

## **Public Summary Document**

# Application 1183– Ultrasound Imaging in the practice of anaesthesia

Applicant: Australian Society of Anaesthetists

Date of MSAC consideration: MSAC 62<sup>nd</sup> 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 ultrasound imaging for the practice of anaesthesia for patients requiring a central line catheter for vascular access or percutaneous neural blockade was received from Australian Society of Anaesthetists (ASA) by the Department of Health and Ageing in January 2012. The application was further updated in May 2012.

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

After considering the available evidence in relation to safety, clinical effectiveness and cost-effectiveness, MSAC does not support public funding because of uncertain cost-effectiveness due to additional costs not captured in the economic model and the potential for significant additional cost to the MBS.

MSAC acknowledged that ultrasound imaging is current best practice care in the practice of anaesthesia and did not consider an MBS listing was necessary. MSAC further noted that in most cases ultrasound imaging would be provided at limited or no cost to the anaesthetist, who would benefit from reduced complexity and improved efficiency of providing the service using ultrasound.

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

MSAC noted that this application was for MBS listing of ultrasound imaging for the practice of anaesthesia for patients requiring a central line catheter for vascular access of percutaneous neural blockade. Vessel cannulation for venous access is required for anaesthesia and monitoring and regional nerve anaesthetic blockade is a very useful adjunct to or replacement for general anaesthetic/pain management. Both of these procedures can be performed via anatomical landmarks with or without ultrasound guidance.

MSAC noted that prior to 1 November 2012, ultrasound imaging for anaesthesia practice had been claimed through MBS item 55054. Subsequent to this, access to MBS item 55054 was removed for anaesthetists, as the use of ultrasound in conjunction with an anaesthetic procedure has never been assessed for safety, effectiveness and cost-effectiveness. Currently, percutaneous nerve blocks placed for management of post-operative pain management are claimed under item numbers 22040, 22045 and 22050. It was also noted, that current MBS items for vascular access are 13185, 13319 and 22020 for central venous access and items 13818 and 22015 for central arterial access. MBS items 22015 and 22020 are relevant in association with anaesthesia.

MSAC noted that the comparator for this intervention was the landmark technique, which may still be valid for experienced practitioners and for more accessible locations. Electrical nerve stimulation (ENS) has been the "gold standard" modality to guide nerve blocks prior to the introduction of ultrasound, however, MSAC did not consider ENS as an appropriate comparator.

MSAC considered the analysis of safety and effectiveness for ultrasound imaging in the practice of anaesthesia.

It was noted that ultrasound localisation of central vascular access was associated with significantly reduced risk of vascular puncture, haematoma, pneumothorax and haemothorax. In addition, ultrasound use for the administration of nerve block significantly reduced the risk of vascular puncture, haematoma, and nerve injury. It was concluded that the use of ultrasound reduces the prevalence of most safety outcomes compared to the landmark technique (for vascular access) and both landmark and ENS comparators (for percutaneous neural blockade).

MSAC noted that ultrasound localisation for central vascular access reduced the cannulation time; reduced the number of attempts required; decreased the risk of failed attempts; and decreased the risk of failure on first attempt. MSAC also noted that ultrasound use for the administration of nerve block reduced the time to administer the block; reduced the number of needle redirections; reduced the risk of nerve block failure; reduced the time for onset of an overall assessment of nerve block; and reduced the time for patients to be ready for surgery. Ultrasound was equivalent for either the landmark technique or ENS methods for the number of skin punctures; onset time of motor block or sensory block; and time to first analgesia.

MSAC does not support a new MBS listing for a procedure which utilises a technique that enhances clinical practice in performing a faster and more reliable procedure. It is likely that ultrasound guidance will be adopted irrespective of MBS funding, as ultrasound guidance is a compulsory component of anaesthetic training, and is becoming standard of care practice.

MSAC noted that the incremental cost per failed cannulation avoided for internal jugular vein (IJV) increased from \$256 without MBS benefit and associated assumed patient co-payment to \$1,467 with MBS benefit and associated assumed patient co-payment. For subclavian vein (SCV) access, ultrasound results in fewer failed cannulation attempts and hence is the dominant procedure. Therefore, the incremental cost per failed cannulation avoided is \$600 if the proposed MBS benefit and associated assumed patient co-payment are included.

MSAC noted that for nerve blockade, the use of ultrasound compared with nerve stimulation results in an additional cost of \$12 per procedure if the proposed MBS benefit is not included. However, if the proposed MBS benefit and associated patient co-payments are included, the additional cost per procedure with ultrasound compared with nerve stimulation is \$121.

Overall, MSAC noted that assuming a patient co-payment of \$65 per procedure, it is estimated the total patient co-payment in 2015/2016 with the use of ultrasound guidance in 60% and 90% of nerve block and vascular access procedure would be \$4.7 million and \$7.1 million, respectively.

MSAC noted that MBS fees for anaesthetic services are time based, and that providing ultrasound guided services reduced the complexity of the service and the time required to deliver it. It was concluded that, while ultrasound guidance was superior to the landmark technique and delivered benefits to both the patient and the provider, use of ultrasound was predominantly a standard of care issue and an additional MBS item was not required to incentivise adoption.

## 4. Background

The intervention has not previously been considered by the Medical Services Advisory Committee (MSAC).

## 5. Prerequisites to implementation of any funding advice

Over 200 ultrasound systems are listed on the Australian Register of Therapeutic Goods (ARTG) as of May 2012, of which approximately 60 are listed in the category applicable to this report with 46 of these 60 being deemed fit-for-purpose. These instruments are approved by the Therapeutic Goods Administration (TGA). As such, appropriate ultrasound technology reflected in the included studies and necessary to deliver the services covered by the proposed new MBS items is available for use within Australian clinical practice.

Generally public hospitals and large private hospitals would provide the ultrasound machines for use in the anaesthesia practice. Some ultrasound machines may be dedicated to anaesthesia use. However, hospital-owned equipment may be used for other purposes as well, and may not be readily available for use with anaesthesia.

The specialist training curriculum of the Fellowship of the Australian and New Zealand College of Anaesthetists (FANZCA) includes compulsory training in the use of ultrasound. The Australian and New Zealand College of Anaesthetists (ANZCA) and the Australian Society of Anaesthetists (ASA) hold regular workshops on the use of ultrasound in anaesthesia practice. In addition, various institutions offer continuing education and training courses for anaesthetists to gain and practice relevant skills. All specialised courses and training are coordinated by the Anaesthesia Continuing Education Coordinating Committee (ACECC) (ACECC 2011), as a part of the Australian and New Zealand College of Anaesthetists (ANZCA) (ANZCA 2013), the ASA and the New Zealand Society of Anaesthetists (NZSA).

#### 6. Proposal for public funding

The proposed MBS item descriptors for the percutaneous major vascular access and percutaneous neural blockade for delivery of surgical anaesthesia are present in the tables below.

#### Proposed MBS item descriptor major vascular access

Category 3 Group T10, Subgroup 19 – Therapeutic Procedures

The use of two-dimensional ultrasound scanning to assist percutaneous major vascular access in anaesthesia

[Explanatory note. This item applies to the use of ultrasound guidance during catheterisation (and cannulation) of major blood vessels. The item may be used in addition to the relevant item for vascular catheterisation (and cannulation). Explanatory note. T.1.20. Therapeutic procedures may be provided by a specialist trainee, applies]

Fee: \$58.35 (3 RVG units)

Category 3: Therapeutic procedures; Group T.10: Relative Value Guide for Anaesthesia; Subgroup 19: Therapeutic and Diagnostic Services. RVG: Relative Value Guide.

#### Proposed MBS item descriptor for percutaneous neural blockade

Category 3 Group T10, Subgroup 19 – Therapeutic Procedures

The use of two-dimensional ultrasound guidance to assist percutaneous neural blockade in anaesthesia

[Explanatory note. This item may be used in addition to the relevant nerve block item. Explanatory note. T.1.20. Therapeutic procedures may be provided by a specialist trainee, applies]

Fee: \$58.35 (3 RVG units)

Category 3: Therapeutic procedures; Group T.10: Relative Value Guide for Anaesthesia; Subgroup 19: Therapeutic and Diagnostic Services. RVG: Relative Value Guide.

According to the application the proposed fee for both MBS items includes a professional component (\$29.20) and a practice component (\$29.15). The allocation of three RVG units is based on a comparison of the nature of the service to other services of similar complexity and skill, already funded by the items of Group T10. The fee is not expected to vary according to patient sub-population. Practitioners other than anaesthetists may use ultrasound guidance for both vascular access and placement of neural blocks; however, access to the proposed items is limited to the practice of anaesthesia.

A team from the Australian Safety and Efficacy Register of New Interventional Procedures-Surgical (ASERNIP-S) and the Centre for Health Economics Research and Evaluation (CHERE) was engaged to conduct a systematic review of the literature and an economic evaluation of ultrasound imaging for the practice of anaesthesia for patients requiring the insertion of central lines for vascular access or for percutaneous neural blockade.

Not all patients requiring major vascular access or nerve blockade procedures as part of their anaesthesia care will require ultrasound guidance. Certain experienced practitioners may be confident to provide these procedures in the absence of ultrasound guidance.

Paediatric patients may be more likely to require ultrasound guidance because of small vessels.

Practitioners other than anaesthetists may use ultrasound guidance for both vascular access and placement of neural blocks; however, access to the proposed items is limited to anaesthetists.

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

Consumers noted that costs (out of pocket, via people's private health insurance payments and taxpayers costs via the MBS) may rise significantly if new technology, particularly technology that can be used for multiple procedures, is subsidised per procedure. Ultrasound

is likely to be increasingly used as a standard tool and cost reimbursement might be better pursued based on the equipment, not per procedure.

ESC noted there was a lack of public comment on this application and potential inequity in terms of access to equipment.

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

Ultrasound imaging for anaesthesia practice had been claimed through the MBS item 55054. On 1 November 2012, access to MBS item 55054 was removed for anaesthetists, as the use of ultrasound in conjunction with an anaesthetic procedure has never been assessed for safety, effectiveness and cost-effectiveness. Nerve block for anaesthesia can be claimed under generic anaesthesia items. Percutaneous nerve blocks placed for management of post-operative pain management are claimed under item numbers 22040, 22045 and 22050. Current MBS items for vascular access are 13815, 13319 and 22020 for central venous access and items 13818 and 22015 for central arterial access. MBS items 22015 and 22020 are relevant in association with anaesthesia.

Ultrasound scanning has two main applications in anaesthesia practice:

- Percutaneous major vascular access indicated for anaesthesia care and monitoring in the majority of patients who are likely to undergo major surgery, for example cardiac surgery, neurosurgery and trauma. These patients may also have significant comorbidities, particularly cardiovascular.
- Percutaneous neural blockade for patients who are receiving regional or local
  anaesthesia by a single needle insertion and/or the placing of a catheter adjacent to a
  nerve or nerve plexus. Catheterisation is used when continuous anaesthetic agents
  need to be supplied to maintain the anaesthetic effect. Percutaneous neural blockade
  may be used in association with various surgical procedures, for post-operative
  analgesia or as the primary form of anaesthesia in patients undergoing surgery if
  general anaesthesia poses a higher risk or is contraindicated.

Not all patients requiring major vascular access or nerve blockade procedures as part of their anaesthesia care will require ultrasound guidance to facilitate placement. Certain experienced practitioners may be confident to provide these procedures in the absence of ultrasound guidance. It may be that lower numbers of ultrasound devices in certain rural and remote areas may limit the use of ultrasound guidance in certain locations.

Reviewing the Australian and New Zealand Registry of Regional Anaesthesia (AURORA) data for nerve blocks performed between January 2006 to May 2008 (Barrington et al 2009) and June 2011 to February 2012 (Barrington and Kluger 2013) reveals that individual hospitals included in the registry are performing 32 to 42 neural blocks per month. For these procedures the preference for guided placement that utilises ultrasound with or without electrical nerve stimulation (ENS) has increased from 63 per cent (2006 – 2008) to 86 per cent (2011 – 2012) (AURORA). In addition, there has been a move away from procedures that utilise ENS assisted placement (with or without ultrasound). The preferred technique is now ultrasound without accompanying ENS.

MBS data show that between 2008 and 2011, the proportion of claims under item 55054 that were associated with anaesthesia increased from 0.95 per cent to 14 per cent of the total claims under this items. This represents a practitioner preference for the use of ultrasound guidance within anaesthesia for either the insertion of major vascular access lines or placement of neural blocks. Prior to 2008, the low number of claims is not reflective of the

proportion of procedures recorded with AURORA that utilised ultrasound during the placement of neural blockade.

The use of percutaneous neural blocks in both adult and paediatric populations is established in Australian clinical practice (Barrington and Kluger 2013). Nerve blocks are used either as standalone anaesthesia or for postoperative analgesia in combination with systemic anaesthesia and may also be used for chronic pain. The benefits include, but are not limited to, better post-operative pain management and reduced morbidity. Increasing awareness of, and improvements in, ultrasound technology will impact clinical advice and patient choice. As of 2010, evidence synthesised in systematic reviews on the use of ultrasound in regional anaesthesia indicate that ultrasound is at least equivalent to other placement techniques and depending on the location of the nerve may improve the block performance as well as reduce the risk of complication.

Ultrasound guidance has been used in clinical practice to aid central vascular access for a number of years (la Grange et al 1978). Visualisation of anatomical structures identifies interpatient variations thereby improving both placement and performance of central lines. For paediatrics central lines are often the preferred access over peripheral sites due to vessel size. In this population, complications are not rare when inserting central lines, which is also in part attributable to variability in vascular anatomy (Costello et al 2013). Similar to adults, the use of ultrasound in the placement of central lines may improve placement and hence reduce risk of complications.

The current clinical algorithm for percutaneous nerve blockade and central vascular access is illustrated in Figure 1. For the proposed new items, the clinical algorithm remains the same (

Figure 2), although the costs of the ultrasound component will be incurred by the MBS. The algorithms are taken from the Protocol 1183.

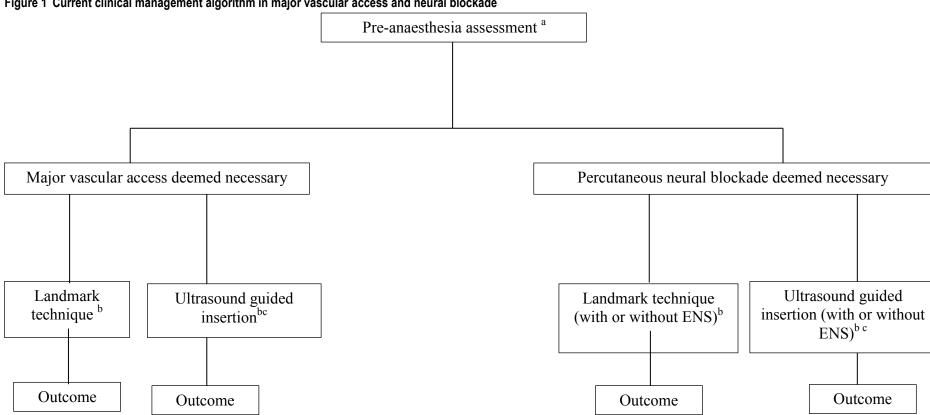


Figure 1 Current clinical management algorithm in major vascular access and neural blockade

Landmark technique: Insertion of a cannula, catheter or needle performed based on anaesthetist's knowledge of human anatomy, experience and judgement; ENS: Electrical nerve stimulation.

a Any circumstance that require anaesthesia for surgery. Patients who require independent pain management or analgesia are not a part of this population. b Insertion of a cannula, catheter or needle.

c MBS Item 55054 (access has been restricted for the current purposes on 01 November 2012)

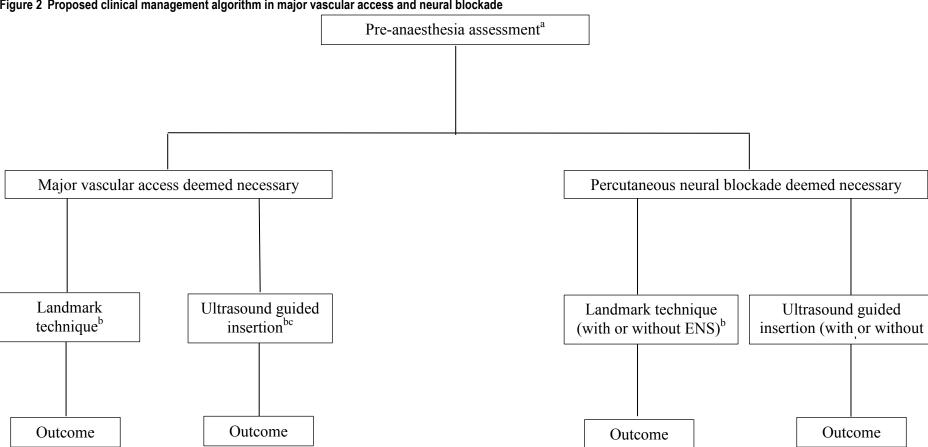


Figure 2 Proposed clinical management algorithm in major vascular access and neural blockade

Landmark technique: insertion of a cannula, catheter or needle performed based on anaesthetist's knowledge of human anatomy, experience and judgement; ENS: Electrical nerve stimulation

a Any circumstance that require anaesthesia for surgery. Patients who require independent pain management or analgesia are not a part of this population. b Include insertion of a cannula, catheter or needle.

c Proposed MBS items.

## 9. Comparator

#### Landmark technique

Landmark technique of inserting a cannula, catheter or needle in major vascular access and percutaneous neural blockade is currently performed based on the anaesthetist's knowledge of human anatomy, experience and judgement, which differ from practitioner to practitioner. It does not require additional resources and there is no associated MBS item.

#### Electrical nerve stimulation

In patients who receive percutaneous nerve blockade, ENS can be used in combination with the landmark technique to indicate the location of nerves (Abrahams et al 2009; Macintyre et al 2010). Nerve stimulation has been the 'gold standard' modality to guide nerve blocks prior to the introduction of ultrasound (Abrahams et al 2009). Some nerve blocks may be performed with a combination of ultrasound and electrical nerve stimulation guidance.

Whilst ENS indicates the location of nerves the technique has limitations. It does not identify vessels, muscles, fascia and visceral structures. Evidence of nerve location disappears after injecting 1–2 ml of the anaesthetic agent; hence, nerve stimulation cannot be used to localise nerves thereafter (Perlas et al 2006). The threshold of the electrical stimulus required to stimulate a nerve differs between nerves. The electrical stimulus elicits a motor response. If the neural structures are 'sensory only', or a patient has had a muscle relaxant as part of their anaesthesia technique, ENS cannot be applied, as no motor response will be obtained.

ENS devices vary in complexity and cost (see Economic Considerations). There is no MBS item for the use of ENS in providing anaesthesia. Existing MBS items for neural blockade provide the same fee regardless of the technique used to locate the neural structure.

## Scientific basis of comparison

#### Vascular access:

A total of seven systematic reviews were identified that were relevant to this report. These reviews were published between 1996 and 2013. Three of the systematic reviews were rated as being good quality using a modified AMSTAR appraisal tool (Appendix I). The reviews investigated patients undergoing central venous access (six reviews), and peripherally-inserted central catheter (PICC) access (one review) with subpopulation analysis of anatomical location of the access and the age of patients.

In addition, nine RCTs were identified that were not published in the systematic reviews.

#### Nerve block

A total of ten systematic reviews were identified that had relevance to this report. These reviews were published between 2009 and 2013. All systematic reviews were critically appraised using a modified AMSTAR tool (Appendix I); three were rated as being of good quality. The reviews investigated a range of populations (patients requiring nerve blocks as a component of anaesthesia for surgery, or use of neural blockade for postoperative analgesia as well as non-operative pain management). The reviews also assessed upper and lower extremity nerve blocks as well as truncal blocks.

In addition, 30 RCTs were identified which were not published in the systematic reviews.

## 10. Comparative safety

#### Vascular access:

#### Systematic reviews:

All of the systematic reviews concluded that ultrasound localisation of central vascular access was equivalent to or an improvement on the anatomical landmark technique for all reported safety and effectiveness outcomes.

#### Meta-analysis:

Results from 34 randomised controlled trials (RCTs) were pooled to inform the metaanalysis. The following outcomes were statistically significant in favour of ultrasound guidance compared to the landmark technique:

- Inappropriate vascular puncture was reported in 28 RCTs with a total patient population of 4,409. Ultrasound use significantly reduced the risk of vascular puncture (RR 0.32, 95%CI: 0.22-0.47, P<0.001).
- Haematoma was reported in 17 RCTs with a total patient population of 3,423. Ultrasound use significantly reduced the risk of haematoma (relative risk (RR) 0.34, 95% confidence interval (CI): 0.20-0.58, P<0.001).
- Pneumothorax was reported in seven RCTs with a total patient population of 1,847. Ultrasound use significantly reduced the risk of pneumothorax (RR 0.21, 95% CI: 0.06-0.71, P=0.01).
- Haemothorax was reported in three RCTs with a total patient population of 703. Ultrasound use significantly reduced the risk of haemothorax (RR 0.10, 95% CI: 0.02-0.56, P=0.009).

Ultrasound was equivalent to the landmark method for the following outcomes:

- Aggregate adverse events, reported in two RCTs with a patient population of 119 (RR 0.92, 95% CI: 0.50-1.69, P=0.797).
- Catheter related adverse events, reported in three RCTs with a patient population of 266 (RR 0.64, 95% CI: 0.29-1.43, P=2.82).
- Infection, reported in one RCT with a patient population of 38 (RR 1.36, 95% CI: 0.46-4.04, P=0.583).
- Nerve damage, reported in one RCT with a patient population of 201 (RR 0.14, 95% CI: 0.01-2.96, P=0.209).

#### Percutaneous nerve blockade

#### Systematic reviews:

All of the systematic reviews concluded that ultrasound guided placement of percutaneous nerve blocks was either equivalent to or an improvement on the comparators of landmark or electrical nerve stimulator techniques.

#### Meta-analysis:

Upper and lower limb nerve blocks formed the majority of the evidence base. Results from 54 RCTs were pooled to inform the meta-analysis. The following outcomes were statistically significant in favour of ultrasound guidance compared to the landmark or electrical nerve stimulator techniques

• Inappropriate vascular puncture was reported in 17 RCTs with a total of 1,071 patients. Ultrasound significantly reduced the risk of inappropriate vascular puncture (RR 0.27, 95% CI: 0.15 - 0.50, P < 0.001)

- Haematoma was reported in seven RCTs with a total of 423 patients. Ultrasound significantly reduced the risk of haematoma (RR 0.28, 95% CI: 0.1 0.74, P = 0.01)
- Nerve injury was reported in 11 RCTs representing 1,577 patients. Ultrasound reduced the risk of nerve injury (RR 0.51, 95% CI: 0.37 0.72, P < 0.001).</li>
   Ultrasound was equivalent to either the landmark or ENS methods for the following outcome:
- Paraesthesia was reported in ten RCTs with a total of 676 patients (RR 0.62, 95% CI: 0.26 1.5, P = 0.292).

#### Overall conclusion with respect to comparative safety:

Overall the use of ultrasound reduces the prevalence of most safety outcomes compared to the landmark technique (vascular access) and both landmark and ENS comparators (percutaneous neural blockade).

No incidence of major events (for example seizure, permanent nerve damage or embolisms) were reported for patients in any group. HESP has advised that major adverse events are rare.

Main issues/caveats regarding these conclusions:

- Assessing the impact of ultrasound on the reported adverse events is limited by their
  infrequent occurrence in RCTs primarily designed to assess effectiveness outcomes.
  This is especially true for serious adverse events requiring clinical intervention. This
  is further compounded by small sample size associated with most of the included
  RCTs.
- For vascular access the current evidence base mainly addresses central venous access
  with the limited evidence for arterial access and PICC line placement. There does
  appear to be congruency of evidence for different access sites; however, caution
  should be exercised in extrapolating evidence from central venous studies to arterial
  access and PICC line placement.
- For percutaneous neural blockade the evidence base is dominated by upper (brachial) and lower (sciatic) extremity neural blocks. In the three RCTs on truncal blocks no adverse events were reported.

## 11. Comparative effectiveness

#### Vascular access

All of the systematic reviews concluded that ultrasound localisation of central vascular access was equivalent to or an improvement on the anatomical landmark technique for all reported outcomes.

#### Meta-analysis:

The following outcomes were statistically significant in favour of ultrasound guidance compared to the landmark technique:

- Cannulation time was reported in 17 RCTs with a total patient population of 1,486, ultrasound use significantly reduced the cannulation time (DM -0.78, 95% CI:-1.16 0.40, =<0.001).
- The number of attempts required was reported in 17 RCTs with a total patient population of 3,060. Ultrasound use significantly reduced the number of attempts required (DM -1.19, 95% CI: -1.49 -0.89, P<0.001).

- The number of failed attempts was reported in 32 RCTs with a total patient population of 6,229. Ultrasound use significantly reduced the risk of failure (RR 0.26, 95% CI: 0.19-0.37, P<0.001).
- The risk of failure on first attempt was reported in 12 RCTs with a total patient population of 1,697. Ultrasound use significantly reduced the risk of failure on first attempt (RR 0.52, 95% CI: 0.43-0.63, P<0.001).

#### Percutaneous nerve blockade

#### Systematic reviews:

All of the systematic reviews concluded that ultrasound-guided placement of nerve blocks was either equivalent to or an improvement on the comparators of landmark or electrical nerve stimulator techniques.

#### Meta-analysis

The following outcomes were statistically significant in favour of ultrasound guidance compared to the landmark or ENS-guided technique:

- Time to administer block was reported in 26 RCTs with a total of 2,025 patients. Ultrasound significantly reduced time to administer a nerve block (difference in mean time (min) -1.66, 95% CI: -2.32 to -1.01, P < 0.001).
- Number of needle redirects was reported in 14 RCTs with a total of 834 patients. Ultrasound significantly reduced number of needle redirections necessary to place a nerve block (difference in mean number of attempts, -1.23, 95% CI: -1.83 to -0.64, P < 0.001).
- Failed nerve blocks were reported in 42 RCTs with a total of 4,611 patients. Ultrasound significantly reduced the risk of nerve block failure (RR 0.41, 95% CI: 0.34 0.50, P < 0.001).
- Onset time was reported in seven RCTs with a total of 500 patients. Ultrasound significantly reduced the time for onset of an overall assessment of nerve block (difference in mean time (min) -4.41, 95% CI: -8.84 to -0.08, P = 0.046).
- The outcome of time for patient readiness for surgery was reported in two RCTs with a total of 191 patients. Ultrasound significantly reduced the time for patients to be ready for surgery (difference in mean time (min), -12.23, 95% CI: -20.73 to 3.72, P = 0.005).

Ultrasound was equivalent to either the landmark or ENS methods for the following outcomes:

- Number of skin punctures was reported in five RCTs with a total of 158 patients (difference in mean number of punctures, -0.04, 95% CI: -0.25 to -0.18, P =0.735).
- Onset time motor block was reported in three RCTs with a total of 169 patients (difference in mean (min) -2.85, 95% CI -9.65 to -3.95, P = 0.411).
- Onset time sensory block was reported in 11 RCTs with a total of 613 patients (difference in mean (min) -2.87, 95% CI -6.24 to -0.49, P = 0.094).
- Time to first analgesia was reported in three RCTs with a total of 151 patients (difference in mean (hr) 2.82, 95% CI -3.32 to 8.96, P = 0.367).

## Overall conclusion with respect to comparative clinical effectiveness:

Overall the use of ultrasound to facilitate major vascular access and percutaneous nerve blockade results in improved procedural and clinical performance.

Main issues around the evidence and conclusions for clinical effectiveness:

Blinding of the proceduralists to intervention technique is impossible for ultrasound guided vascular access and percutaneous neural blockade. The use of appropriately blinded assessors was not explicitly reported for all of the included studies. Also, blinding of patients to the intervention was rarely reported and patient knowledge may have influenced the security of assessor blinding. The potential impact of this on the reported outcomes could not be assessed

The other methodological issue related to poor description of patient withdrawal, both with regard to numbers that were withdrawn and reasons why withdrawal occurred. However, given that most studies focused on immediate effects of the procedure a significant number of studies had a 100 per cent patient retention.

For vascular access, in the majority of studies, time to complete cannulation is considered skin-to-skin. Although statistically significant, the mean difference between techniques is less than one minute. The clinical impact of this time efficiency is minimal for most clinical scenarios. There was no evidence regarding the pre-procedure preparation time and only limited evidence on the impact of imaging on the overall procedure time. As such, the impact of these parameters on the overall complexity and time to perform ultrasound guided vascular access cannot be assessed from the available evidence.

Overall, the observed improvements in effectiveness associated with the ultrasound should have a positive impact on patient comfort; however, no or only limited evidence of patient-related impacts was extractable from the evidence base included in this assessment.

For nerve block, a range of anaesthetic agents were used in the included RCTs. Drug use regimes were reported as being those used in clinical practice to affect appropriate levels and duration of anaesthesia. As such the choice of anaesthetic agent was not considered in the assessment of ultrasound effectiveness when compared to landmark and electrical nerve stimulation guidance methods.

The use of ultrasound resulted in a statistically significant reduction in the skin-to-skin time for placement of nerve blocks when compared with ENS. In contrast, ultrasound extended the time for placement when compared with a landmark method. However, the observed differences in procedure time were less than three minutes for the ENS comparator and one minute for landmark techniques. The clinical significance of these differences is considered low, but this is not assessable from the current evidence base. The procedural metric of needle redirects was defined by the need to retract the needle by a defined distance and then readvance without breaking the skin. Ultrasound reduced the necessity for needle redirects and this reflects the direct visual identification of the anatomy and ability to visually monitor placement in real-time. The impact of this should reduce the potential physical damage associated with repositioning of the needle.

Overall: the use of ultrasound for guiding the placement of neural blockade is at least equivalent, if not better than comparator techniques. Furthermore, the improvement in block characteristics should have a positive benefit for patients and patient flow through a surgical unit.

#### 12. Economic evaluation

#### Ultrasound cost per procedure

The total cost per ultrasound procedure is summarised in Table 1, and is based on 100 to 1000 procedures per machine per year, an ultrasound machine cost of \$25,000 to \$45,000,

and is with and without the proposed MBS fee. The capital cost per ultrasound procedure is sensitive to the cost of the ultrasound machine and the total number of procedures performed. Under the base case assumptions (assuming an ultrasound machine cost of \$40,000 and 500 procedures per machine per year), the capital cost per ultrasound procedure is \$22. Including costs for consumables (\$16), the total cost per procedure is \$38. With the most conservative assumptions (that is \$45,000 machine cost and 100 procedures per year) the figure rises to \$139; under the most optimistic assumptions (that is \$25,000 machine cost and 1,000 procedures per year) the figure falls to \$23.

Table 1 Ultrasound cost per procedure by procedures per year and machine cost

Procedures per machine per year	Machine cost: \$25,000 - proposed MBS fee	Machine cost: \$25,000 + proposed MBS fee <sup>a</sup>	Machine cost: \$40,000 - proposed MBS fee	Machine cost: \$40,000 + proposed MBS fee <sup>a</sup>	Machine cost: \$45,000 - proposed MBS fee	Machine cost: \$45,000 + proposed MBS fee <sup>a</sup>
100	\$89	\$197	\$126	\$235	\$139	\$247
500	\$31	\$139	\$38	\$147	\$41	\$149
1000	\$23	\$132	\$27	\$136	\$28	\$137

a Proposed MBS fee is \$58.35, therefore the 75% MBS benefit is \$43.76. The assumed patient co-payment is \$65;

The Applicant has proposed an MBS fee of \$58.35 for ultrasound guidance for both vascular access and neural blockade (Protocol, page 12). This is based on three Relative Value Guide (RVG) units to align it with the fees and units allocated to the existing RVG ultrasound items. The Applicant states this fee includes a professional component (\$29.20) and a practice component (\$29.15) and that the allocation of three RVG units is based on a comparison of the nature of the service to other services of similar complexity and skill, already funded by the items of Group T10. According to the Protocol (page 8), the pre-service component of ultrasound includes an explanation to the patient about the use of ultrasound, its benefits, the procedure and preparation and checking of the device. According to the Applicant, preservice takes approximately 10–15 minutes. The scan itself takes another 5–10 minutes.

Following feedback from the Department of Health, and noting that the procedures for which ultrasound guidance is proposed already have existing MBS items, the MSAC considered if an additional fee is appropriate for the ultrasound procedure and the level of reimbursement. This service may not reduce or increase the time for the vascular access or reward blockade and therefore may have no impact on the time taken to perform these services.

The results of the economic analysis are presented with and without the inclusion of the proposed fee. Based on anaesthetist-related claims for MBS item 55054 for the financial year 2012/2013, the assumed patient co-payment is \$65. The total cost per ultrasound procedure for the base case scenario, including the MBS benefit and assumed patient co-payment is \$147 (\$38+\$43.76+\$65).

#### Nerve stimulation cost per procedure

Assuming a machine cost of \$1,000 and 500 procedures per year, the cost per nerve stimulation procedure is \$0.42. For 1000 and 100 procedures per year, the cost per procedure is \$0.21 and \$2.10, respectively. For nerve stimulation there are no additional costs for consumables and there is no relevant MBS item.

#### Vascular access economic analysis

The benefits of using ultrasound compared with the landmark technique for vascular access include fewer failed cannulations and a reduction in the incidence of complications. The results of the cost-effectiveness analysis are presented as the incremental cost per failed

cannulation avoided. The cost of the ultrasound procedure and the cost implications of treating pneumothorax and haemothorax events are considered. Given the majority of evidence is for venous access, specifically for internal jugular vein (IJV) and subclavian vein (SCV) access, this is the focus for the vascular access economic analysis.

Table 2 summarises the failed cannulation attempts avoided, and pneumothorax and haemothorax events avoided, with the use of ultrasound guidance compared with the landmark technique. The incidence of pneumothorax and haemothorax is higher for SCV cannulations and therefore the results are presented separately for IJV and SCV cannulations. With the use of ultrasound, the risk of a failed cannulation attempt was avoided in 9% of IJV cannulations and 14% of SCV cannulations. For IJV cannulations, ultrasound resulted in 0.98 fewer pneumothorax events and 1.03 fewer haemothorax events for every 100 cannulations, and the cost saving is estimated to be \$15 (\$8 + \$7). For SCV cannulations, ultrasound resulted in 3.45 fewer pneumothorax events and 4.03 fewer haemothorax events for every 100 cannulations, and the cost saving is estimated to be \$63 (\$35 + \$28).

Table 2 Risk of failed cannulation attempts, and incidence and cost of pneumothorax and haemothorax events

	Risk ratio (95% CI)	Landmark	Ultrasound	Risk difference	Cost per event	Total cost
	` (A) ´	(B)	(C=B x A)	(D=C-B)	(E)	(D x E)
Failed cannulation attempts						
IJV	0.22 (0.13, 0.35)	11%	2%	9%	NA	NA
SCV	0.11 (0.03, 0.45)	16%	2%	14%	NA	NA
Pneumothorax						
IJV	0.19 (0.03, 0.89)	1.25%	0.26%	0.98%	\$782	\$8
SCV	0.41 (0.03, 5.64)	4.37%	0.92%	3.45%	\$1,027	\$35
Haemothorax						
IJV	0.10 (0.02, 0.56) <sup>a</sup>	1.15%	0.12%	1.03%	\$704	\$7
SCV	0.10 (0.02, 0.56) <sup>a</sup>	4.48%	0.45%	4.03%	\$704	\$28

IJV, internal jugular vein; NA, not applicable, SCV, subclavian vein

The incremental cost per failed cannulation avoided is summarised in Table 3 for IJV and SCV access.

For SCV cannulations, the savings due to fewer pneumothorax and haemothorax events (\$63) with ultrasound is greater than the ultrasound capital and consumable costs (\$38). Ultrasound also results in fewer failed cannulation attempts and hence is the dominant procedure. If the proposed MBS benefit and associated assumed patient co-payment are included, the cost of the ultrasound procedure (\$147) is greater than the savings due to fewer complications (\$63), and the incremental cost per failed cannulation avoided is \$600.

The incidence of complications with IJV cannulations is lower than for SCV cannulations and the savings due to the avoidance of complications with ultrasound is less (\$15 versus \$63). Without the proposed MBS benefit, the incremental cost per failed cannulation avoided is \$256. Including the proposed MBS benefit increases the incremental cost per failed cannulation avoided to \$1,467.

Sensitivity analyses demonstrate the results are sensitive to the assumed number of procedures performed per ultrasound machine per year. For IJV access, the incremental cost per failed cannulation avoided varies from \$133 (for 1,000 procedures per year and no MBS

a Risk ratio is for all cannulation sites combined as insufficient data for analysis by subgroups according to site.

benefit) to \$1,233 (for 100 procedures per year and no MBS benefit). For SCV access, ultrasound is dominant for 1,000 procedures per year (and no MBS benefit) and the incremental cost per cannulation avoided is \$450 for 100 procedures per year (and no MBS benefit).

For SCV cannulations, the results are also sensitive to the cost of treating pneumothorax events. If the cost of treating each event is reduced from \$1,027 to \$230, ultrasound is no longer dominant and the incremental cost per failed cannulation avoided is \$15.

Table 3 Incremental cost per failed cannulation avoided with the use of ultrasound vs landmark technique for vascular access

	IJV access without MBS benefit	IJV access with MBS benefit <sup>a</sup>	SCV access without MBS benefit	SCV access with MBS benefit <sup>a</sup>
Base case analysis				
Cost of ultrasound procedure (A)	\$38	\$147	\$38	\$147
Cost savings from complications avoided with ultrasound vs landmark				
Pneumothorax (B)	\$8	\$8	\$35	\$35
Haemothorax (C)	\$7	\$7	\$28	\$28
Total cost (A – B – C)	\$23	\$132	-\$25	\$84
Reduction in failed cannulation attempts with ultrasound vs landmark	0.09	0.09	0.14	0.14
Incremental cost per failed cannulation avoided	\$256	\$1,467	Dominant	\$600

a Proposed MBS fee is \$58.35, therefore the 75% MBS benefit is \$43.76. The assumed patient co-payment is \$65.

The resource and clinical implications of avoiding a failed cannulation attempt are difficult to quantify, but potentially include avoidance of delays starting surgery, and reducing the risk of complications. Calvert (2004) estimated the cost of a failed cannulation due to a 10-minute delay to surgery to be GBP73 (2002 prices). From the data shown in Table 3, the use of ultrasound for IJV cannulations would be cost neutral if each failed cannulation attempt cost \$256 (where there is no additional MBS fee for ultrasound guidance).

The economic analysis considers the cost of treating pneumothorax and haemothorax events but not the clinical implications for the patient. Further, other complications such as nerve damage, infections and catheter-related venous thrombosis may be avoided with the use of ultrasound (Lamperti et al 2012); however, there are insufficient data to quantify the impact of ultrasound on these events. The clinical implications of these events are generally short-term, but in rare cases can be serious and even fatal (Cook and MacDougall-Davis 2012).

#### Nerve block cost analysis

The benefits of using ultrasound compared with nerve stimulation or the landmark technique for peripheral nerve blocks are varied and include reduced need for supplemental anaesthesia, improved postoperative analgesia, a lower dose of local anaesthetic and a reduction in the incidence of complications. Because the benefits cannot easily be incorporated into a single effectiveness measure a cost analysis is presented for nerve blockade. The costs of the ultrasound and nerve stimulation procedures and the local anaesthetic, and the cost implications of improved postoperative pain control and treating local anaesthetic systemic toxicity (LAST) events, are considered.

Based on data from the AURORA registry, analgesia is the aim for close to 100% of nerve blocks. In 40% of blocks the aim is anaesthesia, primarily together with analgesia. Data from the AURORA registry also suggest ultrasound has replaced nerve stimulation in

Australian clinical practice. Therefore, the main focus of the economic analysis for nerve blockade is a comparison of ultrasound and nerve stimulation.

A summary of the potential cost offsets with ultrasound guidance compared with nerve stimulation for nerve blockade is presented in Table 4.

A number of RCTs have demonstrated the dose of local anaesthetic can be reduced when using ultrasound guidance compared with nerve stimulation or the landmark technique. A reduction of 48 milligrams of ropivacaine is assumed based on data from the AURORA registry, and the associated cost saving is \$4. This saving may not be realised as the ampules are single use and hence a reduction in dose may lead to increased wastage rather than a reduction in the number of ampules used. However, as anaesthetists gain confidence with using lower doses of local anaesthetic when using ultrasound, the dose may be further reduced as reductions of greater than 50% were observed in some of the RCTs.

A statistically significant reduction in block failure was demonstrated with ultrasound compared with nerve stimulation or the landmark technique. For procedures in which the nerve block is being used to provide anaesthesia, a reduction in the rate of block failures may reduce the need for supplemental nerve blocks or general anaesthesia. A reduced need for supplemental anaesthesia has not been consistently demonstrated in the RCTs, and therefore the cost implications associated with this have not been calculated; any reduction in supplemental anaesthesia would decrease the incremental cost for ultrasound. For procedures in which the nerve block is being used to provide postoperative analgesia, a reduction in the rate of block failures may lead to improved postoperative pain management. Improved postoperative pain control and reduced use of opioids has been demonstrated in some RCTs.

However based on a systematic review, Choi and Brull (2011) concluded that there is insufficient evidence to define the effect of ultrasound guidance on acute pain control. An economic analysis however data have been collected as part of the AURORA registry (Barrington and Kluger 2013). Ultrasound guidance significantly reduced the incidence of LAST compared with no ultrasound guidance (0.59 vs 2.1 per 1000 blocks, p=0.004). Approximately 40% of the LAST events were classified as major and included clinical symptoms such as seizures and cardiac arrest. The cost of treating a seizure is estimated to be \$3,311, and the savings associated with the reduced incidence of major LAST events is approximately \$2. This is potentially an underestimate of the savings as only the costs associated with treating major LAST events have been considered. An economic analysis conducted alongside a RCT demonstrated that ultrasound resulted in a reduction of postoperative morphine and bupivacaine, and postoperative nursing care compared with nerve stimulation (Ehlers 2012). Applying Australian costs to the resource use results in a saving of \$20 (\$3 + \$5 + \$12).

Vascular puncture and hence injection of local anaesthetic into the vascular system may in rare cases result in LAST. The incidence of LAST is too low to be assessed in RCTs,

Table 4 Potential cost offsets associated with using ultrasound for peripheral nerve blocks

Resource	Units	\$/unit	Cost	% of cost
Reduced dose of local anaesthetic, mg	48	\$0.09	\$4	15%
Reduced dose of postoperative morphine, mL	14.8	\$0.21	\$3	12%
Reduced dose of postoperative local anaesthetic, mL	15	\$0.30	\$5	19%
Reduced nursing time postoperative, minutes	19	\$0.63	\$12	46%
Reduced incidence of major LAST, events per 1000 blocks	0.65	\$3.31	\$2	8%
Total cost savings with ultrasound		•	\$26	100%

LAST, local anaesthetic systemic toxicity

A summary of the overall cost implications of using ultrasound compared with nerve stimulation for nerve blockade is presented in Table 5.

Without inclusion of the proposed MBS benefit, the additional cost per procedure with ultrasound compared with nerve stimulation is \$12. With the inclusion of the proposed MBS benefit and patient co-payment, the additional cost per procedure with ultrasound compared with nerve stimulation is \$121 (\$12 plus the proposed MBS benefit of \$43.76 and assumed patient co-payment of \$65). Sensitivity analyses demonstrate the results are sensitive to the assumed number of procedures performed per ultrasound machine per year. Without the proposed MBS benefit, the incremental cost per ultrasound procedure varies from \$1 (for 1,000 procedures per year) to \$100 (for 100 procedures per year). The results are also sensitive to the cost offset for improved postoperative pain management. Excluding this cost increases the incremental cost per ultrasound procedure from \$12 to \$32.

Table 5 Incremental cost with the use of ultrasound vs nerve stimulation for nerve blockade

	Without MBS benefit	With MBS benefit <sup>a</sup>
Base case analysis		
Cost of ultrasound procedure (A)	\$38	\$147
Cost of nerve stimulation procedure (B)	\$0.42	\$0.42
Incremental cost of procedure (A - B = C)	\$38	\$147
Potential cost offsets (D)	\$26	\$26
Incremental cost per procedure with ultrasound (C - D)	\$12	\$121

<sup>&</sup>lt;sup>a</sup> Proposed MBS fee is \$58.35, therefore the 75% MBS benefit is \$43.76. The assumed patient co-payment is \$65.

## Overall conclusion with respect to comparative cost-effectiveness:

#### Vascular access

For SCV cannulations, the savings due to fewer pneumothorax and haemothorax events (\$63) with ultrasound is greater than the ultrasound capital and consumable costs (\$38). Ultrasound also results in fewer failed cannulation attempts and hence is the dominant procedure. If the proposed MBS benefit and patient co-payment are included, the cost of the ultrasound procedure (\$147) is greater than the savings due to fewer complications (\$63), and the incremental cost per failed cannulation avoided is \$600.

For IJV cannulations the savings due to the avoidance of complications with ultrasound is \$15. Without the proposed MBS benefit, the incremental cost per failed cannulation avoided is \$256. Including the proposed MBS benefit and patient co-payment increases the incremental cost per failed cannulation avoided to \$1,467.

## Nerve blockade

Without inclusion of the proposed MBS benefit, the additional cost per procedure with ultrasound compared with nerve stimulation is \$12. With the inclusion of the proposed MBS benefit and associated patient co-payment, the additional cost per procedure with ultrasound compared with nerve stimulation is \$121.

The potential cost offsets associated with using ultrasound are highly uncertain and may not be realised in practice. For vascular access the resource use costs associated with avoiding pneumothorax and haemothorax events are based on a single study conducted in the United Kingdom. For nerve blockade the costs associated with improved postoperative pain control, a reduced dose of local anaesthetic and avoidance of major LAST events have been estimated. The reduced resource use associated with improved pain management is from a single trial conducted in Denmark in which patients received a continuous sciatic nerve block. The applicability of the results from this study to Australian clinical practice is unknown. There is evidence that the dose of local anaesthetic can be reduced with ultrasound guidance, however the optimal dose is currently unknown and will vary by nerve location. LAST events are rare, and hence the impact of ultrasound guidance on these events can only be assessed in large registries, such as AURORA.

## 13. Financial/budgetary impacts

MBS services for vascular access procedures (MBS items 22015 and 22020) and nerve block procedures for postoperative analgesia (MBS items 22040, 22045 and 22050) for the financial years 2008/2009 – 2012/2013 are summarised in Table 6. MBS services for nerve block procedures for anaesthesia have been estimated assuming 40% of all nerve block procedures are for anaesthesia.

Table 6 MBS services for vascular access procedures (MBS items 22015 and 22020) and nerve block procedures for postoperative analgesia (MBS items 22040, 22045 and 22050), and estimated number of services for nerve block procedures for anaesthesia

Financial year	Item 22015 (vascular access)	Item 22020 (vascular access)	ltem 22040 (analgesia)	Item 22045 (analgesia)	Item 22050 (analgesia)	Nerve blocks for anaesthesia	Total	Growth
2008/2009	5062	19866	20638	6327	14379	27563	93835	
2009/2010	4937	20528	22338	6619	15992	29966	100380	7.0%
2010/2011	4946	20892	22878	6904	16417	30799	102836	2.4%
2011/2012	4964	21787	23789	6651	17286	31817	106294	3.4%
2012/2013	5303	22294	24668	6645	18110	32949	109969	3.5%

Source: MBS statistical reports (http://www.medicareaustralia.gov.au/statistics/mbs\_item.shtml)

Prior to 1 November 2012, ultrasound guidance was claimed by anaesthetists using MBS item 55054. The number of anaesthetist-related claims for item 55054 for the 2008/2009 – 2011/2012 financial years are presented in Table 7.

In 2008/2009 ultrasound was used in 9% of vascular access and nerve block procedures, and this increased to 30% in 2011/2012, and to 34% in the period July to October 2012. In 2011/2012 and 2012/2013 approximately 10% of anaesthetist-related claims for item 55054 were for vascular access, 55% were for nerve blocks for postoperative pain management, and 35% were not for either of these services and hence were likely for nerve blocks for anaesthesia.

Table 7 Anaesthetist-related MBS services for ultrasound guidance (MBS item 55054) and use as a percentage of vascular access and nerve block procedures

Year	Total services for vascular access and nerve blocks (A)	Anaesthesia related claims for Item 55054a (B)	Use of ultrasound (B/A)	
2008/2009	93835	8744	9%	
2009/2010	100380	19094	19%	
2010/2011	102836	27290	27%	
2011/2012	106294	32041	30%	
July-Oct 2012	38319	13205	34%	

Source: MBS statistical reports (http://www.medicareaustralia.gov.au/statistics/mbs\_item.shtml)

a Data provided by Department of Health. An anaesthetist-related claim was defined as a claim by a Provider with one of the following registered specialties current on date of service or derived specialty for the quarter of service being one of these specialties: Anaesthetics-specialist (051), Anaesthetics-intensive care (060), Resuscitation (075), Anaesthetics-non-specialist (216) and Anaesthetics-trainee (400).

Based on a 3.4% annual growth in the number of services for nerve block and vascular access procedures, use of ultrasound in 60% of procedures and the proposed MBS benefit of \$43.76, the cost to the MBS in 2014/2015 and 2015/2016 is \$3.1m and \$3.2m, respectively (Table 8).

Assuming the proportion of procedures in which ultrasound guidance is used increases to 90%, the cost to the MBS in 2014/2015 and 2015/2016 is \$4.6m and \$4.8m, respectively.

Table 8 Estimated MBS services and benefits for ultrasound guidance

			•		
Year	Estimate total services for nerve block and vascular access <sup>a</sup>	60% use of ultrasound: Services	60% use of ultrasound: MBS benefit	90% use of ultrasound: Services	90% use of ultrasound: MBS benefit
2013/2014	113708	68225	\$2,985,507	102337	\$4,478,260
2014/2015	117574	70544	\$3,087,014	105816	\$4,630,521
2015/2016	121571	72943	\$3,191,972	109414	\$4,787,959

a Assuming a 3.4% annual increase in the number of services

Assuming a patient co-payment of \$65 per procedure, the total patient co-payment in 2015/2016 with the use of ultrasound guidance in 60% and 90% of procedures would be \$4.7m and \$7.1m, respectively.

The capital and consumable costs for each ultrasound guided procedure is estimated to be \$38 (equipment = \$22, consumables = \$16). Based on 72,943 services (use in 60% of procedures) in 2015/2016, the capital and consumable cost is approximately \$2.8m. Based on 109,414 services (use in 90% of procedures) in 2015/2016, the capital and consumable cost is approximately \$4.2m. The potential reductions in health care costs due to reduced postoperative care, reduced use of local anaesthetic and pain medications, and a reduced incidence of complications have not been quantified for the financial forecasts as the cost savings are uncertain and may not be realisable.

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

ESC discussed whether the service could be restricted to a certain population groups where access was an issue and considered that it would difficult to restrict the procedure, because it would be unusual to determine patients who have abnormal anatomy before the service is delivered.

ESC had no concerns with the safety of ultrasound imaging in the practice of anaesthesia and noted that ultrasound guidance in the localisation of central vascular access and placement of percutaneous nerve blocks was found to be equivalent to, or resulted in an improvement in, safety outcomes when compared to use of the anatomical landmark technique or the electrical nerve stimulator technique (for percutaneous nerve blocks).

ESC also noted ultrasound guidance significantly reduces the risk of vascular puncture & haematoma, pneumothorax and haemothorax in localisation of central vascular access and that ultrasound guidance significantly reduced the risk of inappropriate vascular puncture and nerve injury in placement of nerve blocks.

ESC noted the positive impact of ultrasound on clinical effectiveness. Ultrasound guidance in the localisation of central vascular access and placement of percutaneous nerve blocks was found to be equivalent, or resulted in an improvement in clinical outcomes compared to the anatomical landmark technique or electrical nerve stimulator technique (for percutaneous nerve blocks).

In terms of localisation of central vascular access, ultrasound guidance was found to significantly reduce cannulation time, the number of attempts and risk of failure, and reduced the time to administer a nerve block, the number of needle redirections, nerve block failure and nerve block onset for placement of nerve blocks.

ESC noted that, to a considerable extent, the application reflects equipment and professional practice issues rather than a service issue. The use of ultrasound occurs at the same time as the anaesthetic service, and the claims of additional RVG units to provide the service could not be supported.

ESC noted that, as the cost of the ultrasound machine and disposables are often met by the hospital where the procedure is performed, this would require further justification of the proposed MBS Item Fee. It was also noted that the machines (whether owned by anaesthetist or the hospital) would be used for more than these processes leading to lower unit costs to amortise the cost of the machines.

ESC raised concern about the economic basis used to determine the proposed MBS Item Fee. The MBS Item Fee has been determined through calculating the average MBS Item Fee of services with similar complexity and required skill level and that these items require further reporting and have additional practice costs without noting that the use of ultrasound may in fact reduce anaesthetist time and certainly does not increase it so it is not clear there is a need for a further fee than that applied to the provision of the anaesthetic.

ESC noted that the service may actually reflect current clinical practice and this service will continue regardless of a specific item being assigned to it.

ESC noted that rapid adoption of the proposed MBS Item could have a significant impact on the budget. It is estimated that the proposed MBS Item could be claimed for 60% to 90% of percutaneous major vascular access and percutaneous neural blockade procedures for the delivery of anaesthesia in the financial year 2015/2016.

ESC noted that the efficiency benefits of ultrasound use in anaesthesia accrue overwhelmingly to the anaesthetist in terms of clear time savings and simplification of delivery.

ESC was not convinced that it would be appropriate to list an item of the MBS which would increase fees for a profession when the overall service was made faster and simpler. ESC also questioned whether there would be a case for the existing anaesthetic service to require ultrasound, while attracting the same fee as it does currently.

ESC also noted that anaesthesia has very high out of pocket costs, and expressed concern that introducing an item could drive an increase to out of pocket costs by justifying an additional item on a patient's bill.

ESC noted that the descriptor described the pivotal elements, the intervention and the eligible population. The principle issues are - should the items (if approved) be in the DI or Anaesthesia section of the schedule, noting that the applicant has requested a listing in the Anaesthetic part of the schedule. If in the former then the providers practice would need to be accredited and automatic indexation of fees would not be applied.

ESC discussed that given the service is rebated for the time required to insert the cannula/catheter and ultrasound tends to make this more efficient, whether an additional payment is required.

ESC discussed that if a fee is justified, the fee which notionally contains a practice component appears reasonable given the hospital may cover costs of the ultrasound machine and disposables.

## 15. Other significant factors

Nil.

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

The ASA notes that MSAC intends to recommend rejection of application 1183. The safety and effectiveness cases have been proven. The economic aspects are however less certain, due to a lack of available evidence. It is unfortunate that MSAC has overlooked favourable aspects of the economic argument due to "uncertainty", such as cost savings afforded by avoiding serious complications, while accepting equally "uncertain" assumptions on cost. On balance the application is supported on evidence and rejected on assumptions, many of which are clearly inaccurate. The ASA is disappointed that the Australian public may well be disadvantaged by this unsupported decision. The ASA has prepared a detailed commentary on its concerns regarding this PSD. This document can be viewed on the ASA website, <a href="https://www.asa.org.au">www.asa.org.au</a>, by following the links "News/Latest News".

#### 17. Further information on MSAC

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