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Final Decision  
Analytic Protocol  
(DAP) to guide the  
assessment of  
ultrasound guidance  
for major vascular  
access and  
percutaneous neural  
blockade

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27 February 2013

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## MSAC and PASC

The Medical Services Advisory Committee (MSAC) is an independent expert committee appointed by the Australian Government Health Minister to strengthen the role of evidence in health financing decisions in Australia. MSAC advises the Commonwealth Minister for Health and Ageing on the evidence relating to the safety, effectiveness, and cost-effectiveness of new and existing medical technologies and procedures and under what circumstances public funding should be supported.

The Protocol Advisory Sub-Committee (PASC) is a standing sub-committee of MSAC. Its primary objective is the determination of protocols to guide clinical and economic assessments of medical interventions proposed for public funding.

### Purpose of this document

This document is intended to provide a draft decision analytic protocol that will be used to guide the assessment of an intervention for a particular population of patients. The draft protocol will be finalised after inviting relevant stakeholders to provide input to the protocol. The final protocol will provide the basis for the assessment of the intervention.

The protocol guiding the assessment of the health intervention has been developed using the widely accepted "PICO" approach. The PICO approach involves a clear articulation of the following aspects of the research question that the assessment is intended to answer:

**P**atients – specification of the characteristics of the patients in whom the intervention is to be considered for use;

**I**ntervention – specification of the proposed intervention

**C**omparator – specification of the therapy most likely to be replaced by the proposed intervention

**O**utcomes – specification of the health outcomes and the healthcare resources likely to be affected by the introduction of the proposed intervention

## **Purpose of application**

An application requesting MBS listing of ultrasound imaging for the practice of anaesthesia was received from the Australian Society of Anaesthetists (ASA) by the Australian Government Department of Health and Ageing in January 2012. The application was further updated in May 2012.

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. The Applicant proposes two new MBS items for ultrasound guidance of percutaneous major vascular access and percutaneous neural blockade for delivery of surgical anaesthesia. The new items are proposed to be listed in the Therapeutic and Diagnostic Services Subgroup of Group T.10 (Category 3 Therapeutic procedures), instead of the category 5 – Diagnostic Imaging Services.

This decision analytic protocol was developed to guide the assessment of safety, effectiveness and cost-effectiveness of ultrasound imaging for the practice of anaesthesia in order to inform MSAC's decision-making regarding public funding of the intervention.

## **Intervention**

### **Background**

Anaesthesia is a state of unconsciousness that eliminates all sensations, which allows medical and surgical procedures to be undertaken without causing undue distress or discomfort (ANZCA 2012). In some instances, anaesthesia is also used to facilitate non-therapeutic procedures (eg diagnostic angiography).

There are several forms of anaesthesia: general anaesthesia, regional anaesthesia, local anaesthesia and combinations of these. According to the Australian Institute of Health and Welfare, a total of 3,849,220 patients received anaesthesia over the 2009-2010 period in Australia. The majority of these patients (86%) received general anaesthesia, 11 per cent received nerve blocks and less than 1 per cent received epidural or spinal anaesthesia (AIHW 2012).

General anaesthesia is a drug-induced total loss of all sensation achieved by administration of an anaesthetic drug via vascular access or inhalation. An unconscious state is accomplished by sensory and motor inhibition at the level of the brain. Cannulation of peripheral vessels is sufficient for the vast majority of cases while major vascular access is required for specific indications such as monitoring of cardiovascular physiology, the administration of certain therapeutic agents and the administration of large volumes of fluid.

Regional anaesthesia is used when loss of sensation is required in a large part of the body. There are two types of regional anaesthesia based on level of neural inhibition - central and peripheral. Epidural, spinal and paravertebral (collectively known as neuraxial) anaesthesia are considered central because they directly inhibit the central nervous system. Peripheral regional anaesthesia is achieved

via nerve blocks - single nerve blocks or nerve plexus blocks. Anaesthetic agents are administered by single shot needle insertion or catheterisation adjacent to nerves or nerve plexuses.

Local anaesthesia is used when absence of sensation is required in a relatively small part of the body such as an area of skin, and is also facilitated by percutaneous nerve blocks. Percutaneous nerve blocks may also apply to patients requiring post-operative analgesia. For instance, local analgesia is used in pain management following limb surgery and invasive abdominal surgeries.

A general guide to the type of anaesthesia recommended for major surgery in different regions of the body is shown in Table 1 (Dobson et al 2003). The exact approach for anaesthesia depends on a variety of clinical and non-clinical considerations including the type of anaesthesia indicated (general, regional, local anaesthesia or combinations of these), complexity of surgery, site of the surgery, the patient's medical status and the resources available.

**Table 1 Widely used anaesthesia techniques according to different locations of major surgery**

Type of surgery	Anaesthetic techniques
Head, neck, upper abdomen, intra-thoracic (laparotomy and laparoscopic approaches)	general anaesthesia
Upper limb	general anaesthesia; regional anaesthesia (nerve blocks or intravenous regional anaesthesia)
Lower abdomen, groin perineum	general anaesthesia; regional anaesthesia (central)
Lower limb	general anaesthesia; regional anaesthesia or combination of general and conduction anaesthesia*.

\* Regional and local anaesthesia collectively known as conduction anaesthesia.  
Source: World Health Organization (Dobson et al 2003).

### Ultrasound guidance in major vascular access and nerve blockade

The Applicant proposes the introduction of two new MBS items for the use of ultrasound guidance for percutaneous major vascular access and neural blockade in the practice of anaesthesia. Note that the proposal and associated MBS items use the term 'major' vascular access. This is a broad term which does not distinguish between centrally- or peripherally-located vessels. However, PASC does not expect that ultrasound should be commonly used to assist difficult peripheral venous or arterial access. In addition, insertion of peripheral venous lines is not MBS funded.

Conventionally, major vascular access and nerve blockade are performed without imaging guidance and therefore rely on the sound anatomical knowledge of the anaesthetist. This will be referred to as the landmark insertion technique. Accurately localising neuro-vasculature can be difficult when inter-individual anatomical variations are present. In addition, access to neurovascular structures becomes difficult when patients are hypovolaemic, hypoxic and/or hypotensive. Difficulty may be experienced when administering regional anaesthesia to children and adolescents, as well as those who are thin or obese. Patient posture can also affect the relative location of neurovascular and surrounding organs.

Complications arising from the incorrect placement of a needle, cannula or catheter can result in inadvertent injection of an anaesthetic agent and other injuries. Inadvertent vascular access could damage neighbouring structures, for example the physical penetration of a needle into a major vessel or pleural cavity and thromboembolism may be life-threatening, or could lead to less severe events such as abscesses and haematomas. Accidentally entering a local anaesthetic agent into the vasculature can result in drug toxicity leading to seizure or depression of cardiovascular and central nerve systems, which can be fatal (Cameron et al 2007; Grewal et al 2006).

Nerve injuries may result from excessive pressure, direct contact or undue stretching. Symptoms of direct nerve injuries include anaesthesia, paraesthesia (tingling, burning, pricking, or numbness of the skin), hypaesthesia (decreased sensation), hyperaesthesia and pain. According to the Royal College of Anaesthetists, nerve injury as a result of peripheral nerve blocks is uncommon (<3%) and the majority (92-97%) of affected patients recover within four to six weeks, while 99 per cent recover within a year. Permanent nerve damage is estimated to be between 1 in 5,000 and 1 in 30,000 nerve blocks (Brull et al 2007; Fischer 2007; Greensmith and Murray 2006). The classification of potential nerve injuries is listed in Table 2. In rare cases, injuries may lead to paresis or even paralysis of affected muscles, resulting in muscle wasting, joint stiffening and bone demineralisation (Greensmith and Murray 2006; Neal et al 2008).

**Table 2 Classification of potential nerve injuries (Seddon and Sunderland classifications)**

Classification		Function	Pathological basis	Prognosis
Seddon	Sunderland			
Neurapraxia	Type 1	Focal conduction block	Local myelin injury, primarily larger fibres. Axonal continuity, no Wallerian degeneration.	Recovery in weeks to months.
Axonotmesis	Type 2	Loss of nerve conduction at injury site and distally.	Disruption of axonal continuity with Wallerian degeneration.	Axonal regeneration required for recovery. Good prognosis since original end organs reached.
	Type 3	Loss of nerve conduction at injury site and distally.	Loss of axonal continuity and endoneurial tubes. Perineurium and epineurium preserved.	Disruption of endoneurial tubes, haemorrhage and oedema produce scarring. Axonal misdirection, poor prognosis. Surgery may be required.
	Type 4	Loss of nerve conduction at injury site and distally.	Loss of axonal continuity. Endoneurial tubes and perineurium. Epineurium remains intact.	Total disorganisation of guiding elements. Intra-neural scarring and axonal misdirection. Poor prognosis. Surgery necessary.
Neurotmesis	Type 5	Loss of nerve conduction at injury site and distally.	Severance of entire nerve.	Surgical modification of nerve ends required. Prognosis guarded and dependent upon nature of injury and local factors.

Ultrasound guidance for cannulation, catheterisation and needle insertion may be used in order to minimise the incidence of complications. Ultrasound use in anaesthesia practice dates back to 1978, when La Grange and colleagues described its use for supraclavicular block (La Grange et al 1978).

An ultrasound machine consists of a pulser, pulse controls, a probe, a display monitor, a keyboard and printer (See Figure 1). The ultrasound device creates acoustic pulses and measures the returning

echo to provide a map of the tissue. The monitor displays the signals in a variety of modes in near-real time.

“Live” images facilitate the interpretation of the neuro-vasculature compared to still images. Images can be recorded in the computer in still or video formats and provide details of any tissue movement, including responses to pressure arising from the insertion and from the probe itself. The shape of the ultrasound display depends on the size, shape and configuration of the probe (transducer). In a typical ultrasound image, black represents fluid, soft tissues are represented in grey tones; soft-tissue/air interfaces cause near-complete reflection of the ultrasound beam, whereas ultrasound energy is almost completely absorbed by bone, so that tissues in or beyond air-filled or bony structures cannot be evaluated.

**Figure 1**                      **Ultrasound machine**



Ultrasound modes provide specific details about the focal point and scanning zone.

- Doppler mode - is used specifically for spectral blood flow analysis.
- A-mode (Amplitude mode) - allows the operator to visualise interfaces along a single line, permitting accurate depth measurements.
- B-mode - allows the operator to scan through a single body plane (2D mapping) and is the most commonly used image guidance method. Pulsed-wave Doppler mapping permits a colour flow map to be superimposed on the B-mode image.

Modern ultrasound machines are capable of generating three- and four-dimensional images in addition to the conventional 2D images. Three-dimensional images in motion are referred to as four-dimensional.

In general, 2D cross-sectional ultrasound in B-mode is used for the location of neuro-vasculature in anaesthesia practice. B-mode uses 2.5 to 10 MHz probes. Higher frequency probe (10 MHz) is required to identify small superficial nerves while deeper nerve plexuses (eg sciatic, lumbar) are best viewed by a lower frequency probe. B-mode enables accurate real-time needle visualisation (Kumar and Chuan 2009).

Ultrasound is a common guidance method for central vascular cannulation in both elective and emergency circumstances (Dobson et al 2003). Ultrasound guidance is also recommended when surface landmarks are difficult to identify (eg due to localised swelling, obesity), following difficult or failed insertion attempts, or previous complications (eg pleural puncture, pneumothorax, arterial/venous puncture, nerve injury), when there are limited sites for access (eg other cannula/catheter in situ, local surgery or infection), or when there are known vascular abnormalities, coagulopathies and/or patient inability to remain in a supine position (eg due to dyspnoea or increased intracranial pressure) (Hatfield and Bodenham, 1999a; Hussain et al 2011). In the United Kingdom, it is mandatory to use ultrasound guidance during all major venous cannulations, regardless of a patient's risk of complications (NICE 2002).

NOTE: PASC recognises that the current submission is for the delivery of services for peri-operative anaesthesia. However, PASC understands that ultrasound guidance can also be used by anaesthetists when performing procedures outside of the operating theatre. Although the two proposed items are limited to peri-surgical delivery of anaesthesia, the assessment report should also consider the use of ultrasound to guide the nominated procedures when performed by anaesthetists outside of an operating theatre setting, or by other specialties. This may provide evidence for other policy development arising from the use of ultrasound guidance.

### **Administration, dose, frequency of administration, duration of treatment**

Ultrasonography is a non-invasive procedure that does not produce ionizing radiation (Marhofer et al 2005). Medical diagnostic and interventional ultrasonography uses a frequency range from 1MHz to 20MHz (1MHz = 1,000,000Hz). These sound frequencies are poorly transmitted by air and bone, but are effectively transmitted by fluid and soft tissues.

A decision regarding a requirement for the service is made at the pre-anaesthesia assessment, which is compulsorily undertaken prior to any surgical procedure that requires anaesthesia (ANZCA 2010). The assessment, which currently is claimed through MBS items 17610, 17615, 17620 and 17625, allows the anaesthetist to plan anaesthesia on a case by case basis and to consider risks for insertion- and anaesthesia-related complications, and history of previous anaesthesia-related complications. The assessment will also provide an opportunity for the anaesthetist to decide whether ultrasound guidance is required to avoid potential complications of an insertion (ANZCA 2010).

The pre-service component of the proposed service includes an explanation to the patient about use of ultrasound, its benefits, the procedure and preparation and checking of the device. According to the ASA pre-service takes approximately 10-15 minutes. The scan itself takes another 5-10 minutes. No post-service component is applicable to the intervention. It is a one-off delivery, and the vast



majority of patients would only require the service once or on a small number of occasions during their lifetime.

To perform an ultrasound-guided needle insertion, anaesthetists insert a needle, cannula or catheter with one hand while controlling the probe with the other hand to monitor the insertion when necessary. Such a manoeuvre demands expertise in ultrasound as well as in insertion techniques. Anaesthetists who are to use ultrasound guidance therefore need training and experience specific to ultrasonography in addition to expertise as an anaesthetist. The skill set required in perform ultrasound guidance insertions for major vascular access and nerve blockade are similar.

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 ASA also hold regular workshops on the use of ultrasound in anaesthesia practice. As such formal training sessions in the use of ultrasound are regularly made available for the purposes of initial training and maintenance of skills.

As stated by the Applicant, general practitioners recognised by ANZCA do provide some anaesthesia services, although training in the use of ultrasound appears not to be an integral part of their training in anaesthesia. Other practitioners such as intensivists, emergency medicine physicians and cardiologists also perform procedures such as major vascular access, and also use ultrasound.

PASC recognises that the Applicant has proposed two items focused on peri-operative anaesthetist services. However, PASC and the Department are also interested in evidence in the use of ultrasound to guide the nominated procedures (major vascular access and nerve blockade) when performed by non-anaesthetists outside of an operating theatre setting. The assessment report should also consider the delivery of these services by other specialties. This may provide evidence for other policy development arising from the use of ultrasound guidance.

### **Co-administered interventions**

In the practice of percutaneous nerve blocks, electrical nerve stimulation (ENS) may also be used in guidance together with, or instead of, ultrasound. The Australian and New Zealand Registry of Regional Anaesthesia records increased utilisation of ultrasound for nerve blockade either alone or in combination with ENS. For 2011, 60 per cent of blocks were performed with ultrasound alone and 20 per cent with ENS alone. The trend in Australia points to a rise in ultrasound and a fall in ENS alone.

Management of potential adverse events result from a cannula, catheter or needle insertion following ultrasound guidance is the same as following landmark technique with or without assistance of ENS.

### **Background**

#### **Current arrangements for public reimbursement**

Ultrasound guidance to facilitate vascular access and nerve blockade procedures in association with anaesthesia has been used in Australia in both public and private practice for the last decade. The

service was claimed through MBS item 55054 (Table 3) until 1 November 2012. The number of claims made for the item from 2000 to 2011 follows in Table 4. There has been a gradual increase in the number of services and number of anaesthesia-related claims over the past 10 years. Private insurance rebates are available for the MBS item and the exact amount varies depending on the insurer, as stated by the Applicant.

MBS item 55026 been also used in a smaller percentage of anaesthesia-related claims. This item is used for ultrasound devices which are over 10 years old. For the purposes of this proposal the focus shall be on the use of MBS item 55054.

**Table 3 Current MBS item descriptor used in ultrasound guidance in the practice of anaesthesia**

Category 5 Group 11, Subgroup 1 - Diagnostic Imaging services	
<b>MBS Item 55054</b>	Ultrasonic cross-sectional echography, in conjunction with a surgical procedure using interventional techniques, not being a service associated with a service to which any other item in this group applies. (See para DIQ of Explanatory Notes to this category)
<b>Fee: \$109.10</b>	<b>Benefit: 75% = \$81.85 85% = \$92.75</b>
Explanatory note DIQ: To provide an incentive to bulk-bill, for out-of-hospital services that are bulk-billed, the Schedule Fee is reduced by 5% and rebates provided at 100% of this revised fee (except for item 61369).	
<Previous - Item 55049 Next - Item 55059>	
Item Start Date: 01-Jul-1993; Description Start Date: 01-Nov-1993; Schedule Fee Start Date: 01-Nov-2004. Category 5: Diagnostic Imaging Services; Group 11: Ultrasound; Subgroup 1: General.	

**Table 4 Number of services claimed for MBS Item 55054**

Financial year	Number of services	Anaesthesia related claims*	Proportion of the total (%)
2000/2001	45,922	NR	NR
2001/2002	53,254	NR	NR
2002/2003	62,188	NR	NR
2003/2004	70,784	NR	NR
2004/2005	81,828	5	<0.001
2005/2006	96,431	108	0.1
2006/2007	107,688	274	0.2
2007/2008	120,093	1121	0.9
2008/2009	142,780	7222	5.1
2009/2010	163,585	17,291	10.6
2010/2011	187,417	26,363	14.1

\*data provided by the Applicant; NR: not reported

Source: Australian Government Department of Health and Ageing

## Regulatory status

Over 200 ultrasound systems are listed in the ARTG as of May 2012. These include B-mode (two dimensional) ultrasonography, Doppler, as well as three and four dimensional devices.

## POLICY ADVICE

This submission covers the ultrasound guidance for vascular access and neural blockade performed by anaesthetists in peri-operative setting. However, PASC noted that ultrasound guidance for major vascular access and neural blockade should also be considered for the following settings:

Ultrasound guidance for vascular access and neural blockade performed by anaesthetists outside of operating theatre

- Ultrasound guidance for vascular access and neural blockade performed by other specialists outside of the operating theatre.

## Patient population

The population is defined as patients who receive ultrasound guidance for delivery of anaesthesia. There are two sub-populations:

1. To assist with percutaneous major vascular access

These patients require major vascular access for anaesthetic delivery. The vast majority of the patients are likely to undergo major surgeries (e.g. cardiac surgery, neurosurgery and trauma) and may have significant comorbidities (particularly cardiovascular).

Major vascular access is generally achieved by cannulation and/or catheterisation of a central vein, while some patients would require major arterial access. The internal jugular vein is the most common access point for major elective surgery, whilst the external jugular, subclavian and femoral veins are also used for access.

PASC acknowledges that patients who receive peripherally inserted central catheters (PICC lines), including via antecubital (basilic and cephalic) veins will also be part of this population. However, PASC does not expect that this population would commonly include patients requiring insertions of peripheral venous or arterial lines.

This population is further divided into:

- ultrasound guidance for peri-operative anaesthesia (the focus of the submission)
- ultrasound guidance for non-operative purposes.

2. To assist with percutaneous neural blockade

This group of patients is likely to receive regional or local anaesthesia by a single-shot needle insertion and/or placing 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.

Some of the most common nerve blocks are listed in Table 5. Additionally, patients receiving epidural, spinal and paravertebral (neuraxial) blocks are also part of this population.

Nerve blockade may be used in association with various surgical procedures (eg limb and abdominal surgeries). It may also be used as the primary form of anaesthesia, often in patients with significant comorbidities for whom other techniques, such as general anaesthesia, may pose a higher risk or be contraindicated.

This population is further divided into:

- ultrasound guidance for peri-operative anaesthesia (the focus of the submission)
- ultrasound guidance for non-operative purposes.

**Table 5 Common nerve blocks**

Region	Nerve blocks
Upper limb	axillary block, infraclavicular block, interscalene block, mid humeral block, peripheral nerve block - median nerve, musculocutaneous nerve blocks, radial nerve block, ulnar nerve block, supraclavicular block, brachial plexus block
Lower limb	ankle block, femoral nerve block, lateral femoral cutaneous nerve block, obturator nerve block, saphenous nerve block, sciatic nerve blocks - gluteal region, popliteal region, proximal thigh region, subgluteal region
Thorax and abdomen	ilioinguinal/iliohypogastric nerve block, neuraxial block, psoas compartment block, thoracic paravertebral block, transversus abdominis plane (TAP) block

Ultrasound guidance in major vascular access and nerve blockade is used in both elective and emergency surgical settings. There are no specific circumstances, medical conditions or patient characteristics in which the use of ultrasound guidance should be limited.

**Note: Delivery of the service to both above populations:**

- The proposal involves the delivery of services by anaesthetists. However, PASC recognises that other specialists may also benefit from the use of ultrasound guidance for patients receiving insertions of peripheral venous or arterial lines, for example in pain management. Therefore all evidence regarding the two above populations should be considered and reported.

**Proposed MBS listing**

There are two proposed MBS items, to be listed in MBS Category 3 (Therapeutic Procedures) (Table 6 and Table 7). The Applicant proposes a new fee for both items of \$58.35 based on three Relative Value Guide (RVG) units to align it with the fees and units allocated to the existing AMA/ASA RVG ultrasound items. This fee 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 the sub-populations.

PASC acknowledges that practitioners other than anaesthetists may use ultrasound guidance for vascular access and neural blockade; however, access to the proposed items has been requested for anaesthetists use only.

**Table 6 Proposed MBS item descriptor for assistance of percutaneous major vascular access**

Category 3 Group T10, Subgroup 19 – Therapeutic Procedures

MBS [item number]

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

Fee: \$58.35 (3 RVG units)

[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]

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

**Table 7 Proposed MBS item descriptor for assistance of percutaneous neural blockade**

Category 3, Group T10, Subgroup 19 – Therapeutic Procedures

MBS [item number]

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

Fee: \$58.35 (3 RVG Units)

[Explanatory note. This item may be used in addition to the relevant nerve block item.

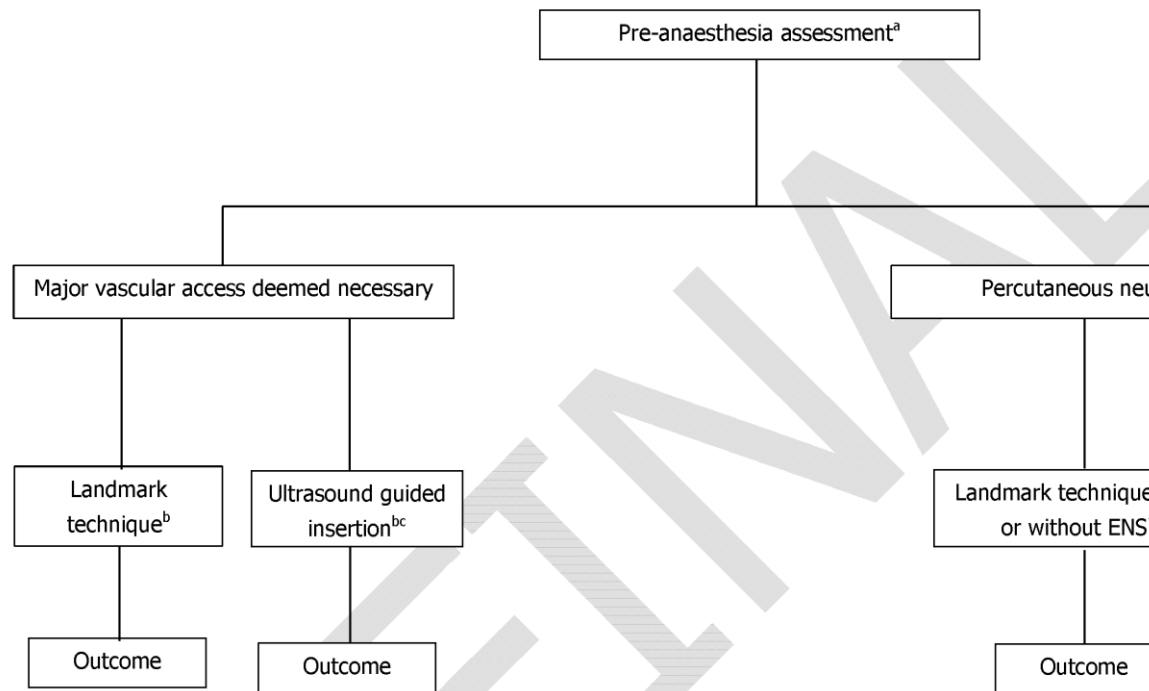
Explanatory note. T.1.20. Therapeutic procedures may be provided by a specialist trainee applies]

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

## Clinical place for proposed intervention

Reimbursement for ultrasound guidance in major vascular access and nerve blockade was claimed utilising the MBS item 55054 (

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



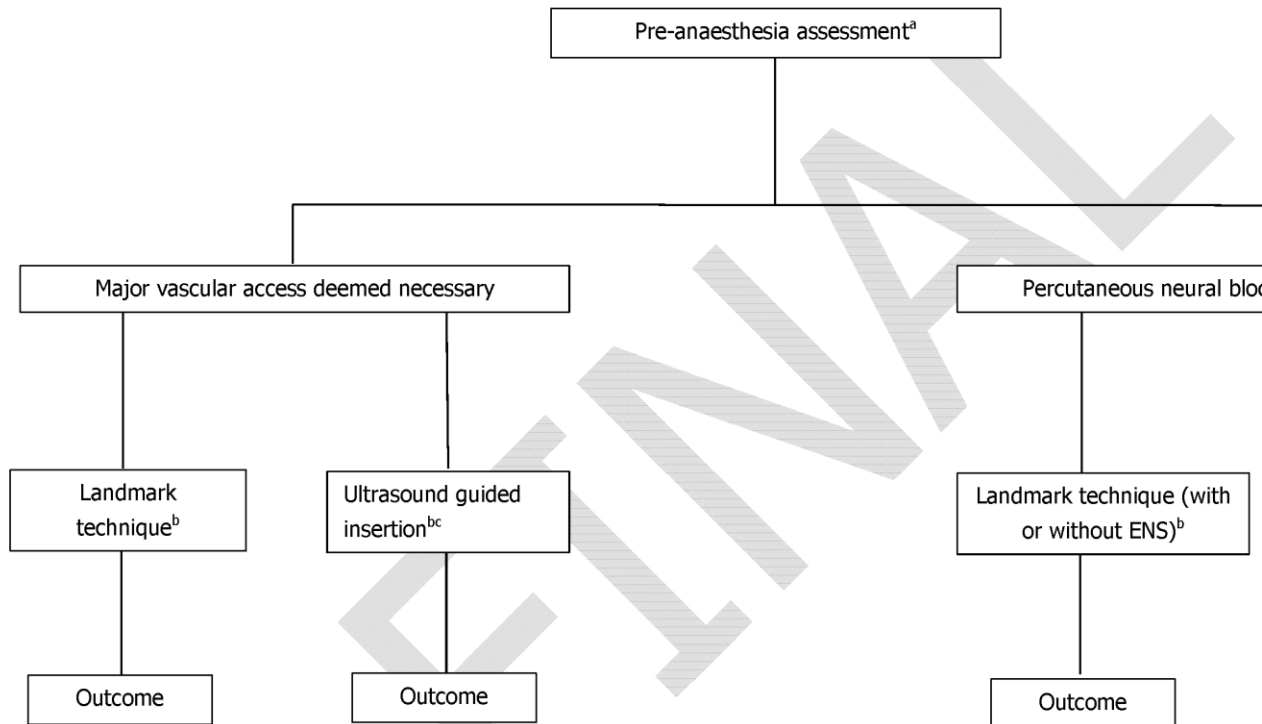
a. any circumstance that require anaesthesia for surgery. Patients who require independent pain management or analgesia are not included.

b. insertion of a cannula, catheter or needle.

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

Landmark technique: Insertion of a cannula, catheter or needle performed based on anaesthetist's knowledge of human anatomy, without the use of ultrasound or nerve stimulation.

Figure 3 Proposed clinical management algorithm in major vascular access and neural blockade



a. any circumstance that require anaesthesia for surgery. Patients who require independent pain management or analgesia are not a part of  
 b. include insertion of a cannula, catheter or needle.  
 c. proposed MBS items.  
 Landmark technique: insertion of a cannula, catheter or needle performed based on anaesthetist's knowledge of human anatomy, experience and nerve stimulation.

). Effective from 01 November 2012, the item is restricted for non-anaesthesia related purposes only, until the safety, effectiveness and cost-effectiveness of ultrasound guidance in anaesthesia practice is assessed. The Applicant proposes two new items (Figure 3) for ultrasound guidance in anaesthesia practice.

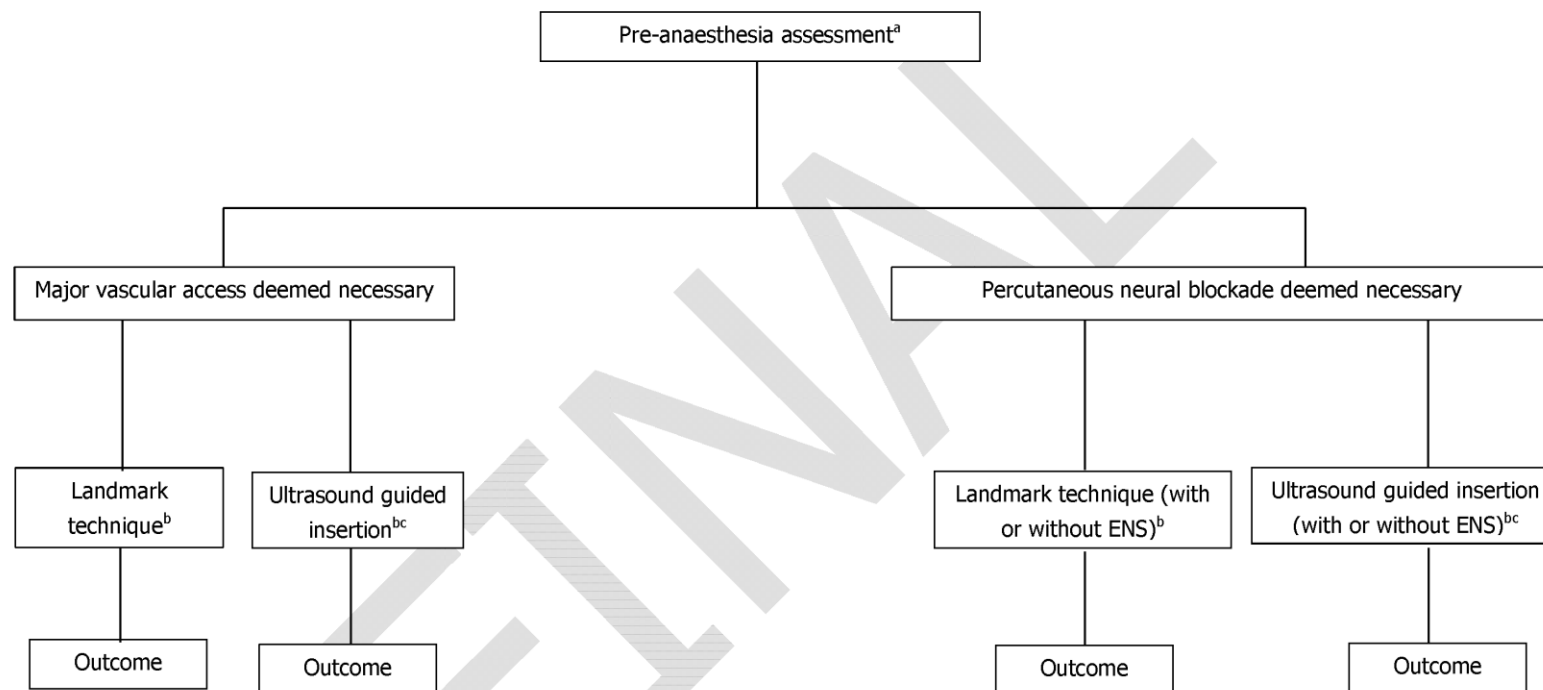
Not all patients requiring major vascular access or nerve blockade procedures as part of their anaesthesia care will require ultrasound guidance. Certain experienced practitioners may be confident to provide these procedures in the absence of ultrasound guidance. It may be that lower numbers of ultrasound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

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

FENVAL



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



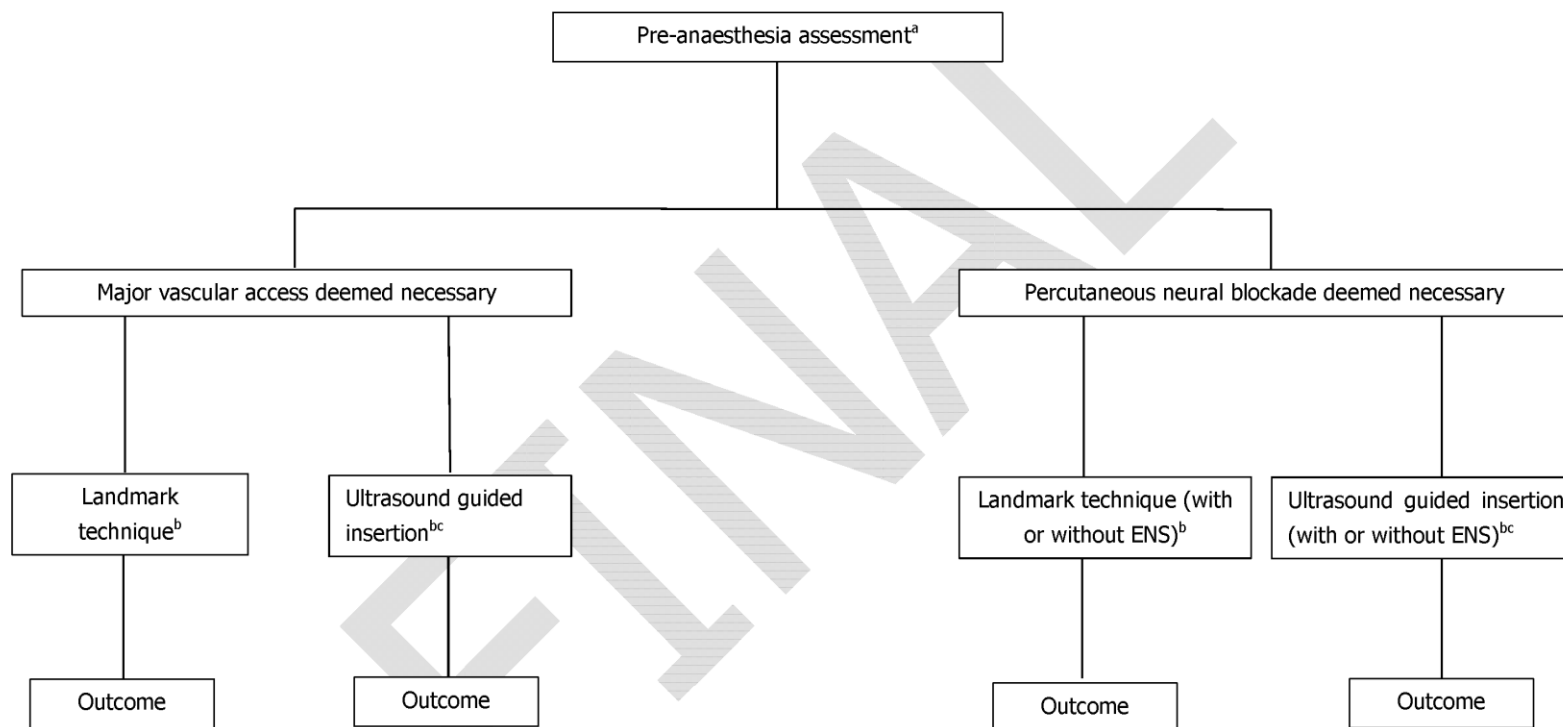
a. any circumstance that require anaesthesia for surgery. Patients who require independent pain management or analgesia are not a part of this population.

b. insertion of a cannula, catheter or needle.

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

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.

Figure 3 Proposed clinical management algorithm in major vascular access and neural blockade



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.

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.

## **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 differs from practitioner to practitioner. It does not require additional resources and there is no associated MBS item.

### **Electrical nerve stimulation (ENS)**

In patients who receive percutaneous nerve blockade, ENS can be used in combination with the landmark technique to indicate the location of nerves (Macintyre et al 2010; Abrahams et al 2009). Nerve stimulation has been the 'gold standard' modality to guide nerve blocks prior to the introduction of ultrasound (Abrahams, 2009). Some deeper nerve blocks appear to be better performed with nerve stimulation alone or with the addition of ultrasound guidance (e.g. lumbar plexus block, anterior sciatic block).

Whilst ENS indicates the location of nerves there are several limitations of the technique. 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. 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.

### **Clinical claim**

The Applicant claims that there will be a higher success rate and fewer adverse events following anaesthetic insertions with ultrasound guidance compared to the landmark technique. This would result in less nursing care and analgesics, patients would spend less time in hospital, and display a more rapid return to normal function.

**Table 8. Classification of an intervention for determination of economic evaluation to be presented**

		Comparative effectiveness versus comparator				
		Superior		Non-inferior	Inferior	
Comparative safety versus comparator	Superior	CEA/CUA		CEA/CUA	Net clinical benefit	CEA/CUA
					Neutral benefit	CEA/CUA*
					Net harms	None^
	Non-inferior	CEA/CUA		CEA/CUA*	None^	
	Inferior	Net clinical benefit	CEA/CUA		None^	None^
		Neutral benefit	CEA/CUA*			
Net harms		None^				

Abbreviations: CEA = cost-effectiveness analysis; CUA = cost-utility analysis

\* May be reduced to cost-minimisation analysis. Cost-minimisation analysis should only be presented when the proposed service has been indisputably demonstrated to be no worse than its main comparator(s) in terms of both effectiveness and safety, so the difference between the service and the appropriate comparator can be reduced to a comparison of costs. In most cases, there will be some uncertainty around such a conclusion (i.e., the conclusion is often not indisputable). Therefore, when an assessment concludes that an intervention was no worse than a comparator, an assessment of the uncertainty around this conclusion should be provided by presentation of cost-effectiveness and/or cost-utility analyses.

^ No economic evaluation needs to be presented; MSAC is unlikely to recommend government subsidy of this intervention

## Outcomes and health care resources affected by introduction of proposed intervention

### Outcomes

The effectiveness and safety outcomes are to be assessed separately for percutaneous major vascular access and percutaneous nerve blockade. Any outcome following use of ultrasound guidance alone should be reported separately to outcomes from using both ultrasound and ENS. All outcomes for peripheral vascular access should be reported separately, where possible, so that any evidence on this use of ultrasound can be collected to inform future policy making decisions. All outcomes are to be presented as rates, where possible.

### Effectiveness

#### Primary effectiveness outcome

- Success rate - viable insertion at first attempt

#### Secondary effectiveness outcomes

- Failed insertion attempts
- Time to perform the insertion (e.g. time to initiate/perform a block) Time to onset of anaesthesia
- Volume or amount of anaesthesia required
- Any patient-related outcome (e.g. quality of life)

### Safety

#### Primary safety outcome

- Complications or adverse events following an insertion (e.g. haematoma, pneumothorax, nerve injuries...etc.)
- Complication or adverse events following the entire procedure
- Anaesthetic toxicity

### **Secondary safety outcomes**

Any other adverse events or complications that occur following the use of ultrasound guidance in cannula (catheter) or needle insertion procedures should be considered as a safety concern and compared against incidences of landmark technique (with or without the assistance of ENS).

The use of ultrasound is expected to reduce the incidence of adverse events. There are no known adverse events related to ultrasound itself. However, major vascular access or nerve blockade procedures may lead to complications.

### **Health care resources**

The cost of ultrasound machines varies depending on the manufacturer. In general, a machine could cost \$25,000 to \$90,000, as indicated by the Applicant. Maintenance and insurance could cost approximately \$1,000 per annum and the lifetime of the device is up to five years. The repair of faults is generally covered by insurance or (in the first year) the manufacturer's warranty.

Generally public hospitals and minority of large private hospitals would provide the ultrasound machines for the use in the anaesthesia practice. However, hospital-owned equipment may be used for other purposes as well, and may not be readily available for use with anaesthesia. Anaesthetists or groups of anaesthetists may purchase their own equipment and maintain their accreditation.

Ultrasound machines should adhere to the Australasian Society of Ultrasound in Medicine recommendations on sterilisation (Barnett et al 2010). As a measure of infection control, probes are disinfected, sterilised and covered. The disposables used include gel, sterile sheaths, specialised needles and guides. Plastic or latex sheaths can be used (Hatfield and Doddenham 1999b). After each use, gel should be washed away from the probe using a mild alkali detergent (free-rinsing) and then dried with a soft disposable towel (ASUM 2012). As stated by the Applicant, gel and sterile sheaths would cost up to \$20 per patient.

The number of claims made via the MBS item 55054 for ultrasound guidance in anaesthesia practice has increased over the last seven years (Table 4). Over 2009/2010 financial year, 17,291 anaesthesia related claims were made (11% of the total number of claims). The number of anaesthesia-related claims increased to 26,363 in the 2010/2011 financial year, which represents approximately 14 per cent of the total number of claims. If this trend remains constant, there will be approximately 35,000 claims for ultrasound-guided anaesthesia during 2011/2012. However, the Applicant suggests that the trend will plateau at some stage over next few years, although no evidence has been provided to support this claim.

Due to the purported advantages of ultrasound-guidance, it is suggested that the utilisation of ultrasound-guidance for anaesthesia will become common practice for many practitioners. If the ultrasound training is a compulsory part of the anaesthetists' expertise, and if machines are readily available in surgical settings, trainees and less experienced practitioners may routinely use the technique with an intention of reducing potential complications. However, certain experienced practitioners may remain confident in using the landmark technique.

The service is limited to operative theatres. Most major vascular access procedures will be confined to inpatients at hospital facilities (public and private), mainly in metropolitan or major rural centres. For anaesthesia, the service is self-determined following a booking or indication to undergo surgery and therefore does not require a specific referral.

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**Table 9 List of resources to be considered in the economic analysis**

Note: The Table need to be updated at the time of the assessment for economical modelling to be accurate using the latest data and indexation available.

	Provider of resource	Setting in which resource is provided	Number of units of resource per relevant time horizon per patient receiving resource	Source of information of number of units*
<b><u>Resources provided to identify the eligible population that would vary from current clinical practice (from Step 2, e.g., diagnostic and other investigative medical services, prior therapeutic interventions). Identify variations where these may vary across different decision options.</u></b>				
- Pre-anaesthesia assessment	Anaesthetists	Inpatient	Once-off use	MBS items 17610, 17615, 17620 or 17625
<b><u>Resources provided in association with the ultrasound guidance in the major vascular access and percutaneous neural blockade (from Step 1, e.g., pre-treatments, co-administered interventions). Identify variations where these may vary across different decision options.</u></b>				
- Vascular cannulation	Anaesthetist	Inpatient	Once-off use	MBS items 13815, 13818, 22015, 22020*
- Nerve blockade	Anaesthetist	Inpatient	Once-off use	MBS items 22040, 22045, 22050*
- Disposables for ultrasound - gel, sterile sheaths, specialised needles and guides	Anaesthetist	Inpatient	Once-off	N/R
*Note that the resources allocated to these interventions are not expected to change regardless of this proposal				
<b><u>Resources provided to deliver the comparator to deliver the current intervention (from Step 4, e.g., pre-treatments, co-administered interventions). Identify variations where there may be more than one comparator or where these may vary across different decision options.</u></b>				
- Landmark technique	Anaesthetist	Inpatient	No resources required	Nil
- Electrical nerve stimulation	Anaesthetist	Inpatient	N/R	N/R
<b><u>Resources provided following the proposed intervention with the proposed medical service (from Step 8, e.g., resources used to monitor or in follow-up, resources used in management of adverse events, resources used for treatment of down-stream conditions conditioned on the results of the proposed intervention). Identify variations where these may vary across different decision options.</u></b>				
- Vascular cannulation	Anaesthetist	Inpatient	N/R	N/R
- Nerve blockade	Anaesthetist	Inpatient	N/R	N/R
- Hospitalisation for management of adverse events	Unknown	Inpatient	N/R	N/R

	Provider of resource	Setting in which resource is provided	Number of units of resource per relevant time horizon per patient receiving resource	Source of information of number of units*
<b><u>Resources provided following the comparator to deliver the current intervention (from Step 7, e.g., resources used to monitor or in follow-up, resources used in management of adverse events, resources used for treatment of down-stream conditions conditioned on the results of the proposed intervention). Identify variations where there may be more than one comparator or where these may vary across different decision options.</u></b>				
- Landmark technique	Anaesthetist	Inpatient – vascular cannulation	N/R	N/R
- Electrical nerve stimulation	Anaesthetist	Inpatient – nerve blockade	N/R	N/R
- Hospitalisation for management of adverse events	Unknown	Inpatient	N/R	N/R

\* Possible sources include experimental or trial data, observational data such as epidemiological data or utilisation data from Medicare Australia, survey data, expert opinion that were available to the Applicant.  
N/R – not reported.



## Proposed structure of economic evaluation (decision-analytic)

**Table 10 Summary of extended PICO to define research question that assessment will investigate**

Patients	Intervention	Comparator	Outcomes to be assessed <sup>^</sup>	Healthcare resources to be considered
1. Patients who receive anaesthesia via percutaneous major vascular access	Two dimensional ultrasound (with or without ENS)	1. Landmark technique	<p><b>Effectiveness</b></p> <p>Primary effectiveness outcome</p> <ul style="list-style-type: none"> <li>- Success rate*</li> </ul> <p>Secondary effectiveness outcomes</p> <ul style="list-style-type: none"> <li>- failed insertion attempts</li> <li>- time to perform the insertion</li> <li>- time to onset of anaesthesia</li> <li>- volume or amount of anaesthesia required</li> <li>- any patient-related outcome (eg quality of life)</li> </ul>	Hospital resources required to manage adverse events and time of service provision. Refer to Table 9 for more details.
2. Patients who receive percutaneous neural blockade		2. Landmark technique with or without guidance of ENS <sup>^</sup>	<p><b>Safety</b></p> <p>Primary safety outcomes</p> <ul style="list-style-type: none"> <li>- complication or adverse events (following an insertion and an entire procedure)</li> <li>-local anaesthetic toxicity</li> </ul> <p>Secondary safety outcomes</p> <p>Any other complication or adverse event that occurs following in cannula, catheter or needle insertion procedures.</p> <p>Potential adverse events may include;</p> <ul style="list-style-type: none"> <li>- hematoma/false aneurysm</li> <li>- pleural puncture (leading to pneumothorax)</li> <li>- nerve damage and injury</li> <li>-immediate catastrophic events</li> </ul>	

<sup>^</sup> outcomes of insertion with ENS should be reported separately to the outcomes of insertion with no ENS, where possible.\* viable insertion at first attempt.ENS: Electrical nerve stimulation

## References

- Abrahams, M. S., Aziz, M. F., et al, 2009. 'Ultrasound guidance compared with electrical neurostimulation for peripheral nerve block: a systematic review and meta-analysis of randomized controlled trials', *British Journal of Anaesthesia*, 102 (3), 408–417.
- AIHW, 2012. 'Procedures data cubes', [Internet]. Available from: <<http://www.aihw.gov.au/hospitals-data-cube/?id=10737419462>>, [Accessed 25 May 2012].
- ANZCA, 2010. 'Guidelines on Sedation and/or Analgesia for Diagnostic and Interventional Medical, Dental or Surgical Procedures', [Internet]. Available from: <<http://www.anzca.edu.au/resources/professional-documents/documents/professional-standards/pdf-files/PS9-2010.pdf>>, [Accessed on 15 May 2012].
- ANZCA, 2012. 'What is anaesthesia?', [Internet]. Available from: <<http://www.anzca.edu.au/patients/anaesthetist>>, [Accessed 20 June 2012].
- ASUM, 2012. 'Promoting Excellence in ultrasound: Policies and statements on the disinfection of transducers' [Internet]. Available from: <[http://www.asum.com.au/newsite/files/documents/policies/PS/B2\\_policy.pdf](http://www.asum.com.au/newsite/files/documents/policies/PS/B2_policy.pdf)>, [Accessed 10 May 2012].
- Barnett, S. B., Abramowicz, J. S., et al, 2010. 'WFUMB symposium on safety of nonmedical use of ultrasound, World Federation for Ultrasound in Medicine & Biology', *Journal of Ultrasound in Medicine & Biology*, 36 (8), 1209–1212.
- Brull, R., McCartney, C. J. L., et al, 2007. 'Neurological complications after regional anesthesia: contemporary estimates of risk', *Journal of Anesthesia & Analgesia*, 104 (4), 965-974.
- Cameron, C. M., Scott, D. A., et al, 2007. 'A review of neuraxial epidural morbidity: Experience of more than 8,000 cases at a single teaching hospital', *Anaesthesiology*, 106 (5), 997-1002.
- Chesapeake Ultrasound Services 2013. Ultrasound products. [Internet] Available from: [http://www.usedultrasound.net/ultrasound\\_products](http://www.usedultrasound.net/ultrasound_products) (Accessed on 05/02/2013).
- Dobson, M., Fenton, P., et al, 2003. Surgical Care at the District Hospital – The WHO Manual, World Health Organization. Geneva. [Internet]. Available from: <[www.who.int/surgery/publications/en/CACHE\\_DUVIE=fc79dff1df97f3773facff5d802427fc/SCDH.pdf](http://www.who.int/surgery/publications/en/CACHE_DUVIE=fc79dff1df97f3773facff5d802427fc/SCDH.pdf)> [Accessed 10 May 2012].
- Fischer, B., 2007. 'Complications of Regional Anaesthesia', *Anaesthesia and Intensive Care Medicine*, 8 (4), 151–154.
- Greensmith, J. E. and Murray, W. B., 2006. 'Complications of regional anaesthesia', *Current Opinion in Anaesthesiology*, 19 (5), 531-537.
- Grewal, S., Hocking, G., et al, 2006. 'Epidural abscesses', *British Journal of Anaesthesiology*, 96 (3), 292-302.

Hatfield, A. and Bodenham, A., 1999a. 'Portable ultrasound for difficult central venous access', *British Journal of Anaesthesia*, 82 (6), 822-826.

Hatfield, A. and Bodenham, A., 1999b. 'Ultrasound: an emerging role in anaesthesia and intensive care', *British Journal of Anaesthesia*, 85 (5), 789-800.

Hope LifeScan 2013. Physics part 2: ultrasound. [Internet] Available from: <http://hopelifescan.com/physicsp2.htm> (Accessed on 05/02/2013).

Hussain S., Khan R. A., et al, 2011, 'A comparative study of supraclavicular versus infra-clavicular approach for central venous catheterization', *Anaesthesia, Pain & Intensive Care*, 15 (1), 13-16.

Kumar A. and Chuan A., 2009. 'Ultrasound guided vascular access: efficacy and safety', *Best Practice & Research Clinical Anaesthesiology*, 23 (3), 299-311.

La Grange, P., Foster, P. A., et al, 1978. 'Application of the Doppler ultrasound flow detector in supraclavicular brachial plexus block', *British Journal of Anaesthesiology*, 50, 965-967.

Macintyre, P. E., Schug, S. A., et al, 2010. 'Working Group of the Australian and New Zealand College of Anaesthetists and Faculty of Pain Medicine', *Acute Pain Management: Scientific Evidence* (3rd edition), ANZCA & FPM, Melbourne.

Marhofer, P., Greher, M., et al, 2005. 'Ultrasound guidance in regional anaesthesia', *British Journal of Anaesthesia*, 94 (1), 7-17.

NICE, 2002. Guidance on the use of ultrasound locating devices for placing central venous catheters. Technology Appraisal no. 49, National Institute of Clinical Excellence, London. [Internet]. Available from: <http://www.nice.org.uk/nicemedia/live/11474/32461/32461.pdf> [Accessed 1 May 2012].

Neal J. M., Bernards C. M., et al, 2008. 'ASRA Practice Advisory on neurologic complications in regional anaesthesia and pain medicine', *Regional Anaesthesia and Pain Medicine*, 33 (5), 404-415.

Perlas, A., Niazi, A., et al, 2006. 'The sensitivity of motor response to nerve stimulation and paresthesia for nerve localization as evaluated by ultrasound', *Regional Anaesthesia and Pain Medicine*, 31(5), 445-450.

## Appendix A

### Questions for public funding

1. What is the safety, effectiveness and cost-effectiveness of ultrasound-guided percutaneous major vascular access compared to landmark technique?
2. What is the safety, effectiveness and cost-effectiveness of ultrasound-guided percutaneous nerve blockade compared to landmark technique with or without assistance of ENS?

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