



Australian Government

Medical Services Advisory Committee

## Public Summary Document

### *Application No. 1402 – Liver Microwave Tissue Ablation*

**Applicant:** N.Stenning & Co. Pty Ltd

**Date of MSAC consideration:** MSAC 68<sup>th</sup> Meeting, 24-25 November 2016

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, [visit the MSAC website](#)

#### **1. Purpose of application and links to other applications**

An application requesting new Medicare Benefits Schedule (MBS) listings for microwave tissue ablation (MTA) for the treatment of unresectable primary and secondary liver tumours was received by the Department from N.Stenning & Co. Pty Ltd.

#### **2. MSAC's advice to the Minister**

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness and cost effectiveness, MSAC supported the MBS funding of MTA for patients with unresectable primary liver lesions for whom MTA is potentially curative, at the same cost as the comparator radiofrequency ablation (RFA). MSAC accepted that the safety and effectiveness of MTA was similar to RFA in population one.

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness and cost effectiveness, MSAC did not support the MBS funding of MTA for (i) patients with unresectable secondary liver lesions, without extra-hepatic spread, for whom MTA is potentially curative and (ii) patients with unresectable neuroendocrine liver metastases, with or without extra-hepatic spread, who are refractory to somatostatin analogue therapy, for whom MTA is palliative treatment of secretory syndromes. MSAC advised that the evidence base in these two patient populations was insufficient. However, MSAC would encourage a future application to list thermal ablation (RFA and MTA) for these populations provided the application was supported by further comparative clinical evidence.

#### **3. Summary of consideration and rationale for MSAC's advice**

MSAC noted that the application to list MTA covered three separate populations:

- patients with unresectable primary liver lesions in whom MTA is potentially curative (population one);
- patients with unresectable secondary liver lesions, without extra-hepatic spread, in whom MTA is potentially curative (population two); and

- patients with unresectable neuroendocrine liver metastases, with or without extra-hepatic spread, who are refractory to somatostatin analogue therapy, in whom MTA is palliative treatment of secretory syndromes (population three).

MSAC noted that the evidence base presented for the use of MTA in liver cancer was generally of lower quality. Systematic reviews comparing MTA with radiofrequency ablation (RFA), the comparator, were available but the majority of studies included in these reviews were retrospective cohort studies with historical control groups, which are considered to be lower level evidence. In addition, MSAC noted that the use of historical control groups made it difficult to determine whether any improvement in safety or clinical outcomes in the studies was due to MTA or due to improvement in the treatment of liver cancers over time.

MSAC accepted that percutaneous and surgical MTA had a similar safety profile in patients with unresectable primary liver lesions (population one) when compared with RFA, although the evidence was considered to be of low quality. There were no significant differences in rates of adverse events between MTA and RFA. Only one retrospective study in people undergoing percutaneous MTA or RFA and using a historical control group reported on mortality (Ding J et al 2013; n = 897). Mortality rates were similar in both arms of the study but the number of deaths was small and the study was likely to have been underpowered to detect any differences in mortality.

MSAC accepted that percutaneous and surgical MTA were similarly effective in population one when compared with RFA, although the evidence was considered to be of low quality. There were no significant differences in rates of complete ablation, local tumour recurrence, recurrence free survival, or overall survival.

MSAC indicated that the introduction of MTA for use in population one is expected to be cost-neutral to the MBS. MSAC noted that while the applicant had requested a graduated fee (which increased according to the number of lesions treated), the similar safety and efficacy of MTA and RFA in population one meant that the same flat fee already paid for RFA was more appropriate. MSAC noted that because MTA is an alternative to RFA in population one, and other associated MBS costs will be the same independent of which procedure is used, there was no incremental cost associated with the use of MTA instead of RFA in the base case. Sensitivity analyses that varied the time taken per MTA session and the number of MTA sessions required to treat a patient from population one indicated the incremental costs of MTA could range from -\$1,447 to \$10,129 per patient.

MSAC noted that the net cost to the MBS for MTA would be less than \$100,000 over five years for population one. Costs were based upon 130 procedures being undertaken at an MBS cost of \$83,000 in the first year rising to 194 procedures at a cost of \$124,000 in year five. However, most of these services were offset by a reduction in the number of RFA procedures and associated costs.

MSAC accepted the use of MTA to treat cholangiocarcinomas (CCAs) in population one. MSAC noted that the current MBS items for RFA (50950 and 50952) are restricted to patients with unresectable hepatocellular carcinoma (HCC). MSAC suggested amending these MBS items so that either MTA or RFA can be used to treat CCAs in population one.

MSAC did not support the use of percutaneous or surgical MTA in patients with unresectable secondary liver lesions that had not spread beyond the liver (population two) due to insufficient evidence regarding safety and clinical effectiveness. The comparator for this population was percutaneous or surgical RFA with or without adjuvant chemotherapy.

MSAC noted that a number of studies comparing MTA and RFA in patients with liver metastases were excluded from consideration because patients underwent ablation in conjunction with resection. As highlighted by ESC, this suggests that population two have more complex disease than population one.

Comparative data on safety in population two was restricted to a single outcome - procedural mortality - in a single retrospective cohort study (Liu Y et al 2013a; n = 89). No procedural-related deaths were reported in either arm of the study. All other safety data in population two relied on case series data - a level of evidence generally considered to be of very low quality. As highlighted by ESC, the more complex nature of disease in these patients makes it difficult to apply safety data from population one to population two.

Comparative efficacy data in population two was also restricted to the same retrospective cohort study (Liu Y et al 2013a; n = 89). MSAC noted that while there was a trend towards improved overall survival up to five years and local tumour recurrence in the MTA arm, this did not reach statistical significance and the small patient numbers made it difficult to draw firm conclusions.

MSAC noted that RFA is not currently listed for use in population two and its inclusion would offer a new option for the treatment of secondary liver metastases on the MBS. MSAC recalled that it was unable to support public funding for RFA treatment of colorectal liver metastases - the main cause of secondary lesions in the liver - when the RFA application was considered in 2003 (see [Application 1052: Radiofrequency ablation of liver tumours](#)). However, MSAC considered that the evidence base may have expanded since this date and encouraged a future application to list thermal ablation (RFA and MTA) for population two.

MSAC noted that there was no evidence for the use of MTA in patients with unresectable neuroendocrine liver metastases, who are refractory to somatostatin analogue therapy (population three). While MSAC noted that MTA was likely to be rarely used in such patients, it could not support its use in population three due to the absence of evidence. MSAC encouraged a future application to use thermal ablation (RFA and MTA) for population three should evidence become available. MSAC advised that such an application should include information on how often these patients are seen; the appropriate setting for such treatment (e.g. large teaching hospitals); and estimates on how often thermal ablation would be considered as a suitable treatment.

MSAC indicated that unlike population one, treatment decisions made for population two and population three would require the input of a multidisciplinary team and this additional cost would need to be factored into economic modelling in any future application.

#### **4. Background**

Currently there is no public funding for MTA for the treatment of liver cancer. The primary comparator for MTA, RFA, is currently funded for patients with unresectable hepatocellular carcinoma (HCC) under two MBS items (50950 and 50952) which allow for percutaneous, laparoscopic or open surgical application. Hospital data indicate that patients receiving RFA as an outpatient (approximately 40 per cent) are bulk-billed and have therefore not been required to make co-payments, and gap costs for patients receiving in-hospital treatment are absorbed by the hospital system or covered by private insurance. It is likely that MTA would be funded in a similar way should it be listed for subsidy.

## 5. Prerequisites to implementation of any funding advice

The application does not specify the type of MTA device to be used. Under the wording of the proposed items any MTA machine listed on the ARTG could be used in conjunction with the procedure being claimed.

## 6. Proposal for public funding

The proposed item descriptors as provided in the PASC-approved final protocol for Populations 1 and 2, and using percutaneous, laparoscopic or open approach, are listed in Table 1. The protocol did not provide an item description for Population 3.

Table 1 Proposed MBS item descriptors

Category 3—THERAPEUTIC PROCEDURES
<p>MBS [item number]</p> <p>NON-RESECTABLE PRIMARY LIVER LESIONS, destruction of, by percutaneous microwave tissue ablation (MTA), including any associated imaging services, not being a service associated with a service to which item 30419, 50950 or 50952 (or other MTA items) applies</p> <p>Fee: \$TBA</p> <p>[Relevant explanatory notes if required]</p>
<p>MBS [item number]</p> <p>NON-RESECTABLE PRIMARY LIVER LESIONS, destruction of, by open or laparoscopic microwave tissue ablation (MTA), including any associated imaging services, where a multidisciplinary team has assessed that percutaneous microwave ablation cannot be performed or is not practical because of one or more of the following clinical circumstances:</p> <ul style="list-style-type: none"> <li>—percutaneous access cannot be achieved;</li> <li>—vital organs/tissues are at risk of damage from the percutaneous MTA procedure; or</li> <li>—resection of one part of the liver is possible, but there is at least one primary liver tumour in a non-resectable region of the liver which is suitable for microwave ablation, including any associated imaging services,</li> </ul> <p>not being a service associated with a service to which item 30419, 50950 or 50952 (or other MTA items) applies</p> <p>Fee: \$TBA</p> <p>[Relevant explanatory notes if required]</p>
Category 3—THERAPEUTIC PROCEDURES
<p>MBS [item number]</p> <p>NON-RESECTABLE METASTATIC LIVER LESIONS, destruction of, by percutaneous microwave tissue ablation (MTA), including any associated imaging services,</p> <p>not being a service associated with a service to which item 30419, 50950 or 50952 (or other MTA items) applies</p> <p>Fee: \$TBA</p> <p>[Relevant explanatory notes if required]</p>

MBS [item number]

NON-RESECTABLE METASTATIC LIVER LESIONS, destruction of, by open or laparoscopic microwave tissue ablation (MTA), including any associated imaging services, where a multidisciplinary team has assessed that percutaneous microwave ablation cannot be performed or is not practical because of one or more of the following clinical circumstances:

—percutaneous access cannot be achieved;

—vital organs/tissues are at risk of damage from the percutaneous MTA procedure; or

—resection of one part of the liver is possible, but there is at least one primary liver tumour in a non-resectable region of the liver which is suitable for microwave ablation, including any associated imaging services,

not being a service associated with a service to which item 30419, 50950 or 50952 (or other MTA items) applies

Fee: \$TBA

[Relevant explanatory notes if required]

MBS = Medicare Benefits Schedule; MTA = microwave tissue ablation; TBA = to be arranged

## 7. Summary of Public Consultation Feedback/Consumer Issues

The PICO Advisory Sub-Committee (PASC) public consultation feedback received one response from a peak body, one response from an organisation, three responses from specialists, one response from a researcher and one response from a consumer/carer.

The responses indicated:

- That the population should include patients with resectable liver lesions.
- That isolated bone metastases are an emerging indication for Microwave Tissue Ablation.
- That Stereotactic Body Radiation Therapy (SBRT) should be a comparator for the intervention.

Consumer feedback indicated that MTA is already used on a regular basis for the treatment of liver tumours in Australia and other industrialised countries.

## 8. Proposed intervention's place in clinical management

According to the clinical management algorithm provided in the protocol, MTA would be a direct substitution for RFA in indicated patients, with no other expected management changes. It is not expected that the MBS listing of MTA would result in any change in the number of patients indicated for ablation.

### Clinical Claim

The clinical claim was that MTA is a safer and more effective therapy than its comparator, RFA, for treating primary and secondary liver cancer. This claim is based on MTA's ability to provide more predictable ablation volume shapes and sizes, reducing the potential for compromise of healthy hepatic and extrahepatic tissue; larger ablation volumes in faster times; and reduced risk of burning and the heat sink effect.

## 9. Comparator

For Population 1, the assessment report nominated RFA as the sole comparator. RFA is similar to MTA in that it uses a current, at a lower frequency than MTA (375–480 kHz), delivered down an electrode to heat and destroy tissue. The resources required for the delivery of RFA are similar to those of MTA, including the need for imaging to guide the procedure and equivalently qualified practitioners to deliver the treatment. RFA for patients

with unresectable HCC is currently listed on the MBS (item 50950 for percutaneous approach and item 50952 for open or laparoscopic approach).

For Population 2, the assessment report nominated RFA with or without adjuvant chemotherapy, or chemotherapy. RFA is not listed on the MBS for this population.

For Population 3, the assessment report nominated multiple comparators: RFA with or without adjuvant chemotherapy, chemotherapy, chemoembolisation, radioembolisation, radiolabelled somatostatin analogue therapy and, rarely, resection. The proposed population in the PASC-approved protocol described this population as ‘unresectable’ and ‘refractory to somatostatin analogue therapy’; thus, resection and somatostatin analogue therapy were unlikely to be found as comparators. RFA is not listed on the MBS for this population.

## **10. Comparative safety**

The evidence from two systematic reviews in percutaneous ablation found a higher number of overall major adverse events in patients undergoing MTA than RFA; however, the differences were not statistically significant, and as the rates were low, the differences are unlikely to be of clinical importance.

Two comparative non-randomised studies that examined patients undergoing surgical ablation found higher rates of adverse events than in percutaneous ablation, in both the MTA and RFA groups, and inconsistent findings between studies. These studies were relatively small, and it is not clear whether the adverse events were defined in a similar way in each study. It is difficult to draw conclusions about the safety of MTA versus RFA in surgical ablation from these data.

No comparative safety data specific to Population 2 or 3 was identified, other than a mention of no procedure-related mortality in either group in the one comparative study. No conclusions can be drawn about the safety of MTA in these populations. As it is likely that the patients in these groups have more complex disease and are more unwell than those in Population 1, it is difficult to judge whether the safety profile for MTA in this group would be similar to that for Population 1.

## **11. Comparative effectiveness**

Overall, the evidence for Population 1 was consistent in reporting few clinically or statistically significant differences between MTA and RFA in this patient group. The findings are summarised in Table 2.

For percutaneous ablation, the systematic reviews were very consistent in their results across the primary outcome measures of local tumour recurrence, complete ablation, overall survival and recurrence-free survival, finding few statistically significant differences between MTA and RFA. The additional comparative studies also provided similar evidence for most outcomes. In studies including patients undergoing surgical ablation, data reporting was limited, but in two studies that reported either rates of recurrence or the relative risk of recurrence, there was no difference between the treatments.

There was some evidence that MTA was superior to RFA in patients with more severe classification of cancer for tumour recurrence; however, as most studies had historical controls, the result could also be due to other changes in cancer treatment over that time, resulting in better outcomes for patients with more severe disease.

Limited data on secondary outcomes were identified; in particular, there was a paucity of data supporting claims that MTA required less ablation time and fewer sessions.

For Population 2, one comparative study found a difference likely to be clinically meaningful, but not statistically significant, favouring MTA for local tumour recurrence. It also found better overall survival in years 2 and 5 for patients who had MTA, although these results were not statistically significant, and the small number of patients in this study makes the results difficult to interpret.

There is no evidence in Population 3 to enable any conclusions to be drawn about the effectiveness of MTA in this patient group.

Table 2 Balance of clinical benefits and harms of MTA, relative to RFA, as measured by the critical patient-relevant outcomes in the key studies for Population 1

Outcomes Follow-up	Studies (K) Participants (P)	Quality of evidence (GRADE) <sup>a</sup>	Range of results :OR/HR and 95% CI, P value	Comments
Local tumour recurrence— percutaneous	K = 3 SR  K = 2 RHCC	⊕⊕⊕⊕	ORs between 1.01 (0.67, 1.50) and 1.17 (0.61, 2.24) ORs between 0.91 and 1.13 (95% CI not reported) HR 2.17 (1.04, 4.50) P = 0.04	No difference between groups
Local tumour recurrence—surgical	K = 2 RHCC K = 1 RCCC	⊕⊕⊕⊕	MTA 0–23% vs RFA 9.1–25.5% with events	No difference between groups
Overall survival 1 year— percutaneous	K = 2 SR	⊕⊕⊕⊕	ORs between 1.11 (0.36, 3.47) and 1.36 (0.73, 2.54)	No difference between groups
Overall survival 3 years—percutaneous	K = 3 SR	⊕⊕⊕⊕	ORs between 0.58 (0.32–1.07) and 0.95 (0.58, 1.57)	No difference between groups
Recurrence-free survival—percutaneous: 1 year 3 years 5 years	K = 1 SR  N = 668 N = 596 N = 353	⊕⊕⊕⊕	OR 0.79 (0.56, 1.13), P = 0.20 OR 1.03 (0.73, 1.45), P = 0.99 OR 0.60 (0.39, 0.94), P = 0.03	No difference between groups except at 5 y
Complete ablation— percutaneous	K = 3 SR	⊕⊕⊕⊕	ORs between 0.98 (0.85, 1.14) and 1.12 (0.67, 6.07)	No difference between groups
Major adverse events— percutaneous	K = 2 SR  K = 1 RCCC	⊕⊕⊕⊕	OR 0.63 (0.29, 1.38)—note MTA was the comparator OR 1.63 (0.88, 3.03), P = 0.12 OR 0.88 (0.43, 1.79), P = 0.73 <sup>b</sup>	No difference between groups; low event rates
Major adverse events— surgical	K = 2 RHCC	⊕⊕⊕⊕	ORs between 0.35 (0.10, 1.20), P = 0.09, and 1.92 (0.47, 7.77), P = 0.36 <sup>b</sup>	No difference between groups; small studies
Procedure-related deaths—percutaneous	K = 1 RCCC	⊕⊕⊕⊕	OR 1.16 (0.10, 12.87), P = 0.90 <sup>b</sup>	No difference between groups; very low rates

CI = confidence interval; GRADE = Grading of Recommendations Assessment, Development and Evaluation; HR = hazard ratio; MTA = microwave tissue ablation; RHCC = retrospective historical control cohort; RCCC = retrospective concurrent control cohort; OR = odds ratio; RFA = radiofrequency ablation; SR = systematic review

<sup>a</sup> GRADE Working Group grades of evidence (Guyatt et al 2013):

⊕⊕⊕⊕ **High quality:** We are very confident that the true effect lies close to that of the estimate of effect

⊕⊕⊕⊕ **Moderate quality:** We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

⊕⊕⊕⊕ **Low quality:** Our confidence in the effect estimate is limited: the true effect may be substantially different

⊕⊕⊕⊕ **Very low quality:** We have very little confidence in the effect estimate: the true effect is likely to be substantially different

<sup>b</sup> ORs and CIs calculated from published figures

On the basis of the benefits and harms reported in the evidence base, it is suggested that, relative to RFA, MTA has non-inferior safety and non-inferior effectiveness in Population 1.

On the basis of limited evidence, it is suggested that, relative to RFA, MTA has non-inferior safety and non-inferior effectiveness in Population 2. There is insufficient evidence to determine the safety and effectiveness of MTA, relative to RFA, in Population 3.

## 12. Economic Evaluation

A stepped approach was taken where the cost of the procedure alone is compared first, and then the cost of other healthcare resources associated with the procedure is added. As the evidence related to the comparative effectiveness of MTA and RFA is limited or inconclusive, various sensitivity analyses are presented for both populations.

### Population 1

When only the procedural costs of MTA and RFA are compared (excluding all other associated anaesthetic and other healthcare costs), there is no incremental cost associated with MTA in the base case (Table 3).

**Table 3 Incremental cost of MTA excluding other associated costs, Population 1**

Item description	MTA	RFA	Incremental cost
Ablation procedure	\$817	\$817	\$0

MTA = microwave tissue ablation; RFA = radiofrequency ablation

When all other associated healthcare costs are included in the analysis, the cost of both MTA and RFA is estimated to be \$7,235. Since in the base case the use of all associated healthcare resources is considered similar across the two procedures, the incremental cost remains the same (that is, \$0).

Table 4 shows the overall costs and the incremental cost per patient as calculated for the intervention and comparator in the analysis, with the base-case assumptions.

**Table 4 Costs associated with MTA and RFA, Population 1**

Item description	MTA	RFA
Ablation procedure	\$817	\$817
Pre-anaesthesia consultation	\$43	\$43
Initiation of management of anaesthesia	\$139	\$139
Other hospital costs	\$6,236	\$6,236
<b>Total</b>	<b>\$7,235</b>	<b>\$7,235</b>
<b>Incremental cost per patient</b>	<b>-</b>	<b>\$0</b>

MTA = microwave tissue ablation; RFA = radiofrequency ablation

### Sensitivity analyses

Sensitivity analyses are presented in Table 5 to assess the impact of varying the costs associated with the procedures. The base-case analysis considered similar costs for MTA and RFA. A sensitivity analysis considering the weighted cost of MTA based on the number of lesions treated per patient (\$817 for treating up to 3 lesions, and \$1,300 for >3 lesions) was performed. Approximately 70 per cent of the patient population with primary liver cancer is estimated to have one to three lesions. The weighted cost of MTA based on 70:30 per cent stratification equates to \$962.

MTA and RFA are similar procedures with similar safety and effectiveness (Section B). As such, the base-case analysis included similar hospital costs for both. However, as per the applicant's and some clinicians' suggestions, if MTA allows faster ablation times than RFA, this would result in cost savings associated with operating/procedure rooms. The operating costs per unit of time could not be identified from the available data, so sensitivity analyses assuming an arbitrary decrease of 10 and 20 per cent in hospital costs associated with MTA are presented. Also, the number of anaesthesia basic units used is decreased from 7 in the base case (MBS item 21922) to 6 and 5, reducing the cost of management of anaesthesia. Sensitivity analyses were also performed to assess the impact of varying the number of MTA or RFA sessions per patient.

Table 5 presents the sensitivity analyses of key parameters discussed above.

**Table 5 One-way sensitivity analyses of key parameters, Population 1**

Sensitivity analyses	MTA	RFA	Incremental cost per patient
<b>Base case</b>	<b>\$7,235</b>	<b>\$7,235</b>	<b>\$0</b>
Weighted MBS fee for MTA: \$962	\$7,380	\$7,235	\$145
Reducing hospital costs of MTA by 10%	\$6,611	\$7,235	-\$624
Reducing hospital costs of MTA by 20%	\$5,988	\$7,235	-\$1,247
Reducing 1 basic units of anaesthesia for MTA	\$7,215	\$7,235	-\$20
Reducing 2 basic unit of anaesthesia for MTA	\$7,195	\$7,235	-\$40
Number of MTA sessions required per patient: 2.4	\$17,364	\$7,235	\$10,129
Number of RFA sessions required per patient: 1.2	\$7,235	\$8,682	-\$1,447

MBS = Medicare Benefits Schedule; MTA = microwave tissue ablation; RFA = radiofrequency ablation  
Shaded cells show analyses indicating a potential cost saving (negative value for incremental cost) with the proposed treatment with MTA

As seen in Table 5, the MBS fee for MTA, hospital costs and the number of sessions required for either procedure are the key drivers of the economic analysis. If treatment with MTA results in a reduction in associated hospital costs or the number of sessions required compared with RFA, it may result in potential cost-savings when the same blanket fee as RFA is applied.

However, if the proposed graduated fee scheme is applied, the incremental cost will vary in the range of -\$814 to +\$11,648 with a base-case incremental cost of \$633.

## Population 2

When only the procedural costs of MTA and RFA are compared (excluding all other associated anaesthetic and other healthcare costs), there is no incremental cost associated with MTA for the base case (Table 6).

**Table 6 Incremental cost of MTA excluding other associated costs, Population 2**

Item description	MTA	RFA	Incremental cost
Ablation procedure	\$817	\$817	<b>\$0</b>

MTA = microwave tissue ablation; RFA = radiofrequency ablation

When all other associated healthcare costs are included in the analysis, the cost of both MTA and RFA is estimated to be \$8,039. And since all other healthcare costs are considered to be similar across the two procedures, the incremental cost remains the same (that is, \$0).

Table 7 shows the overall costs and the incremental cost per patient as calculated for the intervention and comparator in the analysis, with the base-case assumptions.

**Table 7 Costs associated with MTA and RFA, Population 2**

Item description	MTA	RFA
Ablation procedure	\$817	\$817
Pre-anaesthesia consultation	\$43	\$43
Initiation of management of anaesthesia	\$139	\$139
Chemotherapy	\$805	\$805
Other hospital costs	\$6,236	\$6,236
<b>Total</b>	<b>\$8,039</b>	<b>\$8,039</b>
<b>Incremental cost per patient</b>		<b>\$0</b>

MTA = microwave tissue ablation; RFA = radiofrequency ablation

### Sensitivity analyses

Sensitivity analyses are presented in Table 8, and include assessment of the cost impact of varying costs associated with procedures: MBS fees charged (stratified on the basis of number of lesions), hospital costs, anaesthesia cost and number of ablation sessions required. An additional analysis assumed a 10 per cent relative reduction in chemotherapy usage with MTA.

A sensitivity analysis considering the weighted cost of MTA based on the number of lesions treated per patient (\$817 for treating up to 5 lesions, \$1,300 for treating >5 lesions) was performed. Approximately 60 per cent of the patient population with liver cancer metastasis is estimated to have more than five lesions. % stratification equates to \$1,107.

MBS data suggested that, on average, patients required 1.1–1.2 RFA sessions for treating primary HCC. No such data are available to estimate the number of ablation sessions required per patient for Population 2 with secondary liver metastasis. This patient group is expected to be sicker and to have more liver lesions than Population 1. As such, the number of sessions required per patient may be higher than for Population 1.

**Table 8 One-way sensitivity analyses of key parameters, Population 2**

Sensitivity analyses	MTA	RFA	Incremental cost per patient
<b>Base case</b>	<b>\$8,039</b>	<b>\$8,039</b>	<b>\$0</b>
Weighted MBS fee of MTA: \$1,107	\$8,329	\$8,039	\$290
Reducing hospital costs of MTA by 10%	\$7,416	\$8,039	-\$624
Reducing hospital costs of MTA by 20%	\$6,792	\$8,039	-\$1,247
Reducing 1 basic unit of anaesthesia for MTA	\$8,019	\$8,039	-\$20
Reducing 2 basic units of anaesthesia for MTA	\$8,000	\$8,039	-\$40
Number of MTA sessions required per patient: 2.4	\$19,294	\$8,039	\$11,255
Number of RFA sessions required per patient: 1.2	\$8,039	\$9,647	-\$1,608
Number of RFA sessions required per patient: 2	\$8,039	\$16,078	-\$8,039
Relative reduction of 10% in chemotherapy usage with MTA	\$7,887	\$8,039	-\$152

MBS = Medicare Benefits Schedule; MTA = microwave tissue ablation; RFA = radiofrequency ablation  
Shaded cells show analyses indicating a potential cost saving (negative value for incremental cost) with the proposed treatment with MTA

As seen in Table 8, the MBS fee for MTA, hospital costs and the number of sessions required for either procedure are the key drivers of the economic analysis. If treatment with MTA

results in a reduction in associated hospital costs or in the number of sessions compared with RFA, it may result in potential cost-savings when the same fee as RFA is applied.

However, if the proposed graduated fee scheme is applied, the incremental cost will vary from -\$7,077 to +\$13,567 with a base-case incremental cost of \$963.

### 13. Financial/budgetary impacts

There may be some financial implications (cost-savings) for state and territory government health budgets, such as for public hospitals (including inpatient admissions, emergency department visits and outpatient clinic visits) due to the extension of services in the private sector. However, quantification of such cost shifts (from state health budgets to MBS) is harder, since the proposed listing is much broader than the existing listing for RFA, and because both RFA and MTA are being performed currently in Australian hospitals.

Table 9 presents the estimated financial implications of the proposed MTA listing (assuming no growth in the market) for other healthcare budgets. These estimates should be interpreted with caution as there may be some increase in the number of ablations performed in clinical practice, in which case the estimates presented will overestimate the cost offsets associated with MTA listing. The cost of ablation services performed in public hospitals is taken from AR-DRG H05B (Hepatobiliary Diagnostic Procedures without Catastrophic Complications) (Independent Hospital Pricing Authority (IHPA) 2015a) and adjusted for inflation: \$6,840 (\$7,048 in 2016 AUD). MTA performed in the private sector will incur costs to Medicare, private hospitals and patients or private health insurers. Costs to PHIs are calculated as the sum of healthcare costs excluding costs to Medicare and co-payments associated with MTA (\$6,236 + \$204 = \$6,440).

**Table 9 Cost implications for other healthcare budgets (assuming no growth in number of ablations)\***

	2017–18	2018–19	2019–20	2020–21	2021–22
-					
State governments: number of MTA services offset	9	19	29	40	52
Cost savings to state governments	\$58,258	\$127,921	\$196,182	\$273,085	\$355,445

\* It is assumed that there would be no growth in the number of ablations performed; and there will be extension of services in the private settings. Thus, a cost shift from public sector to private sector. MBS = Medicare Benefits Schedule; MTA = microwave tissue ablation

Table 10 presents the financial implications to the private sector (patients or PHI) of listing MTA.

**Table 10 Total costs to private sector associated with MTA listing for Population 1**

	2017–18	2018–19	2019–20	2020–21	2021–22
-					
Number of MTA services	130	145	160	176	194
Cost to private sector	\$825,654	\$922,268	\$1,018,149	\$1,122,653	\$1,232,765
<b>Offsets</b>					
Number of services offset	121	126	131	137	142
Costs offset	\$770,986	\$802,774	\$835,134	\$868,077	\$901,550
<b>Net costs to private sector (including co-payments)</b>	<b>\$54,668</b>	<b>\$119,493</b>	<b>\$183,015</b>	<b>\$254,576</b>	<b>\$331,215</b>

MBS = Medicare Benefits Schedule; MTA = microwave tissue ablation

As seen in Table 9 and Table 10, MTA listing may result in cost shifting from the state government healthcare budgets to Medicare and PHI.

#### **14. Key issues from ESC for MSAC**

ESC noted the following issues in regard to safety:

- Population 1 – difficult to draw conclusions - as safe – non-inferior
- Populations 2 and 3 – no comparative evidence on safety

ESC noted the following issues in regard to effectiveness:

- Population 1 - some evidence of non-inferior safety and effectiveness
- Population 2 - limited evidence of non-inferior safety and effectiveness – however the comparator of RFA is not listed
- Population 3 - insufficient evidence

ESC noted the following issues in regard to the economics and fee:

- Cost minimisation using same fee as RFA
- Key drivers – hospital costs and number of sessions
- Unclear private- public split
- Population 2 potential out of pocket costs if MTA introduced as better than RFA – noting RFA not funded by MSAC in this population
- Based on lack of demonstrated superiority it may be more appropriate that MTA fees are consistent with RFA fees.

ESC noted the Consumer Representatives issues included:

- access for rural and regional;
- its non-inferiority to current practice, and
- incremental costs as the incidence rate increases.

#### **15. Other significant factors**

Nil.

#### **16. Applicant's comments on MSAC's Public Summary Document**

The applicant had no comment.

#### **17. Further information on MSAC**

MSAC Terms of Reference and other information are available on the MSAC Website: [visit the MSAC website](#)