnosis of GORD end up being considered for catheter-free pH monitoring.

MSAC agreed that the issue of where catheter-free testing exactly fits in the clinical pathway remains given it is possible that in practice some patients may be offered catheter-free as a 1st line investigation in place of catheter based, upstream to its proposed position in the clinical pathway. Due to the lack of evidence comparing catheter-free to the nominated comparator, MSAC accepted consideration of evidence where catheter-free was compared to catheter based.

MSAC considered catheter-free to have equivalent safety to catheter based, although noted that the use of the test in a small proportion of children resulted in oesophageal tears. MSAC considered that this was not a significant concern and does not require monitoring.

MSAC considered the comparative clinical effectiveness of catheter-free to have an equivalent diagnostic accuracy to catheter based. MSAC recognised that the reference standard is imperfect in the context of GORD given the poor correlation between various pH thresholds and symptomology. However, this issue equally affects both catheter-free and catheter based.

MSAC noted the economic evaluation was based on the cost-effectiveness of catheter-free compared to no monitoring in those patients who cannot tolerate catheter based testing. The economic model demonstrated an ICER of \$14,457 per QALY. However, when compared to the catheter based, catheter-free had a higher cost and was less effective (due to increased technical failure rate). In addition, MSAC considered that there may be leakage from patients who would otherwise tolerate catheter-based. Overall, the ICER for catheter based versus catheter-free was \$58,429 per QALY. However, MSAC agreed that the paucity of information in the application around the consumable and equipment costs of the catheter based created some uncertainty around comparative costs and that this information would have better informed the economic evaluation.

The likely volume for catheter-free tests in patients who have either failed, or are intolerant to catheter based is estimated to be approximately 400 tests per annum. However, MSAC noted that the volume of catheter based is greater than 3500 tests per annum. The total cost for the MBS item, if only used in the intended population, would be \$0.5 million annually. This would increase to \$3.6 million annually if the catheter-free test was used in the broader population requiring pH monitoring.

MSAC also noted that the listing of catheter-free may increase the rate of pH testing because catheter-free is likely to be better tolerated and patients can continue with their regular activities. MSAC noted the potential issue of MBS leakage (from catheter based to catheter-free) and requested the Department monitor usage. However, MSAC anticipated that leakage is not likely to be significant given that most patients with GORD will still be managed without the need for pH monitoring (even with the addition of the catheter-free). That said, MSAC noted that there may be also an incentive for leakage from providers wanting to recoup upfront capital costs. MSAC noted that a large proportion (62%) of the proposed fee is equipment, and that the proposed cost of the capsule (\$430.40 per capsule) is more than the American Society for Gastrointestinal Endoscopy quote in 2006 which is \$225 per capsule. MSAC considered the inclusion of consumable and reader system costs in the item reimbursement to be inappropriate and outside the remit of the MBS. MSAC suggested that the schedule fee for the professional component of the service should be equivalent to item 11810 (\$174.45) rather than the proposed professional fee of \$350 given that catheter-free is no better than catheter based in terms of diagnostic accuracy.

MSAC agreed that the endoscopic insertion of the capsule would also need to be funded. The Department agreed to review whether the associated cost of endoscopic insertion will be included as part of the total Scheduled fee (i.e. the professional fee plus the endoscopic insertion) or separately through co-claiming of an existing endoscopy MBS item. When performed out of hospital, MSAC also agreed that the catheter free approach should attract an Extended Medicare Safety Net Cap.

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 of catheter-free ambulatory pH testing for the diagnosis of GORD, MSAC supported public funding of a new MBS item for catheter-free ambulatory pH testing for the diagnosis of GORD in patients who have:

- a) failed catheter-based pH monitoring; or
- b) who are not suitable for catheter-based pH monitoring due to nasopharyngeal anatomy.

MSAC supported disaggregation of the proposed fee to remove the cost of the device and reader system. The fee should be for professional services only, including, administration of the device and associated endoscopy procedure for placement, analysis and interpretation of the data and all attendances for providing the service.

The service should be available to patients in-hospital or out of hospital with Medicare extended safety net applying.

MSAC proposed item descriptor:

Category 2– Diagnostic procedures and interventions

MBS [item number]

CLINICAL ASSESSMENT of GASTRO-OESOPHAGEAL REFLUX DISEASE that involves 48 hour catheter-free wireless ambulatory oesophageal pH monitoring including administration of the device and associated endoscopy procedure for placement, analysis and interpretation of the data and all attendances for providing the service, if

(a) a catheter-based ambulatory oesophageal pH-monitoring:

- (i) has been attempted on the patient but failed due to clinical complications; or
- (ii) is not clinically appropriate for the patient due to anatomical reasons (nasopharyngeal anatomy) preventing the use of catheter-based pH monitoring; and

(b) the service is performed by a specialist or consultant physician with endoscopic training that is recognised by The Conjoint Committee for the Recognition of Training in Gastrointestinal Endoscopy.

Not in association with a service to which item 11810 applies. (Aneas)

Service to be provided in-hospital and out of hospital EMSN to apply

Fee: To be advised

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

Covidien/Given Imaging thanks MSAC and the Department for their consideration of our application. We look forward to working with the Department and other stakeholders to the timely finalisation and implementation of this MBS item and procedure.

16. Linkages to other documents

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