
1308

Final protocol to
guide the assessment
of local anaesthetic
nerve blockade for
post-surgical
analgesia

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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 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 protocol that will be used to guide the assessment of an intervention for a particular population of patients.

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:

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

Intervention – specification of the proposed intervention

Comparator – specification of the therapy most likely to be replaced by the proposed intervention

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

Purpose of application

A proposal for an application requesting expanded access by anaesthesiologists to MBS listings of local anaesthesia nerve blockade for post-surgical analgesia was received from the Australian Society of Anaesthetists by the Department of Health in October 2013.

Background

Current arrangements for public reimbursement

Local anaesthetic nerve blocks for post-surgical analgesia are already provided in both the public and the private sector, and are the subject of continuing research and development. MBS funding is available for LA nerve blockade (LANB) under some circumstances. In Category 3/Group T10 of the MBS, which contains the Relative Value Guide (RVG) structured items for anaesthesia, there are currently three items for the peri-operative introduction of regional or field nerve blockade for the control of post-operative pain as outlined in Table 1 (22040, 22045, 22050). In addition there are two MBS items (22031/22036) for neuraxial anaesthesia for postoperative pain management (see Appendix). These items relate to services for the injection of anaesthetic agents around the nerves of the central nervous system by either intrathecal (subarachnoid) or epidural injection. As the objective of intrathecal or epidural injection is to induce nerve blockade that has a regional analgesic effect, these items are not in scope of this application in terms of the intervention but in some instance may be regarded as a comparator (see section titled Comparator). For the purpose of this document the term "regional block" refers to nerve blocks of the peripheral nervous system and the term "local anaesthetic nerve blockade" or LANB refers to those nerve blockades of the peripheral nervous system.

Table 1 Current MBS items for the perioperative regional or field nerve blocks for the control of post-operative pain

Category [3] – [Therapeutic Procedures]
MBS [22040] INTRODUCTION OF A REGIONAL OR FIELD NERVE BLOCK peri-operatively performed in the induction room theatre or recovery room for the control of post-surgical pain via the femoral OR sciatic nerves, in conjunction with hip, knee, ankle or foot surgery (2 basic units) Fee: \$[39.60] Explanatory note T.10.17 Intraoperative blocks for postoperative pain (Items 22031 to 22050) "Benefits are only payable for intraoperative blocks performed for the management of postoperative pain that are specifically catered for under items 22031 to 22050" Explanatory note T.10.21 Regional or field nerve blocks for postoperative pain (Items 22040 to 22050) "Benefits are payable under items 22040 to 22050 in addition to the general anaesthesia for the related procedure"

Category [3] – [Therapeutic Procedures]
<p>MBS [22045]</p> <p>INTRODUCTION OF A REGIONAL OR FIELD NERVE BLOCK peri-operatively performed in the induction room, theatre or recovery room for the control of post-surgical pain via the femoral AND sciatic nerves, in conjunction with hip, knee, ankle or foot surgery</p> <p>(3 basic units)]</p> <p>Fee: \$[59.40]</p> <p>Explanatory note T.10.17 Intraoperative blocks for postoperative pain (Items 22031 to 22050)</p> <p>“Benefits are only payable for intraoperative blocks performed for the management of postoperative pain that are specifically catered for under items 22031 to 22050”</p> <p>Explanatory note T.10.21 Regional or field nerve blocks for postoperative pain (Items 22040 to 22050)</p> <p>“Benefits are payable under items 22040 to 22050 in addition to the general anaesthesia for the related procedure”</p>

Category [3] – [Therapeutic Procedures]
<p>MBS [22050]</p> <p>INTRODUCTION OF A REGIONAL OR FIELD NERVE BLOCK peri-operatively performed in the induction room, theatre or recovery room for the control of post-surgical pain via the brachial plexus in conjunction with shoulder surgery</p> <p>(2 basic units)]</p> <p>Fee: \$[39.60]</p> <p>Explanatory note T.10.17 Intraoperative blocks for postoperative pain (Items 22031 to 22050)</p> <p>“Benefits are only payable for intraoperative blocks performed for the management of postoperative pain that are specifically catered for under items 22031 to 22050”</p> <p>Explanatory note T.10.21 Regional or field nerve blocks for postoperative pain (Items 22040 to 22050)</p> <p>“Benefits are payable under items 22040 to 22050 in addition to the general anaesthesia for the related procedure”</p>

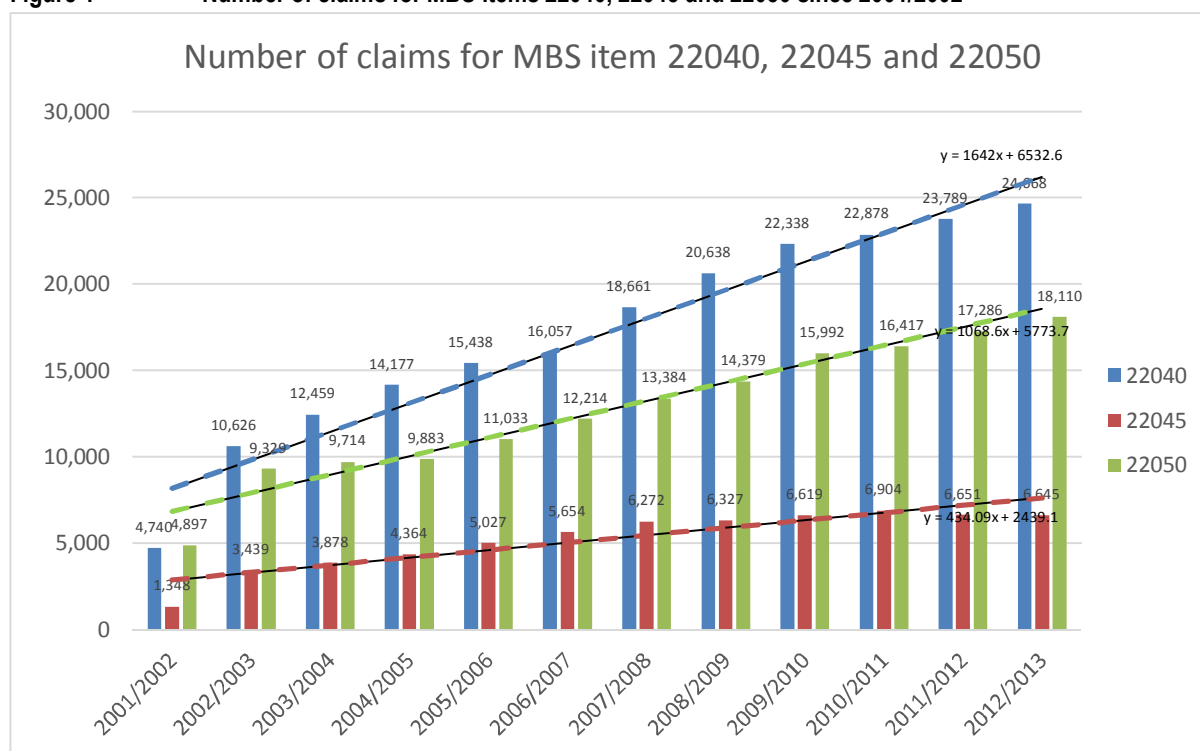
The starting date of the above items (22040, 22045 and 22050) was 1 November 2001 and the current descriptions of the items were amended on 1 November 2003.

The current MBS items restrict LA nerve blockade for post-surgical analgesia to services performed in association with foot, ankle, knee, hip and shoulder surgeries. The current listing specifies the setting of the services as being “peri-operatively performed in the induction room, theatre or recovery room”. This indicates that the delivery of the analgesic nerve blockade medication can be immediately before, during or after the surgery. As stated in the explanatory note T.10.21 (see Appendix), regional or field nerve blocks for post-operative pain (items 22040 to 22050) benefits are payable in addition to the general anaesthesia for the related procedure. This means the LA nerve block for post-operative pain is considered as a separate therapeutic procedure.

The clinical expert of Health Expert Standing Panel (HESP) has advised that the number of femoral/sciatic blocks accounts for approximately 40 per cent of peripheral regional anaesthesia practice. The numbers of services claimed through the current available items are increasing annually (Figure 1). The annual increase for each item varies from approximately 400 to 1,600 additional

claims each year. Item 22040, the item for post-surgical analgesia via femoral or sciatic nerves in hip, knee, ankle or foot surgery has shown the greatest increase.

Figure 1 Number of claims for MBS items 22040, 22045 and 22050 since 2001/2002



In addition to these MBS items for LANB for post-surgical pain there are an additional 44 items in Category 3/Group T7 of the MBS (18233 through to 18298) which also cover for a range of regional or field nerve blocks. However, none of these items are for peri-operative LA nerve blockade for post-operative pain when performed by an anaesthetist. These items are relevant for the treatment of chronic pain, or for nerve blocks administered by a medical practitioner in the course of a surgical procedure undertaken by that practitioner (see Note T7.1, Appendix). Dental LANB is covered by MBS item 22900.

According to explanatory note T.7.1, where anaesthesia involves a regional nerve block for anaesthesia for an operative procedure, benefit will be paid under the relevant anaesthesia item as set out in Group T10. There is no proposed change to this arrangement.

Regulatory status

All medications associated with local anaesthesia nerve block are currently approved by the TGA for the indication of post-operative pain. The main medications account for the vast majority of LA blockade proposed by the Applicant are lignocaine, bupivacaine and ropivacaine, which have been approved by TGA. The most commonly used medication for LA nerve block is ropivacaine, with clinical feedback from HESP suggesting that it accounts for approximately 86 per cent of local anaesthetic nerve blocks performed. Other less common local anaesthetics such as articaine, prilocaine, procaine and levobupivacaine also have TGA approval, and may be used.

Intervention

Description

Pain is a complex sensation which is difficult to define and difficult to measure in an accurate objective manner (Aitkenhead et al 2001). Pain is almost inevitable after surgery and very few patients do not require post-surgical analgesia (Eltringham et al 1998). There are many approaches to reduce and relieve post-surgical pain and they vary depending on types and locations of surgeries, patients' physical characteristics, pain management protocols as well as analgesics being prescribed and/or available. Traditional pain management for post-surgical care comprises standardised dosage of opioid or other systemic analgesics to be given by a nurse or under patient control when the patient's pain threshold has been exceeded. These standard protocols may be subject to many disadvantages including prolonged post-surgical recovery period, adverse drug reactions and low patients' satisfaction.

Local anaesthesia (LA) is one of the most efficacious forms of analgesia as it stops the pain signal from transmitting at its source. LA nerve blockade (LANB) involves variety of local anaesthetic drugs and they act by producing a reversible barrier of peripheral nerve impulses, rather than modifying pain signals once they have already been transmitted into the central nervous system. LANB are performed for a wide variety of procedures, across a wide range of surgical specialties. In general, they will be performed only where:

1. The specific nerve supplying the tissues involved in a surgical procedure can actually be accessed and blocked, with minimal risk;
2. LANB has been proven to provide superior outcomes to other post-surgical analgesia methods.

The timing of the introduction of LA nerve block is typically in the peri-operative period. Most common practice is performed either just prior to the surgical incision, or at the completion of surgery, prior to the patient recovering consciousness. There may be instances where LANB may be performed at a time later than this. It is difficult to predict each patient's exact need of post-surgical analgesic requirements. Therefore, the decision to establish LANB pre-, intra- or post-operatively will depend on many factors including patient issues and the type of surgery. An indwelling catheter may be used for severe post-surgical pain as it will enable extended use of nerve block, either as repeat bolus or continuous flow of the local anaesthesia agent.

Injection of LA agent adjacent to a nerve is the common approach of delivery. The location can be confirmed by the use of anatomical landmarks, electrical nerve stimulation (ENS) or with ultrasound imaging. MSAC is separately considering the merits of ultrasound imaging in the practice of anaesthesia including its use to guide LANB (Application 1183). Common nerve blocks according to anatomical site are summarised in Table 2.

Table 2 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

Table source: (Sawyer et al 2000)

The type and frequency of adverse events associated with nerve blocks may be dependent on the location of the injection, and arise from injury to adjacent anatomical structures. These include pneumothorax and vessel puncture. In addition, there may be injury to the nerve itself, or systemic toxicity may occur according to the analgesic agents used and dosage. A series of possible nerve injuries associated with LANB and their classification are summarised below in Table 3.

Table 3 Classification of potential nerve injuries (Seddon and Sunderland classifications)

Classification	Seddon	Sunderland	Function	Pathological basis	Prognosis
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 endoneural 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. Endoneural tubes and perineurium. Epineurium remains intact.	Total disorganisation of guiding elements. Intra-neuronal 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.

Table source: (Sunderland 1951)

Administration, dose, frequency of administration, duration of treatment

The decision to use local anaesthetic nerve blockage for post-surgery analgesia would be made on a per-patient basis and is guided by anaesthetist experience together with local procedures and guidelines. The method of delivery depends on the specific nerve to be blocked, the surgery

performed, and patient characteristics such as unusual anatomy or obesity. In general, LANB administration techniques can be summarised based on the dosage required:

- Single dose;
- Intermittent bolus via a catheter, or less commonly a repeat injection; or
- Continuous infusion via a catheter.

For post-surgical analgesia, single dose administration would be sufficient in most cases, although occasionally repeated doses are required (Vlassakov et al 2011). Additionally, but less commonly, an indwelling catheter may be inserted to provide a post-surgical LA infusion. With the use of long-acting drugs, a bolus injection may provide analgesia for up to 12 hours (clinical advice of HESP), although this may vary depending on a range of factors.

The decision regarding the type of post-surgical analgesia to provide is made by the anaesthetist at the pre-anaesthesia consultation (items 17610 to 17625).

LANB may be guided by technologies such as electrical nerve stimulation or two-dimensional ultrasound, depending on anatomical, surgical and patient factors.

The most commonly used agents for LANB are lignocaine, bupivacaine and ropivacaine. Due to the variability of surgical procedures and associated post-surgical pain, the dosage and the duration of the analgesic affect can be quite diverse. According to the clinical expert from HESP, ropivacaine has the longest duration with minimal side effects, and is one of the most commonly used analgesic agents for LANB for post-surgical analgesia.

The service is proposed to be almost exclusively performed by medical practitioners registered as specialist anaesthetists, or on some occasions, a medical practitioner training for Fellowship of the Australian and New Zealand College of Anaesthetists (ANZCA), under the direct supervision of a specialist anaesthetist. Much less commonly, the service may be provided by a general practitioner anaesthetist, recognised by ANZCA as adequately trained to provide a limited scope of anaesthesia services, typically working in a rural or remote area.

Medical practitioners training towards Fellowship of ANZCA (FANZCA) receive specific training in regional anaesthesia techniques as part of this programme. This training is "one off" but compliance with continuing medical education requirements is compulsory in order to maintain registration.

The delivery of service will typically be limited to inpatient public and private hospitals, and occasionally day surgery centres. Equipment and facilities are provided by the hospital. A limitation of the service as highlighted by the Applicant is in the rural and remote setting where no or limited accredited specialist anaesthetists may be available, or certain facilities and equipment may not be available such as ultrasound or other techniques for guidance.

Co-administered interventions

All other analgesia practices are independent of the decision to perform LANB. No extra resources are required, apart from the equipment needed to perform the actual LA block. All other equipment and technological and human resources is the same as for standard care for the surgical patient.

Additional forms of analgesia may be required in post-surgical pain management. This may include other analgesics including NSAIDs, paracetamol or opioid-based agents delivered concurrently or immediately after the LANB wearing off. No clinical guidelines or protocols are available from the published literature. However, based on the information from the HESP clinical expert, procedure-specific protocols in actual clinical practice exist but may differ between hospitals.

When continuous LA infusion is used for regional wound analgesia, several methods are available, with standard epidural catheters being sometimes used to good effect while special multichannel soaker catheters from 2.5 to 25 cm in length are sometimes used to infuse LA over a wider area. The portability of infusion pumps provides the potential to continue the regional wound infusion on an ambulatory basis. In Australia, continuous infusion pumps are readily available to regulate the flow of the local anaesthetic agent.

Patient population

Proposed MBS listing

The proposed MBS listing is shown in Table 4. The Applicant proposes that the currently listed MBS items for LANB for post-surgical analgesia (items 22040, 22045, 22050) be replaced with more general post-surgical analgesia items that accommodate a broader range of surgical scenarios requiring postoperative analgesia with LA blockade. The main additional indications for nerve block include intercostal, abdominal and any other plexus nerve. The proposed items are categorised according to major and minor nerve blockade for post-surgical analgesia. For two items the LANB will be administered as a bolus, while the third item is specific for the introduction of a catheter. Repeat administration may be required depending on the situation. The proposal can be regarded as the expansion of the current items where additional effectiveness, safety and cost-effectiveness analyses should be considered for the added locations.

The Applicant considers that any nerve which may need blockade to reduce post-surgical pain should be included and has proposed categorising the new items with reference to major or minor nerves, rather than the current items which are limited to certain anatomical locations and type of surgeries. The clinical expert of HESP has provided clarification of the definitions of major and minor nerves, which depends on both the location and nature of the nerves in question. Major peripheral nerve or plexus blocks include those proximal to the elbow or knee; in these anatomical positions nerves are

complex bundles and typically co-located with other important structures such as major arteries. Minor nerves would typically include single distal peripheral nerves. These nerves are generally not associated with other major structures. In the torso major blocks would include those that are performed close to the spinal cord such as a posterior lumbar plexus and paravertebral blocks. The Applicant has also provided information regarding plexus nerve blocks. Some of the plexus nerves are not relevant to analgesia such as coeliac plexus nerve and Auerbach's plexus nerve due to anatomical structure and functions. The descriptor has been kept broad to allow the use of LANB in any clinically-relevant location.

The Applicant proposes a separate item for major continuous nerve blockade with indwelling catheters. The current MBS items do not exclude indwelling catheters. Patients who have undergone surgery involving significant pain that is likely to exceed 12 hours may benefit from use of an indwelling catheter to enable further administration of local anaesthetic medication. These include but are not limited to patients undergoing arthroplasty, arthroscopy, and surgery with involvement of bony structures, laparotomy, thoracotomy and extensive breast surgery.

Another change to the current MBS items is in terms of the proposed fees. The basic RGV units for the introduction of a regional or field nerve block are increased from 2 units (22040 & 22050) or 3 units (22045) to 4 or 5 units depending on the location of nerves. For minor nerve blocks 2 units are proposed.

Table 4: Proposed MBS item descriptors for local anaesthetic nerve block for post-operative pain relief

Category [3] – [Therapeutic Procedures]
<p>MBS [item number]</p> <p>Major nerve block, proximal to the elbow or knee, including intercostal or abdominal wall nerve blocks, or plexus block (specify type), to provide postoperative pain relief. (Not to be used in conjunction with items X or Y*, or any item in the range 18213 to 18288)</p> <p>(4 units)</p> <p>Fee: \$[79.20]</p> <p>[Relevant explanatory notes]</p>

Category [3] – [Therapeutic Procedures]
<p>MBS [item number]</p> <p>Minor nerve block (specify type) to provide postoperative pain relief (this does not include subcutaneous infiltration) (not to be used in conjunction with items X or Y, or any item in the range 18213 to 18288)</p> <p>(2 units)</p> <p>Fee: \$[39.60]</p> <p>[Relevant explanatory notes]</p>

MBS [item number]

Major peripheral nerve block, performed perioperatively, with the introduction of a catheter to allow continuous nerve blockade, to provide postoperative pain relief (not to be used in conjunction with items X or Y, or any item in the range 18213 to 18288)

(5 units)

Fee: \$[99.20]

[Relevant explanatory notes]

Clinical place for proposed intervention

Local anaesthesia nerve blockade for post-surgical analgesia for major nerve including proximal to the elbow or knee, intercostal or abdominal wall, or plexus block, will be available in addition to the current post-surgical pain relief regimen. The use of local anaesthesia nerve blockade will be restricted by the nature of surgery or non-surgical characteristics of the medical intervention. The decision to provide LANB will be made on an individual patient-by-patient basis.

Factors which may lead to a decision to proceed with LANB might include:

- Surgery which is known to cause severe pain (e.g. major joint surgery);
- The specific nerve being anatomically locatable and able to be blocked with minimal risk of complications;
- Patient conditions which may be worsened by the physiological stress caused by severe pain (e.g. hypertension, ischaemic heart disease, chronic respiratory disease);
- Patients with a low tolerance to pain;
- Patients known to tolerate other analgesics poorly (e.g. opioids).

Factors which may lead to a decision against LA blockade would include:

- Systemic infection or infection at the site of injection;
- Patient factors which would make the procedure difficult (e.g. morbid obesity);
- Bleeding diatheses;
- Patient refusal.

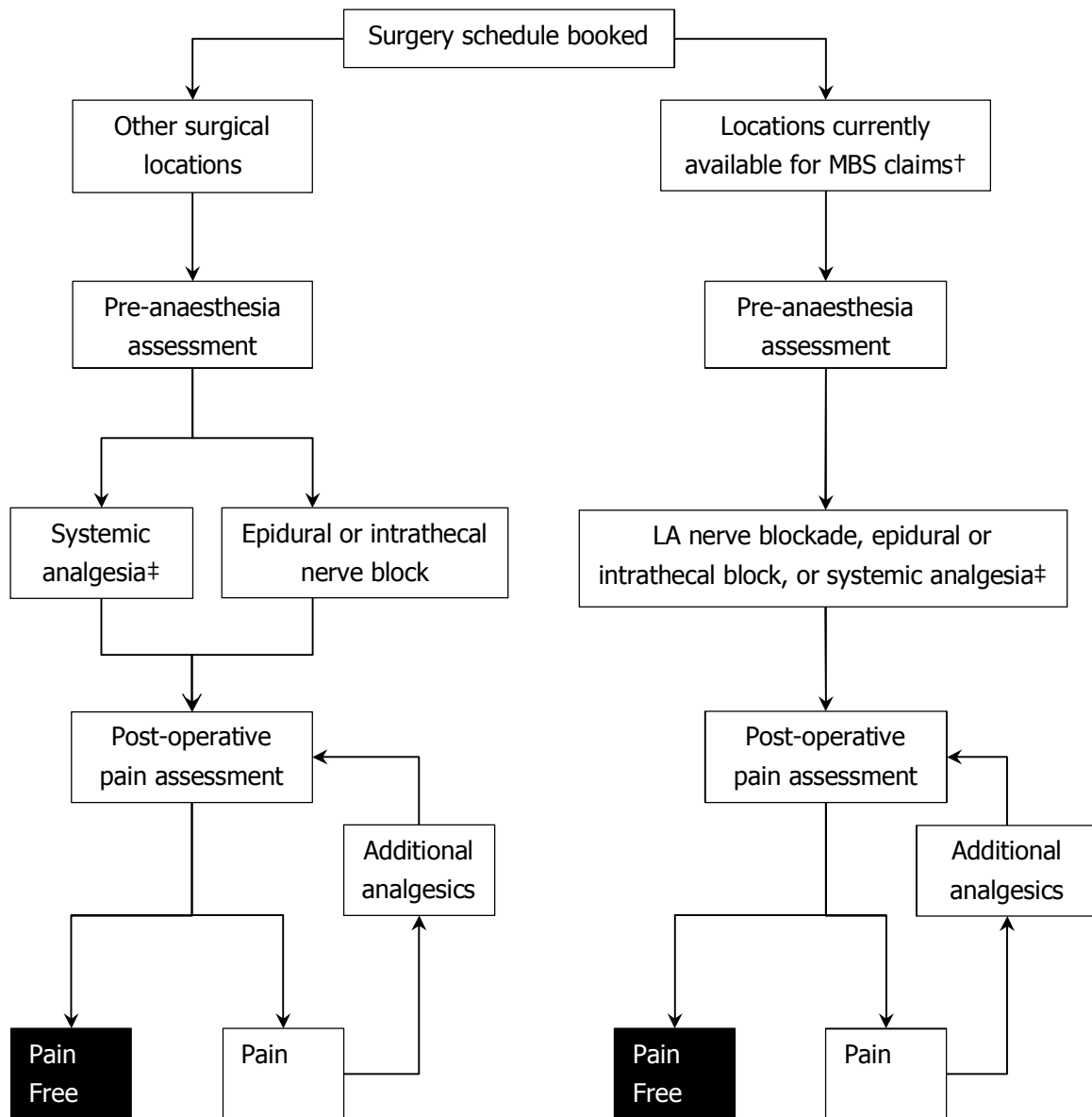
The clinical expert has confirmed that the decision of LANB for post-surgical analgesia will be decided on a per patient basis, and depend on locations, types of surgeries as well as patients' expectations. Clinical guidelines specifically designed for LANB in the post-surgical pain management settings were not identified. However, clinical experts indicated that local protocols and guidelines are available to inform post-surgical pain management in hospitals.

Clinical experts of HESP have confirmed that technologies for the delivery of the LANB such as patient-controlled analgesia (PCA) or continuous infusion devices are widely available and commonly used in clinical practice.

Clinical management algorithms for post-surgical pain relief with or without LANB are demonstrated in Figure 2.

These pathways are shown from an MBS perspective, where locations currently eligible for nerve block have been shown separately as these will not require assessment. Information from the HESP and from the Applicant confirm that in Australia the decision to provide nerve block is made purely as a result of clinical factors and is not dependent on the availability of an MBS item. Where the location is covered by a relevant MBS item costs are incurred to the MBS; where costs are not covered by a relevant MBS item the costs are passed on to the patient using relevant ASA RGV codes.

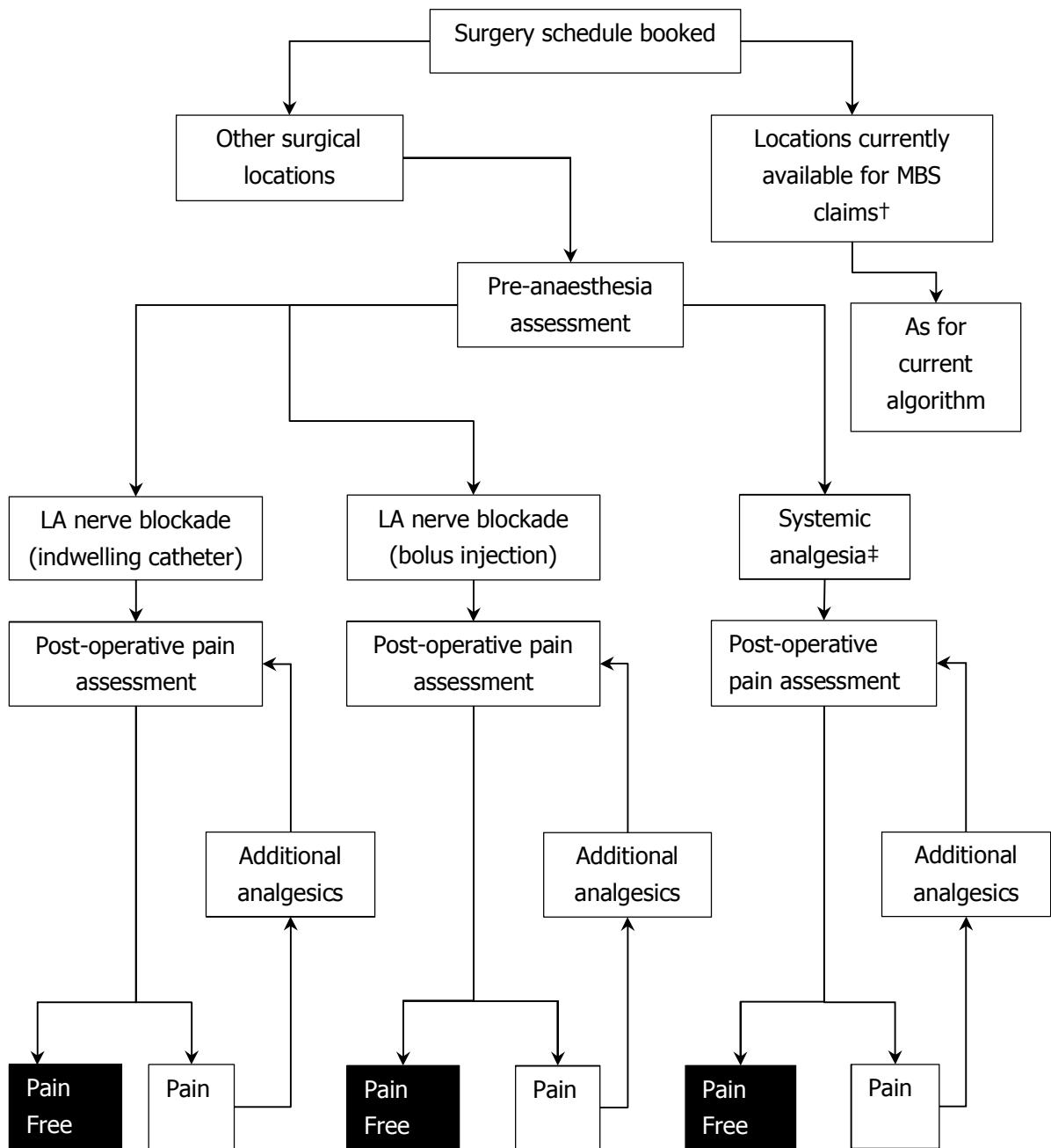
Figure 2-1 Current clinical management algorithm for use of post-surgical analgesia



† Peri-operatively performed in the induction room theatre or recovery room for the control of post-surgical pain via the femoral or sciatic nerves, in conjunction with hip, knee, ankle or foot surgery; or pain via the brachial plexus in conjunction with shoulder surgery.

‡ Systemic routes for administration of drugs such as IV, oral

Figure 3-2 Proposed clinical management algorithm for use of post-surgical analgesia



† Peri-operatively performed in the induction room theatre or recovery room for the control of post-surgical pain via the femoral or sciatic nerves, in conjunction with hip, knee, ankle or foot surgery; or pain via the brachial plexus in conjunction with shoulder surgery.

‡ Systemic routes administration of drugs such as IV, oral, as well as epidural or intrathecal nerve blockade.

The proposed pathway expands the MBS items for LANB for post-surgical analgesia.

Comparator

The current standard alternative approach for post-surgical analgesia is to administer analgesic medication via systemic routes, i.e. by oral, intravenous, intramuscular, subcutaneous and rectal administration. This may be under nurse or practitioner control, or under the control of the patient (e.g. patient-controlled analgesia, PCA). Intrathecal or epidural nerve block for post-surgical analgesia, which are currently available through the MBS, can also be a potential comparator for certain patients. Epidural nerve block is commonly used after major surgeries for analgesic purposes.

Currently, only surgeries including those of the shoulder, hip, knee, ankle, and foot have specific MBS items for LANB for postoperative pain (see current listed MBS items, Table 1). However, all surgical aftercare requires consideration of the analgesia and for most procedures this is prescribed by the anaesthetist. For patients having surgical procedures where LANB might be considered it is probable that the alternative approach would be strong analgesic medication, usually opiates, which may be administered orally, by intermittent injection or by continuous infusion or PCA. These medications may cause adverse events.

No MBS items or costs are currently associated with subcutaneous, intravenous, intramuscular or rectal route for systemic administration of analgesics.

Clinical claim

The type of economic evaluation suggested for the assessment phase is shown in Table 5. The Applicant claims that the LANB for post-surgical analgesia is superior to the current practice due to the improved comparative effectiveness:

- Decreased requirement for other analgesics such as opioids hence reducing the incidence of adverse drug reactions;
- **Reduced incidence of post-surgical chronic pain syndromes;**
- Pre-emptive analgesia; and
- Greater patients' experiences and satisfaction.

Also the cost-effectiveness can be improved by:

- Less time of retention of patients in the post-anaesthesia recovery area.

Table 5: 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

The following issues should be addressed during the assessment phase:

- PASC is interested in the investigation of the proposed fee in the economic evaluation. The investigation should test issues regarding relative effectiveness and other component costs to investigate the proposed higher fees.
- Any costs associated with guidance techniques such as ultrasound or ENS should be accounted for in line with MSAC recommendations from Application 1183.

Outcomes and health care resources affected by introduction of proposed intervention

Outcomes

Effectiveness

Effectiveness outcomes to be measured include:

Primary effectiveness

- Pain intensity
- Health related quality of life
- Incidence of adverse drug reactions
- Effective time of analgesia

Secondary effectiveness

- Recovery period
- Time to discharge

- Use of other analgesics (morphine, NSAIDs etc.)
- Anaesthetist time for delivery of analgesia
- Staff attendance for clinical observation

Safety

All adverse events, including but not limited to:

- Bleedings;
- Infection;
- Nerve damage; also
- Local anaesthetic toxicity;
- Allergic and drug reactions;
- Hypotension;
- Motor blockade and muscle weakness;
- Pneumothorax;
- Urinary retention;
- Neurological complications;
- Vascular complications.

For indwelling catheter administration route, the likelihood of acquiring adverse events may be greater than standard LANB methods. Catheters can migrate and the tip can enter a blood vessel or puncture the adjacent tissues. The length of time for which a catheter is left in place represents a compromise between these possible hazards and the benefits resulting from the analgesia. Therefore, it is recommended that the safety concerns for indwelling catheter administration should be considered and evaluated separately.

Health care resources

The health care resources used in the proposed pathway will depend on the actual patients' scenario, compared with the current clinical practice. During the assessment phase, the following issues should be investigated:

- Number of bolus injections;
- Volume or amount of anaesthesia delivered;
- Number of post-surgery assessments for pain;
- Number and time of anaesthetic or nursing staff to deliver post-surgery assessments and analgesia;
- Requirement and type of supplemental analgesia;
- Requirement of services for chronic post-operative pain (e.g. anaesthetist, nurse, general practitioner);
- Resources required for resolving adverse events;
- The number of patients who will continue to receive standard systemic analgesia even when LANB is available;
- The type and manner of delivery of analgesia for which LANB is used as an alternative;

- Use of indwelling catheters;
- Technique of service delivery (landscape, ultrasound, ENS or combined);
- Use of patients-controlled analgesia (PCA) devices or continuous flow devices in association with anaesthetics.

Table 6 shows some of the resources for consideration in the current and proposed scenarios. Note that almost all patients will require a pre-anaesthesia attendance and this will not require any change in resources.

Table 6: List of resources to be considered in the economic analysis

	Provider of resource	Setting in which resource is provided	Proportion of patients receiving resource	Number of units of resource per relevant time horizon per patient receiving resource	Disaggregated unit cost					
					MBS	Safety nets*	Other govt budget	Private health insurer	Patient	Total cost
<u>Resources provided to identify eligible population (applicable to all patients)</u>										
- Consultation										
- Pre-anaesthesia assessment										
<u>Resources provided to deliver comparator 1 (systemic route administration of analgesics)</u>										
- Professional attendance										
- Analgesic agents										
- PCA or continuous flow devices										
<u>Resources provided in association with comparator 1</u>										
- Adverse events and resolution										
- Supplementary analgesia										
<u>Resources provided to deliver comparator 2 (epidural or intrathecal block)</u>										
- Professional attendance										
- Syringes, needles and facilities required for service delivery										
- Analgesic agents										
- PCA or continuous flow devices										
<u>Resources provided in association with comparator 2</u>										
- Adverse events and resolution										

	Provider of resource	Setting in which resource is provided	Proportion of patients receiving resource	Number of units of resource per relevant time horizon per patient receiving resource	Disaggregated unit cost					
					MBS	Safety nets*	Other govt budget	Private health insurer	Patient	Total cost
- Supplementary analgesia										
<u>Resources provided to deliver proposed intervention</u>										
- Professional attendance										
- Syringes and needles										
- Catheters										
- Analgesic agents										
- PCA or continuous flow devices										
<u>Resources provided in association with proposed intervention</u>										
- Adverse events and resolution										
- Supplementary analgesia										

Proposed structure of economic evaluation (decision-analytic)

The PICO to be used for the economic evaluation are provided in Table 7. This is useful to provide 1) define the research question for public funding, 2) select the evidence to assess the safety and effectiveness of expanding LANB in post-surgical analgesia into more generic settings, and 3) provide evidence-based inputs for any decision-analysis modelling to determine the cost-effectiveness of LANB in post-surgical analgesia.

Table 7-1 Summary of extended PICO to define research question that assessment will investigate: minor nerves

Patients	Intervention	Comparator	Outcomes to be assessed	Healthcare resources to be considered
<p>Patients requiring major limb or joint surgery, open abdominal or thoracic procedures, or other surgical procedures expected to result in significant postoperative pain (including dental patients).</p> <p>Excluded: Patients currently eligible for nerve block for post-operative pain:</p> <ul style="list-style-type: none"> • Via the femoral and/or the sciatic nerves in conjunction with hip, knee, ankle or foot surgery • Via the brachial plexus in conjunction with shoulder surgery. • The use of LA nerve blockade in the management of chronic pain outside the context of surgery 	<p>Local anaesthetic peripheral nerve blockade for post-surgical analgesia with or without ultrasound and/or electrical nerve stimulation guidance.</p> <p>Sub-groups to be reported separately:</p> <ul style="list-style-type: none"> • Single-injection bolus • Indwelling catheter* <p>Excluded: Epidural or spinal cord analgesia.</p>	<p>Analgesia delivered by any other route, including systemic, oral route and subcutaneous infiltration, under nurse, specialist or patient control.</p> <p>Analgesia delivered by epidural or intrathecal nerve block.</p>	<p>Primary effectiveness</p> <ul style="list-style-type: none"> • Pain intensity • Health related quality of life • Incidence of adverse drug reactions and addictions • Effective time of analgesia <p>Secondary effectiveness</p> <ul style="list-style-type: none"> • Recovery period • Use of other analgesics (morphine, NSAIDs etc.) • Anaesthetist time for delivery of analgesia 	<p>Refer to “Health Care Resources” section.</p>

* with/without PCA or continuous infusion devices or repeat bolus

Table 7-2 Summary of extended PICO to define research question that assessment will investigate: major nerves

Patients	Intervention	Comparator	Outcomes to be assessed	Healthcare resources to be considered
<p>Patients requiring major limb or joint surgery, open abdominal or thoracic procedures, or other surgical procedures expected to result in significant postoperative pain (including dental patients).</p> <p>Excluded: Patients currently eligible for nerve block for post-operative pain:</p> <ul style="list-style-type: none"> • Via the femoral and/or the sciatic nerves in conjunction with hip, knee, ankle or foot surgery • Via the brachial plexus in conjunction with shoulder surgery. 	<p>Local anaesthetic peripheral nerve blockade for post-surgical analgesia with or without ultrasound and/or electrical nerve stimulation guidance.</p> <p>Sub-groups to be reported separately:</p> <ul style="list-style-type: none"> • Single-injection bolus • Indwelling catheter* <p>Excluded: Epidural or spinal cord analgesia.</p>	<p>Analgesia delivered by any other route, including systemic, oral route and subcutaneous infiltration, under nurse, specialist or patient control.</p> <p>Analgesia delivered by epidural or intrathecal nerve block.</p>	<p>Primary effectiveness</p> <ul style="list-style-type: none"> • Pain intensity • Health related quality of life • Incidence of adverse drug reactions and addictions • Effective time of analgesia <p>Secondary effectiveness</p> <ul style="list-style-type: none"> • Recovery period • Use of other analgesics (morphine, NSAIDs etc.) • Anaesthetist time for delivery of analgesia 	<p>Refer to “Health Care Resources” section.</p>

Patients	Intervention	Comparator	Outcomes to be assessed	Healthcare resources to be considered
<ul style="list-style-type: none"> The use of LA nerve blockade in the management of chronic pain outside the context of surgery 				

* with/without PCA or continuous infusion devices or repeat bolus

Research questions:

For nerve locations and surgeries not included in current MBS items (22040, 22045 and 22050):

- Is local anaesthesia nerve blockade for postoperative pain management safe, effective and cost-effective compared with alternative post-surgical analgesia regimes?
- Where possible, the clinical utility of nerve block should be reported in the context of the comparator analgesia (e.g. oral or injected opioid, patient-controlled analgesia, epidural and so on).
- The clinical utility of nerve block when administered through an indwelling catheter should be reported separately.

Reference

- Aitkenhead, AR, Smith, G & Robowtham, DJ. 2001, *Textbook of anaesthesia*, 4th, Churchill Livingstone, Edinburgh ; Sydney,
- Eltringham, R, Durkin, M & Casey, W. 1998, *Post-operative recovery and pain relief*, Springer, London ; New York,
- Sawyer, RJ, Richmond, MN, Hickey, JD & Jarratt, JA 2000, 'Peripheral nerve injuries associated with anaesthesia', *Anaesthesia*, vol.55(10), pp. 980-91.
- Sunderland, S 1951, 'A classification of peripheral nerve injuries producing loss of function', *Brain*, vol.74(4), pp. 491-516.
- Vlassakov, KV, Narang, S & Kissin, I 2011, 'Local anesthetic blockade of peripheral nerves for treatment of neuralgias: systematic analysis', *Anesth Analg*, vol.112(6), pp. 1487-93.

Appendix

MBS items mentioned in the main text

Category [3] – [Therapeutic Procedures]
<p>T7.1 Regional or Field Nerve Blocks - General</p> <p>A nerve block is interpreted as the anaesthetising of a substantial segment of the body innervated by a large nerve or an area supplied by a smaller nerve where the technique demands expert anatomical knowledge and a high degree of precision.</p> <p>Where anaesthesia combines a regional nerve block with general anaesthesia for an operative procedure, benefit will be paid only under the relevant anaesthesia item as set out in Group T10.</p> <p>Where a regional or field nerve block is administered by a medical practitioner other than the practitioner carrying out the operation, the block attracts benefits under the Group T10 anaesthesia item and not the block item in Group T7.</p> <p>Where a regional or field nerve block which is covered by an item in Group T7 is administered by a medical practitioner in the course of a surgical procedure undertaken by that practitioner, then such a block will attract benefit under the appropriate Group T7 item.</p> <p>When a block is carried out in cases not associated with an operation, such as for intractable pain or during labour, the service falls under Group T7.</p> <p>Digital ring analgesia, local infiltration into tissue surrounding a lesion or paracervical (uterine) analgesia are not eligible for the payment of Medicare benefits under items within Group T7. Where procedures are carried out with local infiltration or digital block as the means of anaesthesia, that anaesthesia is considered to be part of the procedure.</p>

Category [3] – [Therapeutic Procedures]
<p>MBS [22031]</p> <p>INTRATHECAL or EPIDURAL INJECTION (initial) of a therapeutic substance or substances, with or without insertion of a catheter, in association with anaesthesia and surgery, for postoperative pain management, not being a service associated with a service to which 22036 applies</p> <p>(5 basic units)</p> <p>Fee: \$99.00 Benefit: 75% = \$74.25 85% = \$84.15</p> <p>(See para T10.19 of explanatory notes to this Category)</p>

Category [3] – [Therapeutic Procedures]
<p>MBS [22036]</p> <p>INTRATHECAL or EPIDURAL INJECTION (subsequent) of a therapeutic substance or substances, using an in-situ catheter, in association with anaesthesia and surgery, for postoperative pain management, not being a service associated with a service to which 22031 applies</p> <p>(3 basic units)</p> <p>Fee: \$59.40 Benefit: 75% = \$44.55 85% = \$50.50</p> <p>(See para T10.20 of explanatory notes to this Category)</p>

Category [3] – [Therapeutic Procedures]
<p>T10.17 Intra-operative Blocks for Post Operative Pain - (Items 22031 to 22050)</p> <p>Benefits are only payable for intra-operative nerve blocks performed for the management of post-operative pain that are specifically catered for under items 22031 to 22050.</p> <p>Related Items: 22040, 22045, 22050</p>

Category [3] – [Therapeutic Procedures]
<p>T10.21 Regional or Field Nerve Blocks for Post-operative Pain - (Items 22040 - 22050)</p> <p>Benefits are payable under Items 22040 to 22050 in addition to the general anaesthesia for the related procedure.</p> <p>Related Items: 22040, 22045, 22050</p>

Category [3] – [Therapeutic Procedures]
<p>MBS [17640]</p> <p>ANAESTHETIST, REFERRED CONSULTATION (other than prior to anaesthesia)</p> <p>(Professional attendance by a specialist anaesthetist in the practice of ANAESTHESIA where the patient is referred to him or her)</p> <p>-a BRIEF consultation involving a short history and limited examination</p> <p>-AND of not more than 15 minutes duration, not being a service associated with a service to which items 2801 - 3000 apply</p> <p>Fee: \$43.00 Benefit: 75% = \$32.25 85% = \$36.55</p> <p>(See para T6.2 of explanatory notes to this Category)</p> <p>Extended Medicare Safety Net Cap: \$129.00</p>

Category [3] – [Therapeutic Procedures]
<p>MBS [17645]</p> <p>-a consultation involving a selective history and examination of multiple systems and the formulation of a written patient management plan</p> <p>-AND of more than 15 minutes but not more than 30 minutes duration, not being a service associated with a service to which items 2801 - 3000 apply.</p> <p>Fee: \$85.55 Benefit: 75% = \$64.20 85% = \$72.75</p> <p>(See para T6.2 of explanatory notes to this Category)</p>

Category [3] – [Therapeutic Procedures]

MBS [17650]

-a consultation involving a detailed history and comprehensive examination of multiple systems and the formulation of a written patient management plan

-AND of more than 30 minutes but not more than 45 minutes duration, not being a service associated with a service to which items 2801 - 3000 apply

Fee: \$118.50 Benefit: 75% = \$88.90 85% = \$100.75

(See para T6.2 of explanatory notes to this Category)

Category [3] – [Therapeutic Procedures]

MBS [17655]

-a consultation involving an exhaustive history and comprehensive examination of multiple systems and the formulation of a written patient management plan following discussion with relevant health care professionals and/or the patient, involving medical planning of high complexity,

-AND of more than 45 minutes duration, not being a service associated with a service to which items 2801 - 3000 apply.

Fee: \$150.90 Benefit: 75% = \$113.20 85% = \$128.30

(See para T6.2 of explanatory notes to this Category)

Category [3] – [Therapeutic Procedures]

MBS [17680]

ANAESTHETIST, CONSULTATION, OTHER

(Professional attendance by an anaesthetist in the practice of ANAESTHESIA)

-a consultation immediately prior to the institution of a major regional blockade in a patient in labour, where no previous anaesthesia consultation has occurred, not being a service associated with a service to which items 2801 - 3000 apply.

Fee: \$85.55 Benefit: 75% = \$64.20 85% = \$72.75

(See para T6.3 of explanatory notes to this Category)

Category [3] – [Therapeutic Procedures]

MBS [17690]

-Where a pre-anaesthesia consultation covered by an item in the range 17615-17625 is performed in-rooms if:

- (a) the service is provided to a patient prior to an admitted patient episode of care involving anaesthesia; and
- (b) the service is not provided to an admitted patient of a hospital; and
- (c) the service is not provided on the day of admission to hospital for the subsequent episode of care involving anaesthesia services; and
- (d) the service is of more than 15 minutes duration

not being a service associated with a service to which items 2801 - 3000 apply.

Fee: \$39.55 Benefit: 75% = \$29.70 85% = \$33.65

(See para T6.3 of explanatory notes to this Category)

Category [3] – [Therapeutic Procedures]

MBS [22905]

INITIATION OF MANAGEMENT OF ANAESTHESIA for restorative dental work

(6 basic units)

Fee: \$118.80 Benefit: 75% = \$89.10 85% = \$101.00

(See para T10.14 of explanatory notes to this Category)

Category [3] – [Therapeutic Procedures]

T10.14

Anaesthesia in Connection with a Dental Service - (Items 22900 and 22905)

Items 22900 and 22905 cover the administration of anaesthesia in connection with a dental service that is not a service covered by an item in the Medicare Benefits Schedule i.e. removal of teeth and restorative dental work. Therefore, the requirement that anaesthesia be performed in association with an 'eligible' service (as defined in point T10.2) does not apply to dental anaesthesia items 22900 and 22905.

Related items: 22900, 22905