

**Australian Government** 

**Medical Services Advisory Committee** 

## **Public Summary Document**

# Application No. 1428 – Mechanical thrombectomy for acute ischaemic stroke

#### Applicant: Medtronic Australasia

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, <u>visit the MSAC website</u>

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

An application requesting a new Medical Benefits Schedule (MBS) listing of mechanical thrombectomy (MT) to treat acute ischaemic stroke (AIS) due to a large vessel occlusion (LVO) was received from Medtronic Australasia by the Department of Health.

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

After considering the evidence presented in relation to safety, clinical effectiveness and costeffectiveness, MSAC supported MBS funding of MT for acute ischaemic stroke related to a large vessel occlusion. MSAC agreed that when added to usual care (intravenous thrombolysis or best supportive care for patients ineligible for intravenous thrombolysis), MT had superior clinical effectiveness and acceptable safety and cost-effectiveness.

MSAC advised that the MBS service should only be rendered in a comprehensive stroke centre, and that the cost of the consumables and potential out-of-pocket costs to the patient might be a barrier to use in the private sector due to a lack of definitive funding arrangements for the non-implantable medical technology used to deliver the MBS service.

MSAC noted that MT is listed as an option that may be considered in the draft <u>Australian</u> <u>Clinical Guidelines for Stroke Management (2017)</u>. MSAC supported the creation of a register to monitor volumes and outcomes.

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

MSAC noted that MT involves the delivery of a clot retrieval device via a catheter into the cerebral arteries to remove the obstructing clot and restore blood flow to the brain. MT would be an additional therapy in patients who present within 4.5 hours of stroke onset and are eligible for intravenous thrombolysis, and an alternative therapy in patients who are ineligible for intravenous thrombolysis (usually because they have presented more than 4.5 hours after stroke onset).

MSAC accepted that MT had a reasonable safety profile when compared to usual care (intravenous thrombolysis or medical management in patients ineligible for thrombolysis). In an individual patient meta-analysis combining data from five randomised controlled trials (Goyal M et al 2016; n = 1287), 90-day mortality was slightly higher in the usual care arm (18.9%) than in the MT arm (15.3%) although this was not statistically significant. Rates of symptomatic intracranial haemorrhage and parenchymal haematoma were similar in both arms.

MSAC accepted that MT was more effective than usual care. In the meta-analysis, MT significantly reduced disability at 90 days - as measured by at least a one point reduction in the modified Rankin Scale (mRS) score - compared with usual care (adjusted common odds ratio [cOR] 2.49; 95% CI 1.76–3.53). The number needed to treat to reduce disability in one patient by at least one point on the mRS was  $2 \cdot 6$ . Furthermore, the proportion of patients who were functionally independent (mRS score 0–2) at 90 days was significantly higher in the MT arm than in the usual care arm (46.0% vs. 26.5%; OR 2.35; 95% CI 1.85–2.98).

MSAC noted that the proposed item descriptor specified that the procedure be used within 8 hours of stroke onset or after 8 hours at the discretion of the clinician. MSAC noted that further analysis of the individual patient meta-analysis had been recently published (Saver et al, JAMA. 2016;316:1279–88). This indicated that MT was effective up until 7.3 hours post-stroke. MSAC noted that this did not preclude benefit in some individuals after this period and suggested that there should be clinical discretion to use MT if imaging indicated there was salvageable brain tissue after this period.

MSAC accepted that MT was cost-effective when compared with usual care. Modelling conducted using data from Goyal M et al (2016) over a lifetime indicated that using MT would incur an average cost of \$101,977 and lead to a gain of 2.72 QALYs compared with \$91,311 and 1.89 QALYs for usual care, resulting in an ICER of \$12,880 per QALY. MSAC considered the lifetime horizon to be excessive but noted that the procedure remained acceptably cost-effective when the time horizon was reduced to five years (ICER of  $\sim$  \$43,000 per QALY). In sensitivity analyses conducted on the base case model using the lifetime horizon, cost-effectiveness remained acceptable even with changes in utility values, procedure costs, costs associated with acute/mid-term or long-term management and rates of recurrent stroke.

MSAC noted that recent health technology assessments estimated that 5–10% of patients with an ischaemic stroke could be eligible for MT (Health Quality Ontario 2016; Queensland Department of Health 2015). The 2015 National Stroke Audit reported that there were just under 27,000 strokes in Australia over the year (National Stroke Foundation 2015), suggesting that a maximum of 2,700 patients could be eligible for MT. However, MSAC accepted that it was likely that there would be a limited number of comprehensive stroke centres that could carry out the procedure and this in turn would limit the number of procedures done every year.

MSAC agreed with ESC that the proposed MBS item fee for MT is relatively high compared to other similar procedures, e.g. carotid endarterectomy (\$3500 vs \$1200) and considered better justification of the proposed fee should be provided prior to implementation.

MSAC noted that the applicant assumed that there would be ten Australian private centres equipped to provide MT within 5 years, treating an average of 15 patients per year. Under these assumptions, the net cost to the MBS for MT would be approximately \$2 million over five years. Costs were based upon 78 procedures being undertaken at an MBS cost of

\$273,000 in the first year rising to 150 procedures at a cost of \$525,000 in year five. In sensitivity analyses:

- using the 75% benefit for inpatient procedures in a private hospital reduced the MBS costs to \$394,000 in year five.
- including costs for anaesthesia and imaging increased MBS costs in year five to \$772,000 (\$579,000 using the 75% benefit)
- assuming 300 patients were treated in year five increased MBS costs in year five to \$1.05 million (\$787,500 using the 75% benefit; \$1.2 million using the 75% benefit and including costs for anaesthesia and imaging)

MSAC noted that MT is listed as an option that may be considered in the draft <u>Australian</u> <u>Clinical Guidelines for Stroke Management (2017)</u>.

MSAC noted that the clot retriever devices are not implanted but are removed from the body along with the clot. This means they are not eligible to be included on the Prostheses List and private health funds will not be required to cover the fees for them. MSAC expressed concern this could result in unexpected out-of-pocket expenses for patients or unacceptable delays to treatment. MSAC noted that the cost of the clot retriever should not be a barrier to treatment and suggested the department and the Prostheses List Advisory Committee (PLAC) explore ways to address this issue.

MSAC noted that centres which provide MT will need to be highly specialised and capable of providing a 24-hour, seven day a week service. Provision of MT will require standardised models of care and protocols, including accreditation of providers and facilities, to ensure adequate patient volumes and quality outcomes. MSAC noted that credentialing processes considered in other MSAC applications (e.g. <u>Application 1361.2</u>: <u>Transcatheter Aortic Valve Implantation</u>) could be used as a starting point. However, MSAC noted that any accreditation model for MT needs to factor in that this service is for acute care - not an elective procedure - and should cover ambulance, pre-hospital and in-hospital care. MSAC suggested that consultation with the appropriate professional societies would help inform the credentialing process. MSAC supported a register to monitor volumes and outcomes.

Finally, MSAC noted that there are different types of clot retriever devices available including stent retrievers, coil retrievers and aspiration devices. MSAC noted that the most recent evidence is largely related to the use of stent retrievers. MSAC decided against restricting the listing to stent retrievers as there may be clinical reasons for deciding that another type of clot retriever device is a more suitable option in individual patients.

## 4. Background

MSAC has not previously considered MT to treat AIS due to LVO.

## 5. Prerequisites to implementation of any funding advice

It is proposed that MT should only be provided by suitably trained and accredited operators in suitably accredited hospitals. Consultation with relevant clinical craft groups will be required to determine accreditation and registry participation requirements.

## 6. Proposal for public funding

The proposed MBS item descriptor is shown in Table 1.

## Table 1: Proposed MBS item descriptor

#### Category 3 - THERAPEUTIC PROCEDURES MBS [item number]

Mechanical thrombectomy of patients with a confirmed diagnosis of acute ischaemic stroke caused by large vessel occlusion, of the anterior circulation; procedure to be started within 8 hours of stroke onset; including intra-operative imaging, but in association with preoperative diagnostic imaging items<sup>a</sup>

- either 56001 or 63064 Fee: \$3,500 (Anaes.) (Assist.)

Explanatory notes:

Diagnosis confirmed by imaging: ischaemic stroke with large vessel occlusion on CTA or MRI

Patients selected for treatment according to acute stroke management guidelines.

• Clinician discretion for procedure use in selected patients beyond 8 hours of stroke onset, where clinical assessment indicates patient is likely to benefit from treatment (salvageable brain tissue identified on imaging).

• Service to be provided by suitably trained and accredited operators in suitably accredited hospitals [requirements TBD]. This should include contribution to systematic registry data for audit purposes [requirements TBD].

<sup>a</sup>Examples of relevant CT and MRI items included.

Abbreviations: TBD, to be determined; CTA, computed tomography angiography; MRI, magnetic resonance imaging

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

The PICO Advisory Sub-Committee (PASC) received three responses from peak bodies, three responses from organisations and five responses from specialists. The majority of consultation feedback for the protocol was positive. Issues raised in the responses were:

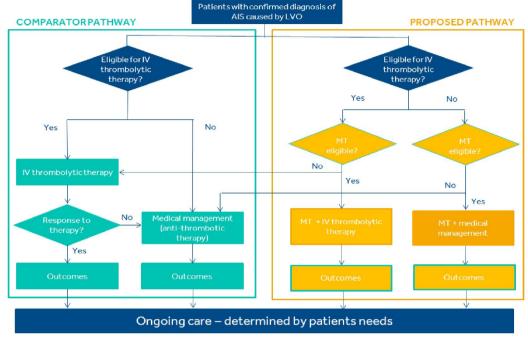
- Difficulty of patient access to the medical service especially in regional areas.
- Requirement for an accreditation process.
- Requirement for a streamlined system for identifying appropriate patients and coordinating transport, imaging and multiple healthcare providers within the critical timeframe.
- Recommendation for compulsory and systematic data collection.
- Suggestion that an MBS item number & fee does not fully account for the wide range of healthcare professionals involved in the medical service. This may result in a fragmented approach with poorer health outcomes and greater expense for the healthcare system.

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

The proposed medical service is the use of a specialised endovascular device to remove an obstructing clot from the artery, thereby restoring blood flow to the brain and minimising brain tissue damage. The devices used to perform MT include coil retrievers, aspiration devices and most recently, stent retrievers. All are delivered to occluded sites with the aid of microcatheters and guidewires, but each type of device uses a slightly different mechanical approach to remove the target clot. This is for patients with a confirmed diagnosis of an AIS caused by a LVO.

MT is proposed as an additional therapy in patients who are eligible for treatment with IV tPA, and as an alternative therapy in patients for whom IV tPA is contraindicated. The proposed clinical algorithm at Abbreviations: LVO, large vessel occlusion; MT, mechanical thrombectomy

is consistent with recommendations from clinical practice guidelines (CPGs) and Australian stroke protocols.



#### Figure 1 Proposed clinical algorithm

Abbreviations: LVO, large vessel occlusion; MT, mechanical thrombectomy

#### 9. Comparator

MT is proposed as an additional therapy in patients who are eligible for IV tPA, and as an alternative therapy in patients for whom IV tPA is contraindicated. The comparators for these respective groups are:

- IV tPA alone (where indicated), and
- Medical management (anti-thrombotic therapy) where IV thrombolytic therapy is contraindicated.

In the submission report the comparators are referred to as 'usual care'.

The assessment report stated that there are strict rules to determine if a patient is eligible for IV tPA - it is recommended in clinical practice guidelines as first line therapy approved for LVOs within 4.5 hours of symptom onset. Hence, presentation > 4.5 hours after stroke symptom onset will preclude access to IV tPA. In addition, patients may be ineligible for IV tPA due to non-time based reasons, examples include: severe, uncontrolled hypertension; previous surgery; widespread ischaemia, patient receiving oral anticoagulants. The only treatment option available to patients who are ineligible for IV tPA (time and non-time based reasons) is medical management, consisting of anti-thrombotic therapy with antiplatelet agents (aspirin) or anticoagulants.

## 10. Comparative safety

Five randomised trials of MT plus usual care and usual care alone were identified which met the PICO-defined inclusion criteria: ESCAPE; EXTEND-IA; MR CLEAN; REVASCAT and SWIFT PRIME.

Death and symptomatic intracerebral haemorrhage outcomes were consistently reported across the five trials and thus analysed in the meta-analysis by Goyal et al. 2016. In the meta-analysis of the individual patient data from the five selected trials (Goyal et al. 2016):

- There was a higher rate of deaths in the control arm than in the treatment arm at 90 days (18.9% vs. 15.3%) although this was not statistically significant;
- There was a similar rate of symptomatic intracranial haemorrhage between both arms (intervention arm = 4.4% vs. control arm = 4.3%)

However, in the REVASCAT trial (that enrolled patients up to eight hours after symptom onset), the rate of deaths was higher in the treatment arm than in the control arm at 90 days (Table 2).

Study ID	MT + usual care	Usual care	RD (95% CI)	RR (95% CI)	
Deaths at 90 days					
Up to 6 hours*					
EXTEND-IA	3/35 (9%)	7/35 (20%)	-11.4% (-27.6%; 4.7%)	0.4 (0.1; 1.5)	
MR CLEAN	49/233 (21%)	59/267 (22%)	-1.1% (-8.3%; 6.2%)	0.95 (0.68; 1.33)	
SWIFT PRIME	9/98 (9.0%)	12/97 (12.0%)	-3.2% (-11.9%; 5.5%)	0.74 (0.33; 1.68)	
Up to 8 hours*					
REVASCAT	19/103 (18.4%)	16/106 (15.5%)	3.4% (-6.8%; 13.5%) 1.2 (0.6; 2.2)		
Up to 12 hours*					
ESCAPE	17/164 (10.4%)	28/147 (19.0%)	-8.7% (-16.6%; - 0.5 (0.3; 1.0 0.8%)		
Meta-analysis					
Goyal 2016	97/633 (15.3%)	122/646 (18.9%)	-3.6% (-7.7%; 0.6%)	0.83 (0.64; 1.03)	

Table 2:Results of key patient-relevant outcome across the randomised controlled<br/>trials

**bold =** statistically significant; CI = confidence interval; MT = mechanical thrombectomy; RD = risk difference; RR = risk ratio.

\* time to initiation of mechanical thrombectomy post stroke symptom onset

The assessment report stated that MT is associated with an increased risk of certain complications compared to usual care alone; in particular, procedural complications and hematoma. However, suggested that these risks should be balanced against the poor prognosis of many patients with AIS and the net benefits of treatment with MT in terms of functional outcomes.

The assessment report proposed that relative to usual care, MT is non-inferior in terms of safety.

#### 11. Comparative effectiveness

The primary outcome presented in the assessment report was the modified Rankin Scale (mRS) at 90 days, which is a measure of functional ability (the lower the mRS score the lower the degree of disability and increased functional independence).

In the meta-analysis of the individual patient data from the five selected trials (Goyal et al. 2016):

- There was a significantly reduced chance of disability measured with the mRS score at 90 days in patients assigned to MT compared with patients assigned to usual care (adjusted common odds ratio = 2.49; 95% CI 1.76 3.53).
- The proportion of patients with an mRS score 0-2 at 90 days was significantly higher in the intervention arm compared with the control arm (odds ratio 2.35; 95% CI 1.85 - 2.98).

Study ID	MT + usual care	Usual care	Relative difference Common OR (95%CI)	
mRS at 90 days	Median (IQR)	Median (IQR)		
Up to 6 hours*				
EXTEND-IA	1 (0 – 3)	3 (1 – 5)	2.1 (1.2; 3.8)	
MR CLEAN	3 (2 – 5)	4 (3 – 5)	1.7 (1.2; 2.3)	
SWIFT PRIME	2 (1 – 4)	3 (2 – 5)	2.6 (1.6; 2.9)	
Up to 8 hours*				
REVASCAT	NR	NR	1.7 (1.0; 2.7)	
Up to 12 hours*				
ESCAPE	NR	NR	2.6 (1.7; 3.8)	
Meta-analysis				
Goyal 2016	-	-	2.49 (1.76; 3.53)	

Table 3	Results of key patient-relevant outcome across the randomised controlled
trials	

**bold** = statistically significant; CI = confidence interval; IQR = interquartile range; MT = mechanical thrombectomy; mRS = modified Rankin scale; RD = risk difference; RR = risk ratio

\* time to initiation of mechanical thrombectomy post stroke symptom onset

The assessment report proposed that relative to usual care, MT is superior in terms of effectiveness.

#### 12. Economic evaluation

The economic evaluation was presented as a cost utility analysis. A summary of the key characteristics are shown in Table 4.

Perspective	Australian health care provider		
Comparator	Usual care		
Type of economic evaluation	Cost-utility		
Sources of evidence	IPD meta-analysis of five RCTs identified in Section B		
Time horizon	Life time		
Outcomes	LYG and QALYs		
Methods used to generate	Trial-based; decision tree and Markov model		
results			
Health states	Seven health states based on mRS score 0 to 6		
Cycle length	1 year		
Discount rate	5%		
Software packages used	Excel		

#### Table 4: Summary of the economic evaluation

IPD = individual patient data; LYG = life year gained; mRS = modified Rankin scale; QALY = quality adjusted life years; RCT = randomised controlled trials.

The economic model consisted of three phases: acute phase from onset to 90 days; mid-term phase from day 91 to 365; and long-term phase from Year 1 to end of patient's life. The acute

and mid-term phase were modelled in a decision tree while the long-term phase was a Markov model consisting of seven health states defined by the mRS score 0 to 6.

The overall costs and outcomes, and incremental costs and outcomes as calculated for the intervention and comparator in the model, and using the base case assumptions, are shown in Table 5. As noted above, this modelling is in stark contrast to the actual data in EXTEND-IA, where MT is dominant at 90 days. This may be due to underestimating the hospital costs in the usual care group in the current evaluation.

Table 5	Results of the economic evaluation			
Component	MT + usual care	Usual care	Increment	
Costs	\$101,977	\$91,311	\$10,666	
QALYs	2.72	1.89	0.83	
Incremental c	\$12,880			

MT = mechanical thrombectomy; QALY = quality-adjusted life years;

#### 13. Financial/budgetary impacts

The Assessment Report estimated that around 2,694 patients may satisfy the eligibility criteria for MT. The critique noted that the financial estimates were derived using a caseload capacity approach.

The financial implications to the MBS resulting from the proposed listing of mechanical thrombectomy are summarised in Table 6.

	2016-17	2017-18	2018-19	2019-20	2020-21
Mechanical thrombectomy					
Number of services	78	96	114	132	150
Sub-total cost (at 75% benefit)	\$204,750	\$252,000	\$299,250	\$346,500	\$393,750
Co-administered					
Sub-total cost (at 75% benefit)	\$96,167	\$118,360	\$140,552	\$162,745	\$184,937
Total services	78	96	114	132	150
Total cost (at 75% benefit)	\$300,917	\$370,360	\$439,802	\$509,245	\$578,687

Table 6 Total costs to the MBS associated with mechanical thrombectomy

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

ESC noted that the devices used to perform MT are coil retrievers, aspiration devices and stent retrievers. ESC considered whether blanket approval of all three methods is appropriate. Clinical input was that the different methods may have different benefits for differing vessel characteristics and that clinical judgement is required to know which retriever is best for which clot and vessel tortuosity. There is no evidence that the current generation of retrievers (stent and aspiration) have different efficacies; coil retrievers are not currently being tested as the sole intervention in a trial. For the applicant's view, see comment in Section 16.

ESC discussed specification issues in the MBS item including:

- Time from stroke onset: recent meta-analysis (JAMA Oct 2016) suggest 8 hours (lower bound for ordinal mRS reaches 1)
- Frequency: once in life or repeated if recurrent stroke; there was no evidence to restrict MT to once per lifetime, especially given the evidence that recurrent strokes tend to be in the same territory as the original stroke.
- Preceding imaging type: advanced imaging is a rapidly developing field and being too prescriptive may mean the item becomes outdated quickly.
- Site requirements: referencing the National Stroke Foundation guidelines, and restricting the procedure to comprehensive stroke centres. This is likely the best way to ensure that the procedure is undertaken in centres that have the infrastructure, processes and clinical expertise to perform it safely and effectively.
- specialist competence requirements

ESC discussed the requirement for flexibility in the MBS item to enable clinical judgement and to take into account the developing evidence base for MT.

ESC noted that validity of MT is well established based on evidence from 8 randomised control trials (RCT's), 3 old and 5 new, 10 pending RCT's, 2 with preliminary data, 9 summary level meta-analyses and 3 IPD meta-analyses. The number needed to treat to prevent one nursing home placement was 5, which is a very strong effect size.

ESC considered the lifetime horizon for the economic model (100 years) to be excessive suggesting that 10 years post-surgery would be appropriate.

ESC noted that there are discrepant findings between the economic analysis from the EXTEND-IA trial/NNT and the economic model used by the applicant. The EXTEND-IA trial showed that the intervention was dominant at 90 days. Utility values used in the applicant's model were taken from Sturm et al based on Australian data and it was considered that these are potentially conservative compared to other available utility values. ESC questioned the accuracy of the inpatient and outpatient costs for stroke patients in the economic model.

ESC noted that the transition from 90 days to 1 year was modelled on 3 years of Swiss data.

ESC considered that the economic model was biased in favour of the intervention as recurrent stroke was counted twice, including once already in the disutility. The model assumed no further changes in modified Ranking Scale (mRS) (including death). ESC considered that long term mRS data should have been used to model death instead of life tables.

ESC considered that the estimated incidence of large vessel occlusion (18,320) is likely to be an overestimation, but that the estimates of total MT procedures per year are more reasonable due to the limited number of comprehensive stroke centres in the private sector.

ESC also considered that as the majority of stroke centres are in the public sector, this raises the potential for cost-shifting. However, listing the service would mean that private patients in the public sector could be charged to help recover the cost of this new technology.

ESC noted that the devices (coil retrievers, stent retrievers and aspiration devices) used in the procedure are not suitable for Part A of the Prosthesis list. ESC instead discussed whether they could be considered for Part C of the Prosthesis list.

ESC considered that the devices may be an out-of-pocket expense.

ESC considered that the proposed MBS fee for MT is relatively high compared to other similar procedures, e.g. carotid endarterectomy (\$3500 vs \$1200).

The item-specific consumer comments presented addressed predicted consumer support for an apparently new and effective treatment. Consumer support was expressed for the requirement to comply with accreditation standards and caution noted re inhibiting clinical judgement where there is no evidence to do so (in response to the time limit issue), and where there could be some benefit to a person.

The report notes some of the out of pocket costs critical to consumers. The consumer presentation also noted the following consumer perspectives which are both specific to the proposed item and potentially to the MBS, and MBS Review, more broadly:

- The submission appears to argue for development of private accredited/comprehensive stroke facilities/centres of excellence: while the ESC seemed to be of the view this would not be an appealing business model in the private sector, it should be noted that privatisation can threaten equity and access. Consumers support universal access to health care: if there is clinically effective care for a predictable need this should be publicly available
- Caution was expressed re the potential for cost shifting
- Concern was expressed re setting reimbursement precedents related to urgency, comparative complexity, time & team members
- Concern was expressed regarding the impact and precedent set in equipment costs
- The question was asked (and not answered) re the lack of proper costing for retrieval/transport for the individual and systems.

#### 15. Other significant factors

Nil

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

Medtronic welcome MSAC's findings and consider the outcome of this application an important step forward in improving outcomes for acute ischemic stroke patients. We recognise that careful implementation of mechanical thrombectomy on the MBS is necessary to optimize patient outcomes.

- MSAC's comments regarding the proposed MBS fee are noted however, we disagree with ESC's advice that carotid endarterectomy is a similar procedure. In the Final Protocol, it was suggested the proposed MBS fee for MT be referenced to the current MBS benefit amount for endovascular coiling of intra-cranial aneurisms (\$2857.55; MBS item 35412). We recognise that further consultation with clinicians who perform these procedures is necessary to fully justify and determine the MBS fee. (See Submission Section C.5.2. for proposed fee justification)
- We share MSAC's concerns regarding the lack of definitive funding arrangements for non-implantable technology used in mechanical thrombectomy procedures. To allow eligible patients timely access to this service, while avoiding potential out-of-pocket costs, it will be necessary to develop funding arrangements to ensure the device is reimbursed in parallel to the processes for MBS implementation. This timing is critical to ensure barriers to access are avoided.
- With regards to this we note ESC's discussion on whether devices used in the procedure could be considered for Part C of the Prostheses List and welcome MSAC's suggestion that the department and PLAC explore ways to address the

potential for out-of-pocket costs and unacceptable treatment delays. The latter point is of particular significance for this time-critical procedure – delays can impact patient outcomes.

- We welcome the consumer perspectives, but would like to clarify that the submission did not propose the development of private centres of excellence per se, but proposed that centres with appropriate facilities and experience in neurointerventional procedures (i.e. sufficient case volumes/operator training) would be the appropriate place to implement the proposed service.
- We would like to clarify at the time of the submission, there was no published evidence that aspiration (or any other) devices have similar efficacy to stent retrievers. Furthermore, MSAC noted that the most recent evidence is largely related to the use of stent retrievers. While MSAC noted there may be clinical reasons for using another type of clot retrieval device this is not aligned with evidence presented in the submission based on studies where the majority of patients were treated with stent retrievers. European consensus recognised the difference in evidence for aspiration devices and stent retrievers KSU Grade C and Grade A, respectively<sup>1</sup>. Lower levels of evidence for aspiration devices are also noted in other guidelines<sup>2</sup>.

MSAC's findings for this application represent an opportunity to ensure that both the mechanical thrombectomy procedure and technology used to deliver this procedure are funded, with no barriers to patient access. This is required to allow consistent, equitable access and the optimisation of this MBS service – essential for achieving the best outcomes for acute ischemic stroke patients and realising cost benefits for the healthcare system.

#### 17. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website: visit the MSAC website

<sup>&</sup>lt;sup>1</sup> Mechanical thrombectomy in acute ischemic stroke: Consensus statement by ESO-Karolinska Stroke Update 2014/2015, supported by ESO, ESMINT, ESNR and EAN. International Journal of Stroke 2016, Vol. 11(1) 134–147. (Available: <u>http://journals.sagepub.com/doi/full/10.1177/1747493015609778</u>, accessed 23<sup>rd</sup> January 2017).

<sup>&</sup>lt;sup>2</sup> Canadian Stroke Best Practice Recommendations: Hyperacute Stroke Care Guidelines, Update 2015. Int J Stroke. 2015 Aug;10(6):924-40; European Recommendations on Organisation of Interventional Care in Acute Stroke (EROICAS), International Journal of Stroke 2016, Vol. 11(6) 701–716