Australian Government

Medical Services Advisory Committee

Public Summary Document

Application 1196 – Repetitive Transcranial Magnetic Stimulation (rTMS) as a treatment for depression

Applicant: **Committee for Therapeutic Interventions & Evidence Based Practice, Royal Australian & NZ College of Psychiatrists**

Date of MSAC consideration: MSAC 62nd Meeting, 26-28 November 2014

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, see at www.msac.gov.au

1. Purpose of application and links to other applications

An application requesting MBS listing of repetitive transcranial magnetic stimulation (rTMS) for the treatment of major depression was received from the Committee for Therapeutic Interventions and Evidence-Based Practice, Royal Australian and New Zealand College of Psychiatrists by the Department of Health in February 2012.

2. MSAC's advice to the Minister

After considering the available evidence in relation to safety, clinical effectiveness and cost-effectiveness, MSAC did not support public funding because of uncertain effectiveness and cost-effectiveness due to insufficient comparative data in treatment-resistant patients against current antidepressant treatments and uncertain costs.

MSAC considered that any reapplication should include:

- better definition of the patient population;
- better definition of the clinical setting for this treatment;
- evidence comparing rTMS against contemporary alternative antidepressants in this patient population; and
- further consideration of the treatment costs of anti-depressants.

MSAC considered that any reapplication should be made via ESC and would require external evaluation.

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

MSAC noted that the proposed eligible population for this treatment is patients with treatment–resistant depression, that is, those who fail to respond to two different classes of antidepressant medication despite adequate dose duration and compliance. MSAC expressed a number of concerns with regards to the patient eligibility descriptor, such as:

- some patients may never meet this definition due to potential side effects with antidepressants thereby limiting the use of different antidepressant classes; and
- the wording "adequate dose duration" and "compliance" is open to interpretation and could lead to use of rTMS in a broader patient group than that intended such as:.
    - as an alternative to drug therapy in major depression
    - in lower severity patients based on personal preference and a desire to avoid short term trials of different antidepressants.

The application proposed that only psychiatrists may determine eligibility for treatment with rTMS. This involves a "mapping" procedure to locate the motor cortex under the patient's scalp (to enable measurement to the dorsolateral prefrontal cortex); and prescription of the dose of rTMS. Delivery of rTMS would be by an allied health professional, a clinical care professional (Honours level qualifications with relevant clinical experience) or a nurse (general or mental health). MSAC noted that the application proposed two new MBS items: one for initial diagnosis, mapping and dose prescription, performed by a psychiatrist trained in rTMS; and one for the rTMS treatment itself, performed by a nurse or allied health professional in an approved hospital setting under medical supervision.

MSAC expressed concern at the lack of detailed information on cost inputs underlying the proposed fee of $150 for the treatment, and queried whether this figure could be justified given that rTMS would be provided by a nurse or allied health professional, especially in light of the low capital costs of the equipment, and the probable high-throughput service models. MSAC questioned whether two new MBS items were required for this treatment, given there is only one MBS item for providing electroconvulsive therapy (ECT), with the prescribing and planning for ECT provided in a single consultation.

A course of rTMS involves between twenty and thirty treatments over a four-to-six week period, with each individual treatment session taking approximately 40 minutes. MSAC noted that consumers may therefore be impacted by compounding travel costs, out of pocket costs and loss of productivity.

MSAC agreed that the main comparator for this intervention, third line use of antidepressants or augmentation with mood stabilisers such as lithium, was appropriate. Although ECT was used as a comparator in the literature the suitability of ECT was questioned by MSAC, as it is often used for serious acute and psychotic episodes requiring a rapid response whereas rTMS is indicated for non-psychotic patients.

MSAC noted that there was no direct comparative evidence of safety outcomes from trial evidence for rTMS compared with either antidepressants or ECT, and that the primary sources of evidence for safety are from US-based, randomised-controlled, open-label extension trials and post-market reviews. From the available evidence presented, rTMS is non-systemic, non-invasive and believed to have a superior safety profile to antidepressants and ECT, however, as the biological mechanism involved in rTMS is not fully understood the long-term safety of rTMS in unknown.

For the primary comparator of antidepressants, MSAC noted that no direct head-to-head trials were identified. Direct RCT level I evidence comparing rTMS with sham, concluded that rTMS is superior to sham. Indirect evidence on remission and response rates shows that rTMS is also at least as equivalent, or more effective, than antidepressants, depending on the agent. Evidence for rTMS efficacy versus ECT was determined by two meta-analyses where ECT was found to be more effective in the overall sample, but this difference was much less when considering non-psychotic depression – the proposed patient population for rTMS.

A cost-utility analysis was undertaken using a Markov micro-simulation model with a three-year duration and two-monthly cycles. In the model, the total cost for one course of rTMS treatment was $4,595 compared with $8,490 for ECT and $505 for antidepressants. The economic model predicted that rTMS is cost-effective compared to antidepressants but not cost-effective compared with ECT, as rTMS produced fewer costs but also fewer QALYs.

MSAC expressed concern over the lack of sufficient detail on the likely practice model for rTMS, which has implications for the economic evaluation and the relevant MBS descriptor and fee. It was noted that the most common model, which is currently not available, will be private practice (private rooms) outpatient model, in which the nurse delivering the rTMS is directly employed and supervised by the psychiatrist.

MSAC noted that the listing of rTMS therapy is expected to have a net cost to the MBS of approximately $9.2 million in the first year, increasing to $13.4 million in the fifth year. In addition, over the next five years, rTMS treatment and psychiatrist consults would cost the MBS approximately $56.2 million after cost-offsets are taken into account. Sensitivity analyses indicate that the net costs to the health budget are strongly influenced by the uncertainty around the expected number of rTMS patients. In the base case, of those who have failed two adequate antidepressants, 0.56% is estimated to receive rTMS but if this increases to 1.5%, the net MBS cost in the first year increases substantially to $16.4 million.

4. Background

An assessment of rTMS for major depression was considered by MSAC in 2007 (Application 1101). rTMS was compared against electroconvulsive therapy (ECT); the application was rejected due to insufficient evidence of effectiveness.

5. Prerequisites to implementation of any funding advice

There are two items listed by the Therapeutic Goods Administration (TGA) which are classified as “Stimulator, magnetic”. The magnetic stimulator was previously listed with the intended purpose “To stimulate the peripheral and central nervous system by the application of magnetic waves”. This has been amended to state the intended purpose as “Treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from two prior antidepressant medications, at or above the minimal effective dose and duration in the current episode.”

6. Proposal for public funding

The application proposed two new MBS items: one for initial diagnosis, mapping and dose prescription, performed by a psychiatrist trained in rTMS (Fee: $350); and one for the rTMS treatment itself, performed by a nurse or allied health professional in an approved hospital setting under medical supervision (Fee: $150).

The proposed MBS items are:

Category 3 – THERAPEUTIC PROCEDURES
MBS [proposed MBS item number] REPETITIVE TRANSCRANIAL MAGNETIC STIMULATION treatment prescription by a psychiatrist Fee: $350 This item enables a psychiatrist to prescribe rTMS, to determine if the patient is eligible to have the treatment, to do the "mapping" procedure whereby the location of the motor cortex on the patients scalp is determined (enabling measurement forward to the dorsolateral prefrontal cortex) and to prescribe the dose of rTMS as a proportion of the motor threshold. This item enables a psychiatrist to prescribe rTMS, to determine if the patient is eligible to have the treatment, to do the "mapping" procedure whereby the location of the motor cortex on the patients scalp is determined (enabling measurement forward to the dorsolateral prefrontal cortex) and to prescribe the dose of rTMS as a proportion of the motor threshold.
MBS [proposed MBS item number] REPETITIVE TRANSCRANIAL MAGNETIC STIMULATION treatment provided by a nurse or allied health professional. Fee: $150 This item enables a nurse or allied health professional to provide rTMS treatment to a patient, under medical supervision. The rTMS treatment must be prescribed by a psychiatrist (as described above) and be given in a setting where immediate medical assistance is available if required.

rTMS is being proposed as a treatment option for patients with major depression who have failed to respond to two different classes of antidepressant medication, despite appropriate dose, duration and compliance.

It is proposed that only psychiatrists may prescribe treatment, and it would be they who would determine if a patient is eligible for treatment with rTMS (i.e. having treatment-resistant major depression). The psychiatrist would then provide a treatment prescription for rTMS, and perform a "mapping" procedure, locating the motor cortex under the patients scalp (to enable measurement to the dorsolateral prefrontal cortex), and prescribing the dose of rTMS as a proportion of the patients motor threshold.

rTMS would be delivered by an allied health professional, a clinical care professional (Honours level qualifications with relevant clinical experience) or a nurse (general or mental health).

7. Summary of Public Consultation Feedback/Consumer Issues

Fifteen responses were received to the public consultation (one research psychologist; three researchers; one professional body; and ten consumers).

Professional body feedback noted that rTMS is currently used in private settings; if it was listed on the MBS it would facilitate equitable access for individuals who currently are not able to access such treatments. It was also noted that countries such as Canada, the United States, Israel and a number of European countries have recognised the efficacy of rTMS, resulting in clinical approval and adoption of the technique. The feedback stated that there is a pressing need for new treatment options for patients with treatment resistant depression, particularly as these patients are typically highly disabled and place a substantial demand on families, private and public health care systems.

Consumer feedback noted that rTMS was the first treatment which alleviated all symptoms in a non-invasive way without any side effects. It was claimed that rTMS will improve patient's self-esteem and confidence, allow them to have a better standard of living, including work and relationships as well as relieving stress on family/carers/partners. Consumers also considered there would be less need for visits to the local GP and psychologists. Listing rTMS would increase availability to people experiencing financial hardship as well as increasing access in rural communities.

Consumer representatives noted access and equity concerns, exacerbated by the frequency and intensity of the treatment regimen for rTMS with resultant impact on quality of life, productivity and therefore potentially income. Consumers may find psychotherapy options preferable, but these options were not presented and compared making the information incomplete in terms of assessing cost and preference from a consumer perspective. Patient preferences should be considered to achieve a true perspective of the patient population.

Consumers may be impacted by compounding travel costs, out of pocket costs and loss of productivity. This impact would be compounded if a course of treatment needs to be repeated. The proportion of patients who would need this is unclear making it impossible to determine longer term impact.

8. Proposed intervention's place in clinical management

Major Depression (DSM IV) is a disorder of mood with features of depressed mood, loss of energy and interest, loss of pleasure, feelings of hopelessness and worthlessness, sleep and appetite disturbance and suicidal thoughts and behaviour. Accompanying disability can be severe and lead to social and occupational disruption.

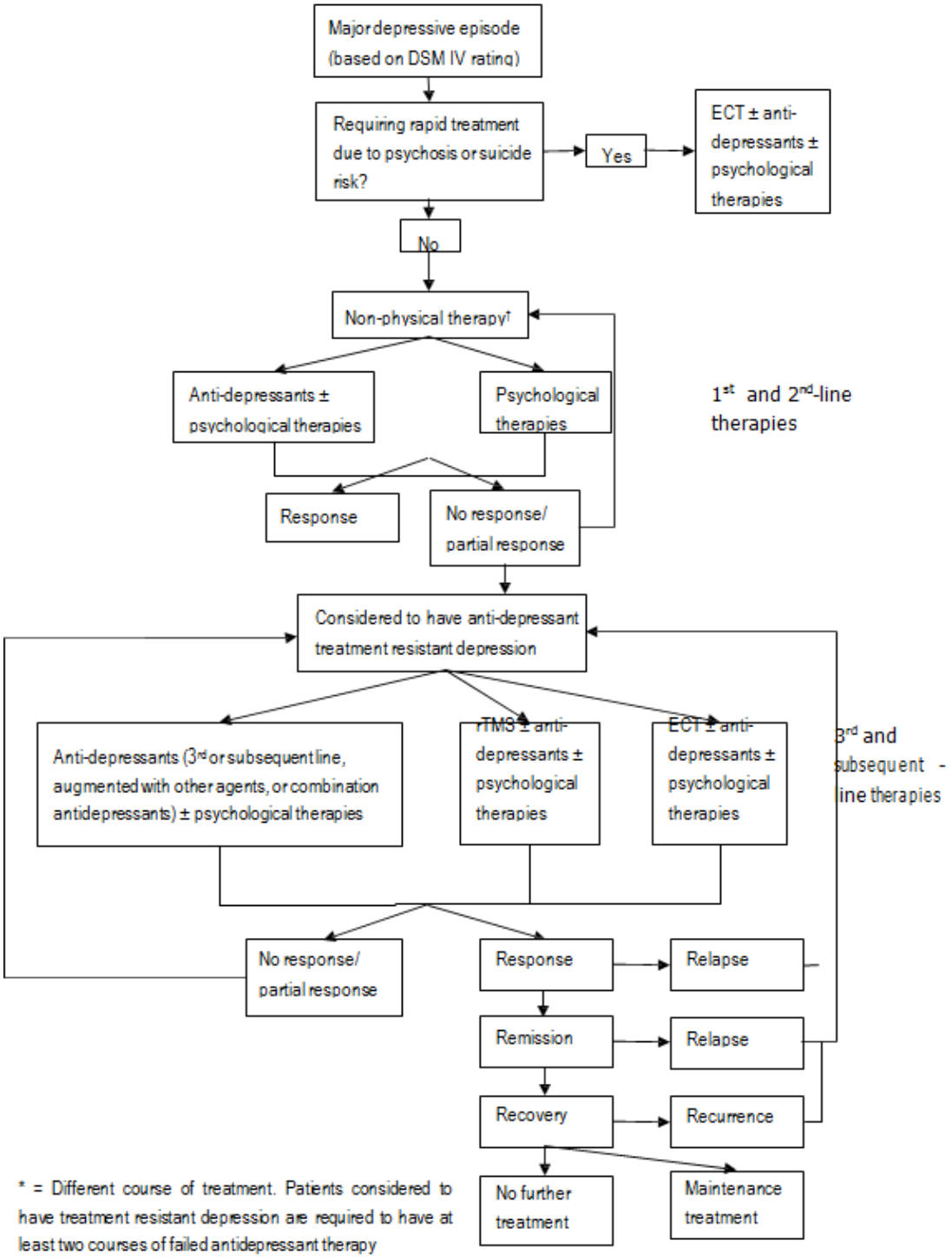
There are a range of different treatments available to treat major depressive disorders, including medication and psychological treatments. However, 10% to 30% of patients with major depression do not respond to antidepressant medication.

rTMS has been proposed as a treatment for depression since the mid-1990s (Fitzgerald 2011). rTMS is a focal brain stimulation treatment. Small electrical currents that pass through an electromagnetic coil held near the patient's scalp stimulate nerve cells in the region of the brain involved in mood regulation and depression. rTMS does not require an anaesthetic and there is no associated cognitive impairment or other serious side effects.

rTMS currently receives no public reimbursement and the costs are not reimbursed by private health insurance. rTMS is currently available in a small number of hospitals in Australia, with the costs being met by either the organisation (such as the Adelaide Clinic at Ramsay Health Care Mental Health Services in South Australia) or the patient (Galletly et al 2010).

rTMS is intended to be used in place of two current (alternative) interventions; 3rd-line antidepressants or ECT. rTMS may also be used in conjunction with antidepressants. It can also be performed with or without concurrent psychological therapies such as cognitive behavioural therapy. The clinical management algorithm below shows the proposed place of rTMS in clinical treatment. The clinical evidence presented in the report addressed the requirements of the agreed DAP.

Figure 1 Management algorithm for patients with major depression



* = Different course of treatment. Patients considered to have treatment resistant depression are required to have at least two courses of failed antidepressant therapy

† Physical therapies = ECT and rTMS

9. Comparator

The main comparator is antidepressant therapy but PASC advised that ECT should also be a comparator in this assessment.

ECT is used as a comparator in the literature and is another form of neurostimulation therapy. However, it was noted that ECT may not be a suitable comparator because it primarily targets a different population than that proposed for rTMS. ECT is often used for serious acute and psychotic episodes requiring a rapid response whereas rTMS is indicated for non-psychotic patients. Therefore, the potential replacement of ECT by rTMS may be small, although from the patient's perspective, rTMS may be a more preferable choice. However both rTMS and ECT can be offered for patients with treatment-resistant depression.

MSAC agreed that the main comparator for this intervention, third line use of antidepressants or augmentation with mood stabilisers such as lithium, was appropriate.

10. Comparative safety

The primary sources of evidence for safety were US-based RCTs, open-label extension trials and post-market reviews. There was no direct comparative evidence of safety outcomes from trial evidence for either antidepressants or ECT. The available evidence indicated that all three treatments have different toxicity profiles. Comparatively, rTMS has the least serious effects of all three options.

rTMS is non-systemic and non-invasive and is widely believed to have a superior safety profile to both antidepressants and ECT. The most serious safety issues are pain at the site of administration which is usually mild and transient and seizures, which are extremely rare. Post-market surveillance on rTMS shows very low levels of serious toxicity in 14,000 patients worldwide since 2008.

However, the assessment noted that the biological mechanism involved in rTMS is not fully understood, but does not address the (unknown) implications of this for the long-term safety of rTMS.

11. Comparative effectiveness

For the primary comparator of antidepressants, no direct head-to-head trial was identified that compared rTMS and antidepressants. The included trials were primarily rTMS vs sham. Indirectly comparing the evidence on remission and response rates shows that rTMS is at least as equivalent or more effective than antidepressants depending on the agent. The indirect comparison was based on the population in the rTMS trials, ie having had a relapse of their depression, having failed at least one and up to four antidepressant trials, but with at least one trial that has been taken for an adequate dose and duration.

Evidence for rTMS efficacy vs ECT was determined by two meta-analyses where ECT was found to be more effective in the overall sample, but this difference was much less when considering non-psychotic depression, the patient sample for which rTMS is proposed.

rTMS is superior to sham using direct RCT level I evidence. However, indirect comparisons with ECT are less consistent and evidence shows rTMS may be equivalent at best to ECT or inferior.

12. Economic evaluation

A cost-utility analysis was undertaken using a Markov microsimulation model with a three-year duration and two-monthly cycles. This provided a structure where sufficient time could elapse to capture the treatment consequences of remission, relapse, maintenance, hospitalisations and re-treatment with rTMS or an alternative. The model inputs were based on reviews of the literature, Australian cost estimates and expert advice where assumptions were necessary. In the model, the total cost for one course of rTMS treatment was $4,595 compared with $8,490 for ECT and $505 for antidepressants. The key results are presented below.

Key economic evaluation findings (3 year duration)

Strategy	Mean Costs	Mean QALYs	ΔCost	ΔQALY	ICER
rTMS	$29,670	1.250	referent	referent	referent
Antidepressants	$31,330	1.180	-$1,660	0.070	rTMS dominant
ECT	$31,260	1.280	-$1,591	-0.030	$75,844

ECT = Electroconvulsive therapy; rTMS = repetitive Transcranial Magnetic Stimulation; QALY = quality-adjusted life years; ICER = incremental cost effectiveness ratio

The economic model predicted that rTMS is cost-effective compared with a strategy of antidepressants but not cost-effective compared with ECT. Compared with ECT, rTMS produced fewer costs but also fewer QALYs. Sensitivity analyses showed there was a 70.5% likelihood that rTMS was cost-effective against antidepressants and 38.8% against ECT at the willingness-to-pay threshold of $50,000 per QALY.

The likely practice models to be used in the delivery of rTMS, has implications for the economic evaluation and the relevant MBS descriptor and fee. The applicant anticipated that the most common model will be a private practice (private rooms) outpatient model, in which the nurse delivering the rTMS is directly employed and supervised by the psychiatrist. It should be noted that this model is not available currently in Australia.

PASC had advised that, because of rTMS's high level of safety, the restriction of rTMS to approved hospitals is unnecessary and rTMS could be provided in a day clinic. The applicant also advised it is anticipated that, if MBS funding were made available, rTMS would be delivered predominantly in a private practice setting.

13. Financial/budgetary impacts

A summary of the overall expected uptake and costs of rTMS is provided in the table below.

Summary of financial estimates for rTMS funding

	2015	2016	2017	2018	2019
Expected number of rTMS patients	2,012	2,233	2,460	2,695	2,935
Total number of rTMS treatments per year	82,777	91,870	101,236	110,872	120,757
Cost of rTMS to MBS	$13,586,786	$15,079,417	$16,616,702	$18,198,329	$19,820,809
Cost saving to PBS from reduced lithium use	-$2,511	-$2,787	-$3,071	-$3,363	-$3,663
Cost saving to MBS from reduced lithium testing	-$20,049	-$22,251	-$24,519	-$26,853	-$29,247
Cost saving to MBS due to reduced ECT use	-$4,393,088	-$4,875,709	-$5,372,768	-$5,884,164	-$6,408,769
Total Net MBS cost	$9,173,649	$10,181,457	$11,219,415	$12,287,312	$13,382,793
Overall Net Cost to the health budget	$9,171,138	$10,178,670	$11,216,344	$12,283,949	$13,379,130

The financial estimates above take into account the numbers of patients requiring reintroduction and maintenance and a small upwards adjustment for increased uptake if more machines are made available in Australia. The listing of rTMS therapy is expected to have a net cost to the MBS of approximately $9.174 million in Year 1, increasing to $13.383 million

in Year 5. Over the next 5 years, rTMS treatment and psychiatrist consults would cost the MBS approximately $56.244 million, after cost-offsets are taken into account. In sensitivity analyses, the net costs to the health budget are strongly influenced by the uncertainty around the expected number of rTMS patients. In the base case, of those who have failed two adequate antidepressants, 0.56% is estimated to receive rTMS but if this increases to 1.5%, the net MBS cost in the first year increases substantially to $16.377 million.

14. Key issues from ESC for MSAC

The proposed eligible population for this treatment is patients with treatment resistant depression i.e. those who fail to respond to two different classes of antidepressant medication, despite adequate dose duration and compliance. ESC noted that some patients may never meet this definition due to potential side effects with antidepressants limiting trials of different antidepressant classes, thereby limiting the achievement of an "adequate dose and duration."

ESC further noted that the wording 'adequate dose duration' and 'compliance' could be open to interpretation. Given the relative safety and tolerability profile, this could lead to leakage of the patients who do not meet these criteria being offered rTMS as an alternative. Therefore ESC was concerned about leakage into lower severity groups on patient preference for treatment. Short term trials of different antidepressants may not be preferred by patients compared to short term treatment with rTMS which may be more appealing.

ESC considered that the main comparator of third line use of antidepressants or augmentation with mood stabilisers such as lithium was appropriate. However, ESC also noted that some of the newer antidepressants, and some augmentation regimes more recently used, may have better response and relapse rates than those used in the studies (such as the Star D trial) considered in the assessment report.

ESC noted that psychotherapy was not a likely comparator in this patient population as in clinical practice it would generally be used early (without medication) in the normal line of treatment of mild-moderate depression. ESC also considered that Electro Convulsive Therapy (ECT) was not a likely comparator for patients at the proposed stage of depression as in clinical practice it is mainly used in very severe treatment resistant patients with rapid onset, suicidal or psychotic illness.

ESC noted the assessment found that rTMS has a superior safety profile over both antidepressants and ECT, based on 6-12 months data showing that adverse events in rTMS treatment are rare and minor. However, ESC was concerned about the implications for the long term safety of rTMS because the biological mechanism of action of rTMS is not fully understood.

ESC was also uncertain about the safety of the settings for rTMS treatment. ESC questioned the validity of the claim that rTMS could be delivered at the same levels as MRI. ESC noted that MRI is not a therapeutic treatment and considered it was most likely that rTMS was delivered at a higher or more acute levels than MRI and therefore suggested consideration of whether the number of treatments patients can have should be limited due to the uncertainty of the effect of long term treatment.

ESC noted that no direct comparative data was available which specifically addressed the PICO population in the final Protocol. However, ESC considered that if rTMS demonstrated effectiveness compared to sham in the presented (albeit) variable trial populations which

were treatment resistant and less likely to respond to further treatment, then it is reasonable to extrapolate those results to the PICO population.

ESC was concerned about the heterogeneity in the rTMS trial populations, in terms of the previous number of drugs patients had tried prior to rTMS treatment. The trials varied between 4 prior medications down to only 1 prior medication. Therefore, the basis of the figure (failure to respond to 2 medications) in the descriptor is uncertain. Nevertheless, ESC considered that since the rTMS trials showed rTMS to be effective in patients who, having tried 1-4 antidepressants, are less likely to respond to treatment, it may be reasonable to extrapolate those results to the PICO population.

As highlighted in the report, ESC also noted the limitations of the Star D study which forms the basis for much of the linked evidence presented, as well as many of the assumptions in the economic model. Although it is commonly cited as a naturalistic "real world" study, it is an American study which required patients to follow a strict treatment algorithm, all of which started with citalopram. Furthermore, it used some medications not approved for use in depression in Australia (such as bupropion). It does not allow any conclusions to be drawn on the relative effectiveness of some newer antidepressants (such as escitalopram, desvenlafaxime), nor any of the recently used augmentation combinations.

Overseas economic models, namely the USA (Simpson) and the UK (McLoughlin et al) models, were not applicable to the Australian setting or the PICO population, and were not used in the report.

The findings of the economic evaluation suggested that rTMS is not a cost-effective alternative to ECT for treatment resistant depressant patients in most cases. However, given ECT is more commonly used in an emergency setting for psychotic patients, a comparison between rTMS and antidepressants was considered more appropriate.

In supporting comments on the assessment, the applicant noted that rTMS and ECT are 'highly unlikely to be comparable therapeutic options for patient at an equivalent illness stage', and questions whether the economic evaluation took sufficient account of the higher costs of ECT (due to its higher rates of associated hospitalization) or the costs of ECT's more severe side effects.

ESC noted that the results for the sensitivity analysis for rTMS vs antidepressants was highly sensitive to the remission rates assumed for antidepressants. A remission rate of 24 % made rTMS lose its dominance, and 36.8% produced an ICER of $100,088.

ESC raised concern that the mean cost of $31,330 for antidepressants in the model over 3 years seemed high, and that this figure had significant implications for the cost-effectiveness analysis. How this figure was reached is uncertain. The cost effectiveness projections did not appear to be related to reductions in hospitalisations. ESC noted the importance of this as the margins were fine.

ESC noted the applicant had indicated a capital cost of $40,000 -$50,000 for the rTMS machine, although an annual running cost was not provided. ESC questioned whether associated costs would be expected to be covered by the hospital provider. However, ESC noted that the proposed model of care anticipated that this service would be provided in a free standing psychiatric practice which is currently not available in Australia.

ESC noted that the revised 5 year net MBS cost estimates provided by the Department, which included savings to the PBS through reduced lithium prescribing, and to the MBS, through reduced lithium monitoring and ECT use, were $56.2 million dollars over the next five years. When these cost trade-offs were not included the estimated 5 year net MBS cost was $83.3 million. ESC questioned whether rTMS would replace antidepressants to the extent postulated in the assessment report, and therefore whether these offsets are valid.

ESC questioned whether the proposed two new MBS items; one for initial diagnosis, mapping and dose prescription, performed by a psychiatrist trained in rTMS; and one for the rTMS treatment itself, performed by a nurse or allied health professional in an approved hospital setting under medical supervision were required for this treatment. ESC noted that there is only one MBS item for providing ECT, with the prescribing and planning for ECT provided in a consultation. ESC noted that there was no argument provided for the proposed rTMS listing to be different to ECT in this regard. The applicant may wish to address this in the pre-MSAC response.

ESC was concerned at the lack of detailed information on cost inputs underlying the proposed fee of $150 for the treatment, and queried whether this figure could be justified given that rTMS would be provided by a nurse or allied health professional, especially in light of the low capital costs of the equipment, and the probable high-throughput service model. There was also no information on the likely fees to be charged and the consequent patient out-of-pocket costs.

ESC also had concerns over leakage for earlier lines of use, and agreed that caution was required in wording the item descriptor to restrict rTMS treatment to the appropriate patient population.

15. Other significant factors

Nil.

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

The applicant group is disappointed that application 1196 regarding repetitive transcranial magnetic stimulation (rTMS) as a treatment for depression was not approved by MSAC. We reiterate, as has been acknowledged in this summary document, that there is robust and substantial evidence for the antidepressant efficacy of rTMS in patients with depression who have failed to respond to antidepressant medication treatment (treatment resistant depression). This includes an extensive series of placebo-controlled trials, some of which have been conducted in Australia, and multiple positive meta-analyses. In fact, this evidence is far more robust than the evidence available for the current standard of treatment for treatment resistant depression (further trials of antidepressant medication) – the current standard treatment is not supported by the type of randomised trials that have demonstrated the efficacy of rTMS, an observation that does not seem to have been taken into account by the committee. We would also like to highlight that, as recognised in the report, rTMS has a significantly beneficial safety profile in comparison to current 'standard' treatments. Finally, we would like to highlight the equity issues raised in the consumer / public consultation process. rTMS is becoming increasingly commonly available in other countries and in the private sector in Australia, placing patients without private insurance or private means at a significant disadvantage.

17. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website at: www.msac.gov.au.