MSAC Application 1741

Continuous nerve blockade using a catheter technique

PICO Confirmation

Summary of PICO criteria to define question(s) to be addressed in an Assessment Report to the Medical Services Advisory Committee (MSAC)

Table 1 PICO for continuous peripheral nerve block for postoperative pain

Component	Description
Population	Patients undergoing surgery associated with moderate to severe postoperative pain that is expected to last 12 hours or longer
Intervention	Continuous peripheral nerve block
Comparator/s	Primary comparator: Single injection block Secondary comparators: Systemic opioids Neuraxial nerve block
Outcomes	**Effectiveness** • Patient-reported postoperative pain score • Time to first mobilisation post-surgery • Patient satisfaction with analgesia • Time to, and rate of supplementary analgesia use • Rate of chronic postoperative pain • Chest infection/pneumonia (consequence of poorly managed severe pain) • Health-related Quality of Life **Safety /adverse effects** • Block-related complications (vascular injury, paraesthesia, motor block, failed block, neurological impairment, pneumothorax) • Catheter AEs including insertion site infection • Local anaesthesia toxicity • Death/mortality • Complications or grade ≥3 AEs for systemic analgesia (short-term and long-term) **Resource Use** • Block re-attempt (block failure) • Hospital length of stay • Re-hospitalisation due to pain • Analgesic use (note time to supplementary analgesia is an efficacy endpoint) • Analgesia requirements post-surgery (including opioid consumption) • Duration of analgesia
Assessment questions	What is the safety, effectiveness and cost-effectiveness of continuous peripheral nerve block versus single injection nerve block, in patients undergoing surgery associated with moderate to severe postoperative pain expected to last 12 hours or longer?

AE=adverse event.

Purpose of application

An application requesting Medicare Benefits Schedule (MBS) listing of continuous peripheral nerve block for postoperative pain was received from the Australian Society of Anaesthetists by the Department of Health.

The proposal is for the continuous block of peripheral nerves. The indication is postoperative pain arising from any surgery likely to cause moderate to severe pain lasting 12 hours or more. This procedure is now approaching standard of care for several types of major joint surgery (Chou et al., 2016). The applicant claims that a continuous block is superior to a single injection block based on duration of analgesia, and is non-inferior in terms of safety.

The proposed nerve block is performed via a catheter to allow continuous analgesia. This is a regional analgesia technique (as distinct from local, systemic or general anaesthesia).

The item is proposed for the Relative Value Guide for Anaesthesia (RVG) of the MBS described in Table 2.

Table 2 Relevant section of the Schedule for listing

MBS Section	Description / Title
Items 22031 to 22041 (and Associated Note TN.10.17)	Nerve or Plexus Blocks for Post Operative Pain
Subgroup 19	Therapeutic and Diagnostic Services
Group T10	Relative Value Guide for Anaesthesia – Medicare Benefits are only payable for anaesthesia performed in association with an eligible service
CATEGORY 3	THERAPEUTIC PROCEDURES

Source: Medicare Benefits Schedule Book, 1 July 2022.

Existing MBS items for nerve or plexus blocks for postoperative pain in the RVG are presented in Table 3.

Table 3 Existing MBS items: Nerve or Plexus Blocks for Post Operative Pain

MBS	Basic units	Fee	*Administration	Purpose	Explan. Notes	Item Start Date	Description updated
22031	5	$104.75	Intrathecal or epidural injection With or without a catheter	In association with anaesthesia and surgery, for postoperative pain management (initial)	TN.10.17	01-Nov-2005	01-Nov-2019
22036	3	$62.85	Intrathecal or epidural injection Using an *in situ* catheter	In association with anaesthesia and surgery, for postoperative pain management (subsequent)	TN.10.17	01-Nov-2005	01-Nov-2005
22041	2	$41.90	Plexus or (peripheral) nerve block *[single injection item]*	Perioperative. Proximal to the lower leg or forearm for post operative pain management	TN.10.17	01-Nov-2019	01-Nov-2019

Source: Medicare Benefits Schedule Book, 1 July 2022.
Item 22042 is not included. Although it is a perioperative nerve block, note TN.10.17 specifies items 22031 – 22041 only, as being for post operative pain.
Items 22031 and 22036 are neuraxial nerve blocks (spinal block via intrathecal injection into spinal canal; or epidural injection into epidural space)
*There are no frequency restrictions specified in the descriptor text on claims per year or patient episode for these items.

MSAC previously considered a related application for minor, major and continuous peripheral nerve blocks (MSAC Application 1308). MSAC did not support this application (see the list of issues in Table 4). For further details, see the Appendix.

Table 4 Issues raised by MSAC for the previous Application 1308 (MSAC meeting April 2017)

Issue	Comment	Addressed In
• "it would be more informative if the scope of the application was changed to only consider particular LANBs with demonstrable and clinically significant health outcome benefits to patients and the healthcare system" (p1) • "MSAC suggested that an alternative approach to seeking MBS funding was to identify particular nerve blocks that have, or are likely to have, clear benefits followed by collection of evidence on these identified 'high value' nerve blocks to determine their safety, effectiveness and cost-effectiveness. MSAC suggested that the applicant provide advice on which nerve blocks are most likely to be 'high value'." (p3)	The current application relates to a subset of the population sought in Application 1308 that are higher need patients; that is, for moderate to severe postoperative pain lasting longer than 12 hours. Changes to approved uses for opioids in Australia also mean that there is greater clinical need for alternatives to opioids for managing acute postoperative pain. Minor and major nerve blocks considered in Application 1308 are now covered by MBS item 22041 (item start date 1 November 2019) and are not included in the current application.	See Population – Clinical need
• "MSAC accepted that there was a clinical need for LANB. However, MSAC was concerned by uncertainty around the clinical efficacy and cost-effectiveness of the different types of nerve block and the considerable uncertainty regarding the estimates of use and financial impacts." (p3)	For Application 1308, MSAC noted the ESC's comment that "evidence for […] nerve blocks […] was greater than that for comparators such as epidural or intrathecal blocks". The proposed clinical claim, that continuous blocks are superior to single injection nerve blocks for moderate to severe pain lasting longer than 12 hours will focus on a subset of evidence. The evaluation can consider evidence of incremental benefit in terms of duration of effect compared with a single injection block. The comparators considered in Application 1308 (systemic opioids, neuraxial blocks) can be secondary comparators for the current application.	See Comparator(s) and Proposed economic evaluation
• "MSAC remained concerned that listing all peripheral nerve blocks on the basis of evidence presented for PVB, TAP block and cPVB may result in nerve blocks that have limited benefits being subsidised on the MBS." (p2)	The application has not been restricted to blocks of specific nerves. This approach is consistent with the existing MBS item (22041) for single-injection nerve blocks, which is also not restricted to specific nerves.	See Intervention – Target nerves
• "MSAC noted that the fees included a patient co-payment but that the applicant strongly disagreed that out-of-pocket costs associated with LANB procedures would be common." (p3) • "From a consumer perspective, ESC noted that anaesthesia costs were a common cause of unexpected out of pocket expenses for patients." (p10)	The current application indicates the overall cost of a continuous nerve block is $303.56, and a proposed MBS fee of $104.75. Further clarification is required to confirm who will bear the additional cost.	See Proposal for public funding – Out of pocket costs
• "MSAC noted that the main comparator for LANBs in any resubmission should be 'no block'. However, MSAC noted that there may also be evidence that compares some nerve blocks to active comparators (e.g., local infiltration or joint infiltration associated with joint replacement surgery)." (p3)	Since MSAC consideration of Application 1308, item 22041 has been listed for 'perioperative introduction of a plexus or nerve block proximal to the lower leg or forearm for post operative pain management'. The applicant has proposed this as the main comparator.	See Comparator(s)
• "MSAC noted that information on other possible benefits of LANB, such as length of hospital stay, recovery time, post-surgical chronic pain and quality of life was either very limited or not presented. MSAC suggested that information on these outcomes, if available, may enable a cost-utility analysis to assist the committee's decision making." (p2)	This proposed superiority claim should enable an evaluation based on duration of effect. Outcomes such as time to supplementary analgesia or opioid consumption – depending on the evidence – should enable a cost-utility analysis in line with the MSAC comments.	See Outcomes, and Proposed economic evaluation

Source: MSAC Public Summary Document Application 1308 (Contracted Assessment) - Local anaesthetic (LA) nerve blockade for post-surgical analgesia. MSAC meeting 6-7 April 2017; MSAC Application 1741- Continuous nerve blockade using catheter technique.

cPVB=continuous paravertebral block; ESC=Evaluation Sub-committee; LANB=local anaesthetic peripheral nerve block; MBS=Medicare Benefits Schedule; MSAC=Medical Services Advisory Committee; PVB=paravertebral block; TAP=transversus abdominus plane block.

PICO criteria

Population

Surgical indications

The proposed item is for continuous peripheral nerve block in patients undergoing surgery associated with moderate to severe postoperative pain where the duration of pain is expected to exceed the duration of a single injection nerve block (maximum 12 hours). The applicant has cited indications for the proposed item in Table 5 – these represent patient groups where postoperative pain is typically more than can be managed by single injection nerve block.

Table 5 List of typical surgeries for the proposed item

Indication / Discipline	Surgical Examples
Joint replacement surgery	Total knee replacement Total shoulder replacement Total hip replacement Elbow joint replacement Wrist / ankle joint replacement
Upper limb surgery	Rotator cuff repair / reconstruction Major elbow arthroscopic surgery *(more likely to be ambulatory surgery patients)* Contracture release
Lower limb surgery	Anterior cruciate ligament repair Major foot and ankle surgery
Thoracic surgery	Cardiothoracic procedures: Sternotomy, Off-pump CABG Thoracotomy Thoracoscopy
Abdominal surgery	Open abdominal procedures Major laparoscopic assisted surgery *Both these groups of patients are likely to receive an epidural block rather than a single injection nerve block according to current practice*
Major breast surgery	Radical mastectomy, mastectomy Major and/or reconstructive breast surgery
Trauma surgery	Rib fractures Upper and lower limb fractures (for example, femoral fracture) and soft tissue injury Traumatic amputation

Source: drawn from 1741 application summary and supporting documents
CABG=coronary artery bypass graft surgery. 'Off-pump CABG' is surgery without a cardio-pulmonary bypass (heart-lung) machine.

The surgeries in Table 5 represent those known to be associated with a high chance of postoperative pain based on medical practice. This is not intended to be an exhaustive list. The applicant has described these patients as those requiring joint arthroplasty, orthopaedic/and or significant soft tissue (muscle, tendon, ligaments, skin) reconstructive surgery, major limb vascular surgery, and patients undergoing trunk surgery, or management of trauma. These patients are selected/recommended for surgery by surgeons, or present as trauma victims to hospital.

PASC noted that the proposed item is similar to the existing item for single injection nerve block in terms of purpose and the list of likely surgeries for the proposed item was not exhaustive. The applicant also confirmed that this item is not intended for patients who do not undergo surgery.

Continuous peripheral nerve block is intended to be offered pre-emptively and is based on an expectation of moderate to severe postoperative pain rather than offering the intervention after the pain has

manifested. Hence, it is not possible to incorporate a definition of moderate to severe pain in a potential item descriptor to aid in determining whether a patient should be eligible for this service. 'Moderate to severe pain' is nevertheless a well understood concept in Australian clinical practice that is commonly used for describing acute pain (see the Australian and New Zealand College of Anaesthetists [ANZCA] monograph on Acute Pain Management; Schug et al., 2020). 'Moderate to severe' corresponds approximately to pain score of 4 or above (with 10 being the maximum pain score) on a numeric pain scale (Gerbershagen et al., 2011).

The applicant confirmed that for patients undergoing trauma surgery, the anaesthetist may determine that a continuous nerve block will aid in postoperative pain management for the patient's other injuries (for example fractured ribs). *PASC considered it was not necessary for the target of the block to be the surgical site under operation.*

Considerations for determining whether a continuous nerve block is the most suitable form of post operative analgesia:

- whether the type of pain and anatomical location is amenable to a nerve block;
- whether epidural anaesthesia is or is not more appropriate
- whether simple short term analgesia including short term oral or parenteral opiates would be sufficient or preferable depending on associated risks – *Note that 'simple' in this context refers to the type of formulation, that is, simple as opposed to modified release;*
- if the surgery is an elective procedure with a short planned postoperative stay and the ability or otherwise for a continuous nerve block to be managed in the home environment after discharge.

Patient characteristics

Existing perioperative MBS items for postoperative pain (Table 3) do not specify any age restrictions and it is expected the same will apply to the proposed item if supported by MSAC. In practice, the majority of planned surgeries in Table 5 will be in adults. At least some of the above indications such as hip surgeries will be in predominantly elderly patients. The age bias of the population currently using the single injection item is confirmed in the utilisation statistics below (see 'Estimated utilisation').

Some patients may also be suitable for continuous nerve block if systemic opioids are not recommended for reasons such as opioid sensitivity, tolerance or dependence, or co-morbidities rendering parenteral opioid administration inappropriate. Consistent with approved Product Information for most opioids for systemic use, relevant co-morbidities are assumed to be respiratory insufficiency or asthma, and less commonly, head injuries, myasthenia gravis, or Parkinson disease (where patients are taking a monoamine oxidase inhibitor). Further warnings and relative contraindications given in the Product Information may also apply, which the anaesthetist will take into account as part of the pre-anaesthesia consultation.

Patients undergoing planned joint reconstruction or replacement, or following other long-standing conditions, are likely to be at higher risk of opioid tolerance due to pre-existing chronic pain associated with many of these surgical indications (AIHW 2020). This will limit effectiveness of opioids in these patients, necessitating higher doses to achieve the same outcome. Patients with a history of opioid use prior to surgery are at higher risk of further long-term opioid use post-discharge.

The applicant noted that patients who return home with the continuous nerve block in place are a highly selected group where it has been judged that they and/or their carer are suitable to manage the elastomeric pump and any likely issues that may arise. This is understood to include consideration of the same issues that would be taken into account in determining whether any patient is suitable for discharge (clinical outlook, support network, home environment, proximity to medical care). Patients with conditions

that preclude the from being discharged with the continuous nerve block in situ would be likely to be cared for as in-patients. The applicant confirmed that patients who return home with the continuous nerve block *in situ* are considered discharged and are not managed as inpatients.

Clinical need

There is a clinical need to offer patients options for moderate to severe postoperative pain. There is also a clinical need to reduce routine opioid prescribing in management of postoperative pain.

MSAC acknowledged the clinical need for some nerve blocks considered in Application 1308, noting that a resubmission should identify high value uses. Since then, the following changes have occurred:

- Item 22041 for single injection nerve blocks was listed on the MBS (1 November 2019).
- In 2020, the Therapeutic Goods Administration (TGA) revised the scheduling, pack sizes and approved indications for some opioids with implications for postoperative pain management.
- Multimodal analgesia has come to the fore of postoperative pain management, which employs a variety of approaches including regional nerve block (Joshi et al., 2016). In part, this reflects the shift away from opioid use, not only in Australia, but overseas, particularly in North America. Effective perioperative multi-modal analgesia is also an essential element of ERAS (Enhanced Recovery After Surgery), which aims to improve patient recovery and optimise outcomes after surgery.

Since the TGA's review, approved indications for opioids in Australia no longer include indications for management of chronic pain[1] aside from cancer pain, and except in very specific situations such as end of life care or managing opioid substance abuse. All opioids in Australia must now carry the following boxed warning:

> *"[This opioid product] should only be used in patients for whom other treatment options, including non-opioid analgesics, are ineffective, not tolerated or otherwise inadequate to provide appropriate management of pain."*

Postoperative pain is considered acute pain – following the TGA's review, routine prescribing of opioids for use beyond a week would not be appropriate for acute pain. This has necessitated a shift away from oral opioids as the standard analgesia for postoperative care, where a patient would be transitioned from intravenous (IV) opioids to oral opioids on the ward prior to discharge, with a further supply of oral opioids to take at home for a week or so.

The most commonly used non-opioid oral analgesics are paracetamol, ibuprofen and the selective cyclooxygenase-2 (COX-2) inhibitor celecoxib. Other less commonly used options include the non-steroidal anti-inflammatory drugs (NSAIDs) mefenamic acid, diclofenac, naproxen; and the selective COX-2 inhibitor parecoxib. These may be used as alternatives (often in combination) or in addition to systemic opioids as part of an opioid sparing strategy.

Long-term opioid use often begins with opioid prescribing for acute pain (Schug et al., 2020). In this context, a recent study of 1,900 osteoarthritis patients undergoing total knee or total hip arthroplasty in 19 Australian centres found that 17.8% of patients were still using opioids at 90 days post-surgery (Jenkin et al., 2023) (note this type of joint surgery is usually indicated after pain becomes unmanageable). These type of surgeries (where patients have a history of chronic pain or are at high risk of postoperative long-

[1] https://www.tga.gov.au/resources/resource/guidance/prescription-opioids-information-health-professionals

term opioid use) would represent the 'high value' uses MSAC was seeking in its consideration of Application 1308 (see Table 4).

In terms of clinical need, the applicant noted that patients expected to benefit most from this intervention are those who are at risk of complications from systemic opioids. This would include patients with conditions such as obesity and obstructive sleep apnoea.

Evidence-based guidelines by the PROSPECT Working Group of the European Society of Regional Anaesthesia (ESRA) recommend a combination of regional analgesia and systemic non-opioid analgesia for postoperative pain, with opioids as rescue medication only (for breakthrough pain) for:

- rotator cuff repair – continuous interscalene brachial plexus block (Toma et al., 2019);
- thoracotomy – continuous paravertebral block (PROSPECT Working Group 2015).

Thus, a strong case can be made for clinical need of non-opioid analgesia, including continuous nerve blocks, as an alternative to IV opioids immediately post-surgery and in particular for patients with a history of chronic pain and high probability of long-term postoperative opioid use.

Evidence that continuous nerve block reduces long-term opioid use remains a question for the Assessment Report.

Estimated utilisation

Recent utilisation of RVG nerve block items is presented in Table 6 and Table 7. Utilisation between 2020-2022 may have been unusually low or otherwise affected by the pandemic, especially planned surgeries.

Table 6 Utilisation of nerve block RVG item 22041 (listed 1 November 2019)

MBS#	FY 2019-2020 [from 1 Nov 2019]	FY 2020-2021	FY 2021-2022	FY 2022-2023 [year to date]	TOTAL
22041	41,740	93,580	92,544	51,436	**279,300**

Source: Medicare Statistics, accessed 21 February 2023.

Table 7 Utilisation of deleted nerve block RVG items (deleted 1 November 2019)

MBS#	FY 2015-2016	FY 2016-2017	FY 2017-2018	FY 2018-2019	1 Jul 2019- 31Oct 2019	TOTAL
22040	28,480	31,437	34,928	36,796	15,422	**147,063**
22045	7,074	7,614	8,352	9,764	4,186	**36,990**
22050	20,391	20,875	21,659	21,341	8,493	**92,759**
TOTAL	**55,945**	**59,926**	**64,939**	**67,901**	**28,101**	**276,812**

Source: Medicare Statistics, accessed 21 February 2023.
Note: details for deleted items are described in Appendix Table 16.

Following listing of the new single injection nerve block (MBS item 22041), annual utilisation of the new item increased markedly (by approximately 30%) compared to the combined utilisation of the deleted items. This can be explained by the increased scope for the nerves that could be subject to a block under the new item (the deleted items only permitted block of the femoral nerve, sciatic nerve, and the brachial plexus). The applicant has also indicated that some use of this item is due to claims for continuous nerve blocks in lieu of a more appropriate item. Actual utilisation may also have been higher had the COVID-19 pandemic not occurred between 2020 – 2022.

For the current and deleted items, utilisation by age group is essentially identical (not shown). Use is predominantly in older adults, with approximately 70% of utilisation in patients aged 55 years and older (approximately 48% in those aged 65 years and older).

According to the applicant's survey of cardiac anaesthetists, of the surgeries currently employing single injection nerve blocks, on average continuous nerve blocks would replace between 2% and 5% of this use in the first year of listing and increasing proportions thereafter. Uptake rates should be justified or tested in the Assessment Report using sensitivity analyses.

The applicant noted there was no data available to support estimate of continuous nerve blocks being claimed as single nerve injection blocks (MBS item 22041) in practice. The applicant considered the use of continuous nerve blocks best practice for some joint surgeries and that the lack of an MBS item has limited its use becoming widespread.

PASC noted that it is likely that utilisation would increase if the item were listed on the MBS. It was unclear whether the utilisation assumptions provided by the applicant were adequately supported but that an upper bound of 10% of single injection nerve block utilisation could be used for the assessment.

The applicant noted anaesthetists most likely to have undertaken further training in this area would be specialists in thoracic anaesthesia, major upper abdominal surgery, those undertaking anaesthesia for emergency surgery and trauma patients, and anaesthetists who have a particular interest in regional anaesthesia (rather than cardiac anaesthetists).

The number of ambulatory patients as a proportion of the likely use remains unknown.

Intervention

The nerve block is for perioperative administration and must be co-claimed with an anaesthesia item. The applicant confirmed the proposed item is only to be used in association with surgery. The proposed item is not for surgical anaesthesia, nor is it for pain unrelated to surgery or trauma. Nerve blocks for pain that it is not associated with surgery (chronic idiopathic pain, cancer pain, neuropathic pain, etc.) would be claimed as services under the items in a different part of the Schedule, Therapeutic Procedures Group T7 *Regional or Field Nerve Blocks*. Group T7 items include the following:

- A range of stand-alone items for single injection block of specified nerves (including intercostal, femoral, saphenous, paravertebral, sciatic and also brachial plexus and others). Most of these items cannot be co-claimed with surgical/anaesthesia items (only T7 items indicated as "(Anaes.)" in the descriptor attract an anaesthetic, for example those for neuraxial or sympathetic chain blocks).
- Items 18222 and 18225 for maintenance of single injection or continuous nerve blocks. These items can be used to top up a nerve block of patients after an initial injection has worn off (as long as it is not administered by the surgeon who performed the original operation).
- Note there is no continuous peripheral nerve block item in Group T7 or elsewhere in the Schedule.

PASC noted that the intervention could include bilateral continuous nerve blocks (for example in the case of bilateral knee arthroplasty) or occasionally more than one site for trauma patients.

Target nerves

The application is for a therapeutic health technology for continuous peripheral nerve block using a catheter technique for postoperative pain management. The technique is broadly the same as the existing MBS item for single-injection nerve block (22041), but with the additional placement of a catheter in close

proximity to the relevant nerves, although it requires a more technically proficient specialist than the equivalent single injection nerve block at the same site. The catheter allows for continuous administration of anaesthetic until the pain has subsided to the point where the block is no longer required.

The proposed technology would be used for postoperative pain management following surgery where the expected pain duration exceeds the duration of a single injection nerve block. Information in Table 5 (see 'Population') provides a non-exhaustive list of the proposed surgery types/indications for which the technology may be used. A non-exhaustive list of specific types of nerve blocks that would be covered by the proposed listing is presented in Table 8.

Table 8 Specific types of nerve blocks for the proposed item

Nerve block type (all continuous)	Target Area
Brachial plexus Interscalene (proximal) approach: shoulder Infraclavicular (mid) approach: elbow	Chest, shoulders, arms, hands
Lumbar plexus Femoral nerve: knee Saphenous nerve (adductor canal approach): knee	Back, abdomen, groin, legs (not including ankles or feet)
Sacral plexus Proximal sciatic nerve (popliteal fossa approach): lower leg Popliteal sciatic nerve: foot and ankle	Pelvis, hips, upper and lower legs, feet
Paravertebral block	Trunk (for surgery of abdominal or thoracic cavities)
Fascial plane blocks: • *Pectoralis* nerve (PEC) blocks • *Erector spinae* • *Transversus abdominis* • *Rectus* sheath • *Serratus anterior* • *Quadratus lumborum*	 Thoracic wall / breast surgery Thoracic and abdominal walls Anterolateral abdominal wall Anteromedial abdominal wall and periumbilical area Thoracic wall (for example, rib fractures, breast surgery) Abdominal and hip

Source: drawn from MSAC Application 1741 summary and supporting documents

The continuous nerve block may be applied to any peripheral nerve except for the peripheral nerves distal to the knee or elbow. This is essentially the same as for the single injection item. The MBS item 22041 wording specifies "proximal to the lower leg or forearm", which excludes injection of the nerves distal to the knee or elbow. The applicant has indicated these distal nerves would be too small / anatomically inaccessible for a continuous nerve block.

PASC noted that as with the list of likely surgeries, the list of target nerves for the proposed item was not exhaustive. The applicant confirmed that the proposed use includes both limb and trunk surgery (thoracic and abdominal but not pelvic).

The proposed nerve block use excludes wound catheters or continuous wound infiltration, and other regional analgesia by continuous subcutaneous infiltration.

Mechanism of action

A continuous nerve block employs the same local anaesthetic agents as for single injection nerve blocks (item 22041). As noted above, the technique is the same as for single injection nerve block, except that a catheter is placed near the target nerve to deliver a flow of local anaesthetic to the target nerve and

surrounding tissue. Both types of blocks and the relevant local anaesthetics were considered in Application 1308 (see the following section on 'Associated Medicines').

The duration of action of a single injection nerve block (maximum 12 hours) is sufficient for many procedures. For procedures where the duration of pain is expected to exceed the duration of a single injection block, introducing a catheter when performing the block allows continuous administration of the sodium channel blocking agent, allowing ongoing pain management for longer than 12 hours.

Associated Medicines

The medicines used in continuous nerve blocks are amino-amide local anaesthetics, shown in Table 9 (not including formulations such as liposomal or adrenaline-containing agents). Amino-amide anaesthetics bind reversibly to voltage gated sodium channels, inhibiting the conduction of pain impulses. These agents are approved by the TGA for nerve blocks for postoperative pain. The three most commonly used agents are ropivacaine, lignocaine (which is shorter acting) and bupivacaine (which is longer acting but has greater cardiotoxicity). Application 1308 reported an assumption that ropivacaine accounted for approximately 86% of local anaesthetic nerve blocks performed.

Table 9 Amino Amide Local Anaesthetics

ATC Code	Local Anaesthetic Agent	PBS Status (injectable forms only)
N NERVOUS SYSTEM N01 ANESTHETICS N01B ANESTHETICS, LOCAL N01BB Amides	Ropivacaine	Not listed
	Lignocaine (lidocaine)	Unrestricted benefit
	Bupivacaine	Not listed
	Articaine	Not listed
	Prilocaine	Not listed
	Procaine	Not listed
	Levobupivacaine	Not listed

ATC=Anatomical Therapeutic Chemical; PBS=Pharmaceutical Benefits Scheme.

Other than lignocaine, which has a broader use as a local anaesthetic, none of these medicines are listed on the Pharmaceutical Benefits Scheme (PBS). This is consistent with anaesthetics in general and other medicines used almost solely for in-patient care.

Of the potential analgesics that could be used for the proposed nerve block item, there are numerous brands, strengths and presentations approved on the Australian Register of Therapeutic Goods (ARTG). Noting the previous consideration of ARTG status and approved indications for these medicines in Application 1308, an exhaustive list with ARTG numbers has not been developed for this PICO.

Nevertheless, as an example, a check of the Product Information for the 75 mg/10 mL vial presentation of ropivacaine hydrochloride 0.2% (Fresenius Kabi, ARTG 195806; dated 13 December 2022) shows it is approved for indications including the following:

- analgesia (adults and children over 12 years of age); continuous peripheral nerve block infusion or intermittent injections for post operative pain management; and
- analgesia (children aged 0 - 12 years); peripheral nerve block in children aged 1 up to and including 12 years.

Specifically for peri- and postoperative pain management the Product Information also states:

> *"There are no safety or efficacy data to support the use of ropivacaine hydrochloride for analgesia for longer than 72 hours. (Data for peripheral nerve block administered as a continuous peripheral infusion or intermittent injections and for continuous wound infusion support the use for up to 48 hours only)."*

Current clinical practice already involves use of amino amide local anaesthetics for use beyond 72 hours. Thus, the proposed use is no different to current practice; however, that practice may include use beyond the limits specified in the Product Information for some of these medicines. These limitations on individual medicines should be taken into account in the Assessment Report in evaluating the safety of the proposed item.

Clinical setting

It is proposed that the nerve block would be administered during the perioperative period in an in-patient hospital setting in patients undergoing planned (elective) or emergency surgery.

Administration of the catheter requires conditions of the operating theatre or equivalent (preoperatively in a procedure room or postoperatively in a recovery room), including appropriately resourced emergency department procedure rooms.

For in-patients, monitoring and removal would be managed on the ward as with any other catheter. For ambulatory / day patients who return to the community with the catheter, monitoring and removal would take place at home by the patient or carer. The patient would return to the hospital in the event there was any sign of infection or difficulty with catheter operation / removal. It is not clear whether patients being sent home with a regional catheter is widespread practice or if it is limited to specific centres. See further discussion in the section on 'Duration and removal'.

Provider type and specialist training

Medical professionals associated with this item are described in Table 10.

Table 10 Medical professionals associated with this item

Purpose	Clinician	Comment
Item ordering / Referral	Anaesthetist General practitioner anaesthetist*	The need for a continuous nerve block would be determined at the pre-anaesthesia consultation. The applicant notes that referral (for example by the surgeon) would require medical assessment of the patient as to the suitability of the procedure, establishing informed consent and determining contraindications for the procedure. It is simpler for the nerve block to be administered by the same physician determining patient suitability for the procedure at the outset. A surgeon may indicate a preference for a nerve block in planning the procedure, but this would still be subject to the pre-anaesthesia consultation with the patient undertaken by the anaesthetist.
Prescribing local anaesthetic	Anaesthetist General practitioner anaesthetist*	–
Service delivery	Anaesthetist Anaesthetic assistant General practitioner anaesthetist*	Anaesthetists having completed the ANZCA advanced training in regional and local anaesthesia. Only GPs accredited to perform this procedure (according to the Joint Consultative Committee on Anaesthesia).

Purpose	Clinician	Comment
Post-anaesthesia care to discharge	Anaesthetist Nurse General practitioner anaesthetist*	Once the patient is released from the recovery unit to the ward, the responsibility for pain management remains with the anaesthetist, as is the usual practice for a post-operative in-patient. All other responsibilities transfer to the surgical team and/or ward staff.
Monitoring and removal	Nurse Anaesthetist General practitioner anaesthetist*	On the ward, this would be done by a nurse as for any catheter or IV. Patients may remove the catheter at home with appropriate guidance from the anaesthetist or the hospital pain management unit. Patients experiencing worsening pain, redness or other potential complications would be directed to return to the hospital.

Source: compiled by the Evaluation Group.
ANZCA=Australian and New Zealand College of Anaesthetists; GP=general practitioner; IV=intravenous
* A General practitioner anaesthetist is a general practitioner who has undertaken accredited and certified anaesthesia training for this technique (in accordance with the Joint Consultative Committee on Anaesthesia (JCCA) requirements).

A specialist anaesthetist is required to order and perform the continuous nerve block procedure. As this is approaching standard of care for the majority of patients undergoing major joint surgery, an experienced anaesthetist should be able to perform catheter placement for a nerve block and would be expected to have completed the ANZCA advanced training module on regional anaesthesia.

In some circumstances, a general practitioner (GP) anaesthetist will undertake this role, if they have undertaken accredited and certified anaesthesia training for this technique (in accordance with the Joint Consultative Committee on Anaesthesia (JCCA) requirements). Although the procedure would be restricted to administration in an inpatient hospital setting, in rural or regional hospitals and associated with surgery, the applicant noted that a GP anaesthetist may also undertake this procedure.

Although on occasion a surgeon may place a field block or even a nerve block if the anatomy is easily accessible, this item is not proposed to include that use, but is instead for routine use by anaesthetists.

Mode of delivery and frequency

Requirement for the procedure will be determined by the anaesthetist at the pre-anaesthesia consultation with the patient (MBS items 17610 – 17625) or in the emergency room for emergency/trauma surgery. Real time ultrasound examination to assist with placement of the catheter is standard of care. Anatomical landmarks may be reliably used for paravertebral and femoral nerve blocks, though the applicant notes that both are more reliably placed using ultrasound. The catheter can be either stimulating (electrical impulses facilitate identification of the correct nerve) or non-stimulating (where the placement relies more on anatomical landmarks and / or ultrasound guidance).

Sterile preparation and draping of the insertion site will be performed, followed by administration of the block and placement of the catheter. Local anaesthetic is injected through the catheter to confirm the correct placement and if not, the procedure is repeated, otherwise the catheter is then secured. Regardless of exact sequence of events, the catheter will be inserted and the pump for the local anaesthetic commenced prior to the patient's exit from the operating suite and transfer to the ward or discharge area.

The catheter will be connected to a local anaesthetic delivery device (electric pump for inpatients, single-use elastomeric pump for patients discharged home with the catheter *in situ*) to provide a continuous infusion of the anaesthetic. Patients may also be provided with a PCRA (patient-controlled regional analgesia) device to enable bolus doses of the analgesic to be administered in addition to the continuous infusion, as required for pain management (with standard limits in place to prevent overdose).

The level of complexity/difficulty in placing the catheter for a nerve block varies depending on the target nerve. In terms of catheter placement, conventional *transversus abdominis* plane block and popliteal/distal sciatic nerve blocks are considered more technically challenging than other target nerves (Huang et al., 2018). The applicant noted in the pre-PASC teleconference that anaesthetists have a learning curve in becoming adept at administering a continuous block as placing the catheter is more difficult than a single injection nerve block. The applicant suggested a trained specialist should be able to achieve a failure rate of less than 5%.

Prior to the procedure, patients will be anaesthetised or sedated as part of the surgical procedure, including insertion of an IV cannula. For monitoring and management of potential anaesthesia toxicity reactions, the ANZCA PG03(A) Guideline[2] recommends:

> *"monitoring during establishment of major regional analgesia should include frequent and regular blood pressure measurement, respiratory rate, and conscious state evaluation. An electrocardiograph and pulse oximeter should be available. Oxygen should be administered in the presence of sedation. This level of monitoring should be continued for at least 30 minutes or until the patient's vital signs are stable."*

The patient will be followed-up post operatively to ensure the catheter is functioning effectively. Trouble shooting may involve manipulation or replacement of the catheter if required.

PASC noted that patient or next-of-kin consent for the intervention would be obtained where required in the same manner as would usually occur for surgery, whether it be a planned or emergency intervention. In the event of an emergency where it is critical to act quickly without obtaining consent, the usual procedures would be followed.

Post-anaesthesia care is provided for patients (in-patients and day patients) according to usual clinical practice, and as reflected in the ANZCA Position Statement PS04(A)BP (ANZCA 2020). This would include any follow-up required for ambulatory patients experiencing issues with the catheter at home.

The applicant acknowledged that a consultation may be required for a patient with a catheter nerve block (either epidural or peripheral nerve) as part of post-anaesthesia care. This would be claimed under one of the MBS items for specialist in-patient consultations 18222, 18225 or 17640 (prior to discharge).

The applicant explained that a continuous nerve block would otherwise be managed with no additional costs relating to maintenance, monitoring or catheter removal.

Duration and removal

The applicant has proposed, broadly, two scenarios for the duration and removal of the catheter for the continuous block. The block will be used for in-patients undergoing major surgery or ambulatory patients being discharged following day surgery. Under both scenarios the anaesthetist is responsible for providing a plan for catheter removal:

- For in-patients, management, monitoring and removal of the catheter would be responsibility of the nursing staff on the ward as per standard practice for postoperative care and the anaesthetist's specific written instructions. The duration will depend on the surgical indication and patient prognosis. For the majority of patients, 3-5 days prior to catheter removal would be typical. Use beyond seven

[2] Note this guideline states: *"This document is intended to apply to central neuraxial blocks and all other techniques where a catheter is inserted and left in situ […] The purpose of these guidelines is to facilitate the management of major regional blocks including epidural, subarachnoid, plexus and nerve blocks"*.

days would be unusual as most patients would be adequately managed using simple analgesia. In exceptional cases such as traumatic amputation, the continuous block may remain in place for an extended period (the applicant indicated 30 days might be reasonable in such a case, subject to risk/benefit assessment and consideration of special catheter or other techniques).

- For ambulatory patients, the usual maximum time would be 72 hours post-surgery prior to catheter removal. The duration would be limited by the elastomeric pump fill volume (see 'Device – Local anaesthetic delivery device'). The applicant noted that Australian clinical experience indicated that patients had usually transitioned to non-opioid oral analgesics (typically paracetamol) by 48 hours. The applicant has proposed that patients discharged with the catheter *in situ* will remove the catheter approximately 72 hours post-surgery, with instructions for removal provided by the anaesthetist prior to discharge (private patients seeing their specialist in private practice), or by the hospital pain management service (for private patients in public hospitals). The applicant advised that for ambulatory patients, the anaesthetist, in conjunction with the surgeon and hospital, would have a care pathway for post-discharge catheter management, the same as exists for any issues that arise post-discharge after a procedure.

ANZCA Guideline PG03 for the management of major regional anaesthesia states:

> *"A registered nurse, midwife, or other staff member, with the necessary training, may remove the catheter on the orders of the proceduralist. Details of the removal of the catheter, the date, time, and state of the catheter and its tip, as well as the state of the insertion site, should be documented in the patient's record."*

Patient self-removal, even with the supervision of a nurse from the outpatient unit or pain clinic over the phone, is not reflected in this current guideline. Although the applicant has indicated that the patients can be discharged and managed at home (in the experience of at least one NSW hospital), this is not reflected in any supporting materials such as ANZCA guidelines, nor is there any indication that the ANZCA advanced training offered for regional anaesthesia would include how to manage these patients.

According to the applicant, the absence of Australian guidelines post-discharge is because this intervention reflects a relatively new approach. The practice of self-removal of indwelling catheters is common practice in the USA. *PASC noted that the applicant's clinical expert claimed that removal of the catheter by the patient or their carer is frequently used in some hospitals within Australia.* The self-removal of (for example) surgical drains at home happens with some day surgical procedures. The applicant also advised that in their current model of care for removal of catheters that they ensure that the patient has a reliable point of contact should there be any difficulties post-discharge.

Following removal of the catheter it is proposed that the patient would generally be transitioned to non-opioid oral analgesics for pain management as required.

Associated equipment

A list of equipment used for administering the proposed item is in Table 11. The list includes:

- the corresponding Global Medical Device Nomenclature (GMDN) codes (not an exhaustive list);
- the number of devices currently registered on the ARTG for each GMDN; and
- one exemplar ARTG number for each GMDN.

The catheter / catheter kit for the continuous block is similar to that which would be used for a continuous epidural block. It was not clear if any of the single use elastomeric pumps currently on the market include a PCRA. The ARTG item number(s) for the PCRA device remains outstanding.

Table 11 List of equipment for administering a continuous nerve block

Item	GMDN (# ARTG entries under this code)	ARTG Example
Electrical / machine devices		
Ultrasound device (ultrasound machine and probe, not including software)	40761 - Ultrasound system, imaging, general-purpose (76) 40768 - Extracorporeal ultrasound imaging system transducer, hand-held (30)	292801 123896
Local anaesthetic infusion device: Electric pump	46845 - Mechanically-operated infusion pump (2) 46846 - Mechanically-operated infusion pump set (3)	248373 159495
Local anaesthetic infusion device: Electric pump + PCRA device	35932 - Infusion pump, analgesic, patient-controlled (5)	111825
Disposable / consumable items		
Ultrasound transducer cover, sterile	60608 - Body-orifice ultrasound imaging system transducer cover, basic, sterile (6)	400449
Catheter kit	34840 - Anaesthesia kit, brachial plexus (1) 34842 - Anaesthesia kit, epidural (13) 34845 - Anaesthesia kit, spinal (7) 46308 - Anaesthesia kit, epidural/spinal (10) 46383 - Nerve-locating anaesthesia kit, continuous admin. (9) 47191 - Anaesthesia conduction catheterization kit (2)	133630 144119 133640 (continuous) 138951 139569 281941
Tuohy or similar needle (usually supplied in kit)	58293 - Epidural needle, non-threaded (10) 36191 - Needle, anaesthesia, epidural (2)	369910 133641
Catheter (usually supplied in kit)	10704 - Catheter, cerebrospinal (9) 33172 - Catheter, infusion (18) 34898 - Cannula, epidural (1) 64374 - Epidural anaesthesia stand-alone catheter (2)	181743 162583 133641 392933
Sterile dressing pack including catheter fixation devices	(fixation device may be included in catheter kit)	(Standard hospital supplies)
Local anaesthetic infusion device: Single use elastomeric pump	47190 - Elastomeric infusion pump kit (3) 46542 - Elastomeric infusion pump system (12)	312732 142526 *221448* 329420

Source: MSAC Application 1741 summary; evaluator search of ARTG.
ARTG=Australian Register of Therapeutic Goods; GMDN=Global Medical Device Nomenclature; PCRA=patient controlled regional analgesia device.

The applicant noted that three of the elastomeric pumps used for ambulatory patients have recently been deleted as benefits from the Prostheses List though they remain on the ARTG (B Brain Easypump II [ARTG 221448]; LTR Medical Accufuser [ARTG 329420]; ON-Q Pain Relief [ARTG 312732]).

Assuming the MBS fee will be set by the RVG basic units measure of complexity, an exhaustive list of items will not be required for the Assessment Report in order to calculate costs as the basis for a potential fee.

Tests

For certain types of continuous nerve block agents, a blood test may be required (full blood count and coagulation tests, for example, to prevent haematoma in patients on anticoagulant therapy). These tests would have already been conducted in preparation for surgery in the normal course of clinical practice.

Consumables

A single-use catheter kit is used to administer the block. The kit usually includes a needle (Tuohy or similar), catheter, connector, filter and fixation device. According to the applicant, catheter kits are available in most surgical facilities and are funded by the hospitals (public or private). The elastomeric pump with or without PCRA are single use items and would also be considered consumables.

Device – Ultrasound

The applicant has advised that a current generating point of care ultrasound device is required to ensure safe positioning of the catheter. Use of ultrasound guided imaging for catheter insertion is standard of care for the proposed nerve block (see comment above 'Mode of delivery and frequency') but ultrasound is only funded on the MBS for use with the stand-alone nerve block items in Group T7.

Application 1308 noted that a separate application to MSAC had been considered for use of ultrasound in anaesthesia (MSAC Application 1138, considered at the November 2014 MSAC meeting); however, that application was not supported (see Appendix). The proposed fee for the service at that time was $58.85, although costs for private ultrasound services can exceed $100.

The cost for unfunded ultrasound services to support the proposed item (mainly ultrasound equipment, but also consumables and staff) will fall to the States and Territories for private patients in public hospitals, and the patients themselves (or their private health funds) for private hospital patients. This is currently the situation for all RVG nerve block items.

PASC discussed the use of ultrasound for the placement of continuous nerve blocks and confirmed that ultrasound could not be co-claimed with the proposed item. The applicant advised that ultrasound is not always vital, and that a nerve stimulator may be used instead of ultrasound in some situations.

Device – Local anaesthetic delivery device

A local anaesthetic delivery device is also required. For the two scenarios envisaged, this would be either:

- a conventional electric pump for in-patients, or
- for ambulatory patients, a disposable elastomeric pump set to administer local anaesthetic at a fixed rate, with a PCRA (patient controlled regional analgesia device). The applicant has advised that these pumps are available in most hospitals (approximately $150 per unit). The pump would be filled with sufficient local anaesthetic for a low rate 72-hour infusion (typically 2-5 mL/hour) at discharge. If the patient has breakthrough pain, they use the PCRA to deliver a 5 mL bolus (typically with a 30-minute lock-out).

Existing therapies and current funding

The applicant has advised that at present, continuous nerve blocks are either not performed, self-funded by patients, or some anaesthetists were claiming the single injection nerve block for continuous nerve block services in lieu of a better item. Given the wide utilisation of continuous nerve blocks outlined in the letter of support from the applicant's Regional Anaesthesia Specialist Interest Group, it is unclear whether the procedure is being funded by hospitals (for public patients) or self-funded (by private patients).

Continuous nerve blocks for postoperative pain management are not currently publicly funded on the MBS as stand-alone items in Group T7. The applicant noted that the need for continuous nerve blocks as a stand-alone item without surgery is too limited to warrant an application for an MBS item.

Other relevant considerations

Given the reported current wide utilisation of continuous nerve blocks for postoperative pain management, significant implementation issues would not be anticipated for use in hospital in-patients.

Use in ambulatory patients, who return home to manage the catheter and pump themselves may have a consequent training and quality assurance impact. This mode of use does not appear to be reflected in current guidelines. Where guidelines are lacking, individual hospitals would be responsible for training and hospital quality programmes for regional anaesthesia using a continuous nerve block. The applicant

indicated that as continuous nerve blocks are already in regular use, hospitals already have training in place to support their use.

Use of continuous nerve blocks in ambulatory patients who are discharged home has been a success in at least one NSW hospital according to the applicant.

Comparator(s)

The main comparators for this PICO are listed in Table 12 (the estimated use is of the target patient population).

Table 12 List of potential comparators

Comparator	Details	% Estimated Use	Max Duration	Followed By:
Single injection nerve block	Administered perioperatively via MBS item 22041 Administered as stand-alone item not part of surgery, via Group T7 (items 18222, 18225) sometimes used to top up perioperative nerve block. *In combination with supplementary analgesia for target population. For example, single injection interscalene block for shoulder surgery.*	40-80%	12 hours	Systemic opioids (IV or oral) or non-opioid oral analgesics
No continuous block	For the purpose of the evidence search and assuming comparative evidence only, 'no block' could be placebo, standard care, or sham plus any rescue medication (i.e., supplementary analgesia) employed by the study protocol. *In clinical practice, a patient in this indication would not be untreated and would receive one of the already identified alternatives plus any supplementary analgesics. No continuous block represents a composite of treatment alternatives.*	N/A	N/A	N/A
Neuraxial analgesia – epidural block	Single injection or via catheter, same local anaesthetic agents as for single injection nerve block. Catheter delivery is either continuous, or programmed intermittent epidural bolus or patient-controlled epidural analgesic bolus. Limited patient mobility for catheter patients. *Open abdominal procedures cited as example where continuous block may be used as alternative.*	All neuraxial: 2.5-10%	§ ~72 hours	Systemic opioids (IV or oral) or non-opioid oral analgesics
Neuraxial analgesia – spinal (intrathecal) block	Single injection, same local anaesthetic agents as for single injection nerve block.		† ~12 hours	
Systemic opioids – IV	Often fentanyl in the first instance (short-acting), IV oxycodone, or morphine (especially patients with a PCA). With Normacol or similar. With/without ondansetron (not PBS listed for this indication) Used for any of the surgery types (except where epidural is preferred) unless patient is contraindicated for opioids.	Up to 80%	‡ ~72 hours	Systemic opioids (oral)

Comparator	Details	% Estimated Use	Max Duration	Followed By:
*Systemic opioids – oral	Typically, patients who have responded well to IV opioids are stabilised on an oral equivalent (oxycodone) on the ward and sent home with a week's supply, plus medicines to manage side effects (for example aperients), as discharge meds or script. Now more often prescribed in combination with paracetamol as part of opioid sparing approach.	Variable (up to 80%)	1 week – 10 days	Non-opioid oral analgesics
Other oral analgesics	Paracetamol NSAIDs (unless contraindicated) such as ibuprofen, including COX- 2 inhibitors such as celecoxib. Either used as alternatives (typically in combination) or as part of an opioid sparing strategy.	Variable (probably >80% by the end of the patient's recovery)	Per Product Information	Until pain has abated.

Source: compiled for this PICO Confirmation; % Estimated Use values provided by the applicant in pre-PASC teleconference.
§ Epidural block (continuous): up to maximum of 5-7 days with specific supervision for major thoracic or abdominal surgery in specialist centres
† Spinal block: maximum 3-4 hours with fentanyl, 12-24 hours if subarachnoid morphine is used
‡ Systemic opioids (IV): up to 7 days, depending on the patients' surgery, injuries and ability to treat by other modalities
IV=intravenous route of administration; NSAIDs=non-steroidal anti-inflammatory drugs; OTC=over the counter; PBS=Pharmaceutical Benefits Scheme; PCA=patient-controlled analgesia device.
*Oral opioids, not including any modified release formulations, may include oxycodone, tapentadol, tramadol and buprenorphine.

PASC noted the applicant's estimate that 40-80% of the target patient population would currently receive a single injection nerve block, but that the estimates for each comparator were variable.

Given the typical duration proposed for this intervention (3-5 days) and the indication of moderate to severe pain that is expected to last 12 hours or longer, the use of the available alternatives can be considered in the following context. *PASC noted these strategies constitute the current options for a 'no continuous block' scenario*:

- *single injection nerve block + supplementary analgesia (opioids ± oral non-opioid analgesia);*
- *systemic opioids (IV opioids initially, followed by oral opioids ± oral non-opioid analgesia);*
- *neuraxial nerve block + supplementary analgesia (opioids ± oral non-opioid analgesia).*

The applicant has nominated single injection nerve block (MBS item 22041) as the main comparator. This is appropriate as it is the most likely intervention to be replaced in Australian clinical practice. If continuous nerve block was listed, it is assumed the single injection nerve block use that would be replaced would be for patients who would otherwise receive a single injection nerve block plus systemic opioids – these patients could possibly either have reduced systemic opioid requirement or transition straight to non-opioid oral analgesia.

The other main alternative would be systemic opioids. If continuous nerve block was listed, it is assumed the systemic opioid use that would be replaced would be for patients where non-opioid analgesia was preferable. For some surgery types (open abdominal surgery), continuous epidural block may be used more often than single injection nerve block, but this is only a small subset of the total patients.

The applicant argues that in comparison to the available alternatives, a continuous nerve block allows faster recovery time, earlier mobilisation, decreased rates of opioid use/prescribing, and better postoperative pain control.

The applicant claims the proposed continuous nerve block is superior to single injection nerve block (plus supplementary anaesthesia) in the indicated population based on longer duration of pain control.

"No block" was suggested as a potential comparator in Application 1308 (where the intervention included all peripheral nerve blocks; major, minor and continuous). However, the corresponding comparator for this application would be "no continuous block", representing a composite of existing treatment alternatives. "No continuous block" has not been specified as a comparator given that patients with moderate to severe pain would always be managed with some type of analgesia, which may include one of the above most commonly used options or other non-opioid systemic analgesia.

The applicant notes that there are no agents that can reliably produce a single injection nerve block for more than 12 hours.

In most cases for patients suffering moderate to severe postoperative pain, supplementary analgesia will be IV or oral opioids with an additional non-opioid oral agent. Typically, postoperative patients will be stabilised on oral opioids in hospital (with exception of ambulatory surgery). Once ready for discharge, both ambulatory and in-patients are sent home with a week's supply of analgesics or a script for the same, which until recently has typically been oxycodone (and still is in many cases). The applicant noted that availability and accessibility of postoperative analgesia are also determined by institutional factors, including approved protocols, equipment, nurse training, and nurse-to-patient ratio.

Wound infiltration has not been included as a comparator in Table 12 as the applicant advised this technique was typically inadequate on its own for moderate to severe postoperative pain.

Outcomes

The applicant's proposed claim is that a continuous nerve block for postoperative pain is superior to a single injection nerve block and is non-inferior in terms of safety, based on duration of analgesia that is achievable with the two different types of blocks. The most frequently used alternative would be a single injection nerve block followed by supplementary analgesia once the injection had worn off. The key outcome for a comparative evaluation could therefore be time to supplementary analgesia. Total opioid or supplementary analgesic consumption and pain scores could be appropriate secondary outcomes.

In addition, the applicant claims continuous nerve block offers the following benefits:

- reduced length of stay in hospital;
- better pain management (especially reduction of rebound pain), better ongoing analgesia;
- reduced opioid use and reduced opioid dependence potential;
- improved mobility and recovery from major orthopaedic surgery and trauma;
- improved recovery from other surgeries/injuries (for example, mastectomy or fractured ribs); and
- less pressure on hospital resources (including hospital beds, nursing staff, PCRA pumps, physiotherapy).

Some of these can be measured in patient relevant and resource use outcomes. The outcomes evaluated in Application 1308 and recent systematic reviews, have been adapted for this PICO, shown in Table 13.

PASC acknowledged that different pain reporting tools were subjective (making comparisons difficult) but that reporting patient scores to capture patient perception and change in pain response was key.

Table 13 List of potential outcomes

Outcome Type	Details
Effectiveness	• Patient-reported postoperative pain score • Time to first mobilisation post-surgery • Patient satisfaction with analgesia • Time to, and rate of supplementary analgesia use • Rate of chronic postoperative pain • Chest infection/pneumonia (consequence of poorly managed severe pain) • Health-related Quality of Life
Safety /adverse effects	• Block-related complications (vascular injury, paraesthesia, motor block, failed block, neurological impairment, pneumothorax) • Catheter AEs including insertion site infection • Local anaesthesia toxicity • Death/mortality • Complications or grade ≥3 AEs for systemic analgesia (short-term and long-term)

Resource Use	• Block re-attempt (block failure)
	• Hospital length of stay
	• Re-hospitalisation due to pain
	• Analgesic use (note time to supplementary analgesia is efficacy endpoint)
	  • Analgesia requirements post-surgery (including opioid consumption)
	  • Duration of analgesia

AE=adverse event; NSAIDs=non-steroidal anti-inflammatory drugs.

In considering Application 1308, MSAC stated that *"data on length of hospital stay, recovery time, post-surgical chronic pain and QoL was very limited or not presented. If available, this data may enable a cost-utility analysis to assist the committee's decision making."* MSAC also raised concerns regarding the lack of patient-centred outcomes in the economic model, particularly pain, whereas the impact of nerve blocks on pain was considered key to MSAC's decision-making. *It is possible hospital length of stay will not be needed if information on opioid consumption and time to supplementary analgesia can be presented.*

Rates of long-term chronic pain and chest infection / pneumonia are sequelae of poorly managed severe postoperative pain and as such are included as efficacy outcomes rather than safety.

Neurological impairment cited as a safety outcome associated with nerve blockade usually manifests as muscle weakness or sensory deficit.

Side effects associated with both opioids and NSAIDs are well documented.

Although the applicant claims reduced potential for opioid dependence, it is not known whether the clinical evidence will permit evaluation of this given only a small number of patients are likely to develop opioid dependence as a proportion of all total postoperative patients.

Rate of chronic pain is nominated as an outcome, consistent with a recent Cochrane review (Guay et al., 2017) of nerve block in hip arthroplasty patients, as sequelae of poorly managed postoperative pain frequently include development of chronic pain.

Local anaesthesia toxicity is likely to be observed in the first 1-5 minutes after the block is administered but there are essentially no implications for events occurring later during an in-patient stay or during follow-up as may be the case for other types of drug toxicities.

It is assumed that patients who have gone home with a catheter in place will return to the hospital for any catheter issues such as apparent infection, site swelling or difficulty with catheter removal. This would not involve a general practitioner visit.

Clinical management algorithms

Algorithms for current and proposed management of patients with moderate to severe pain lasting more than 12 hours are presented in Figure 1 and Figure 2, respectively.

The applicant noted that the goal for management of post-operative pain is an incremental stepping down of analgesia requirements and opioid usage to simple analgesia. A regional catheter can remove the requirement for opioids in many situations. The algorithms are a reflection of what occurs in practice; however, the timeframes depicted in the algorithm may be adjusted to each patient.

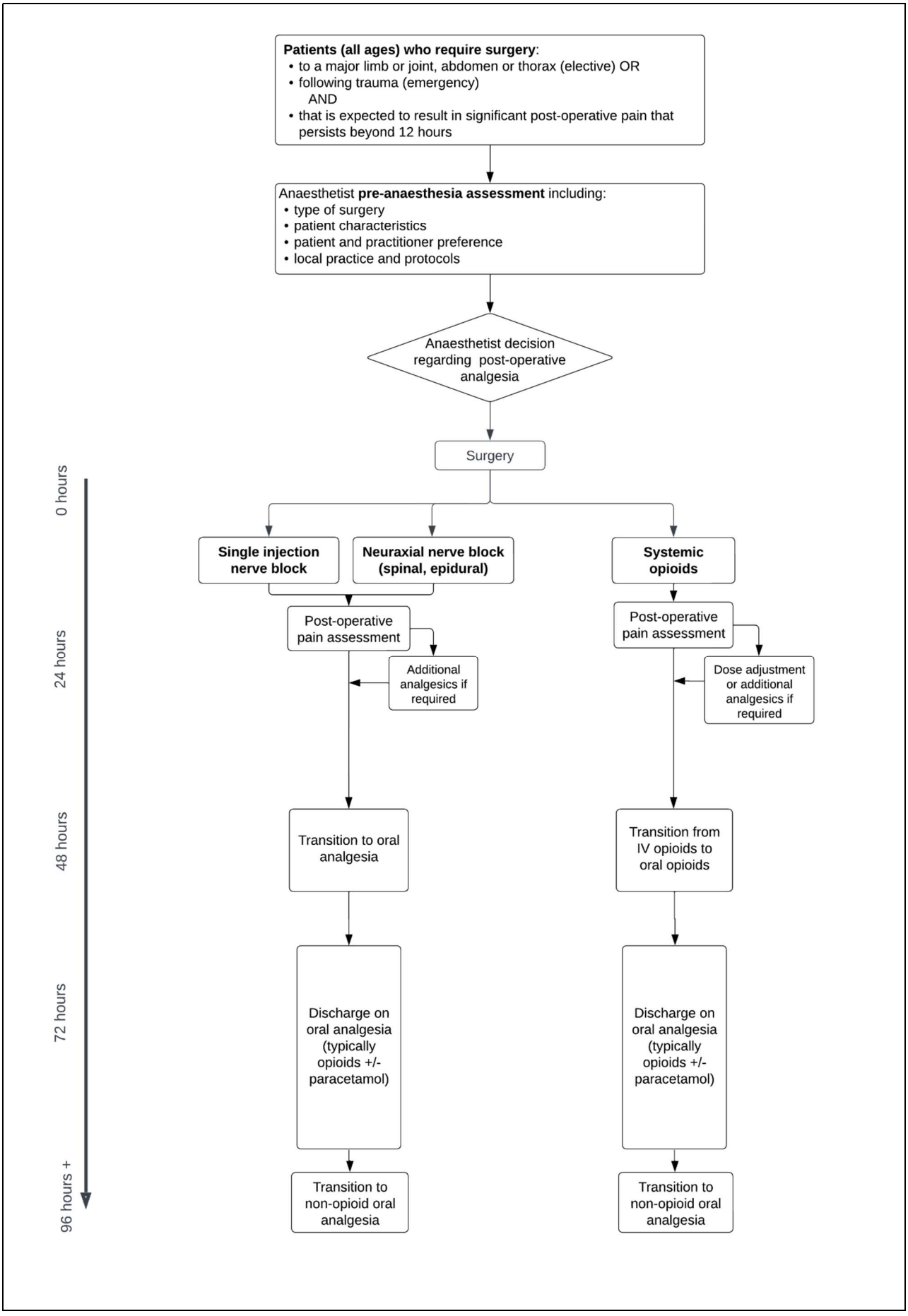

Figure 1 Treatment algorithm for moderate to severe postoperative pain lasting 12 hours or longer: current practice

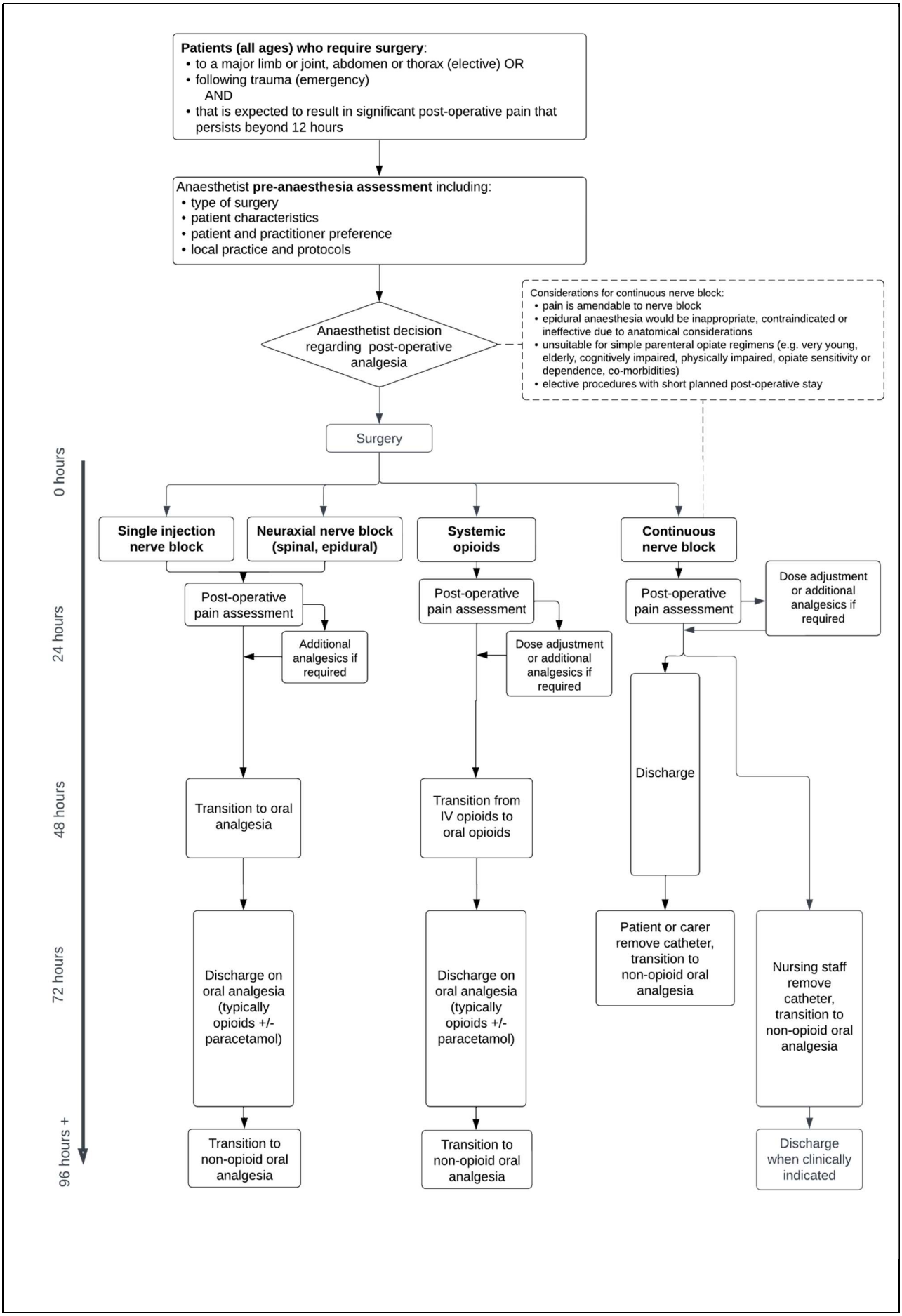

Figure 2 Treatment algorithm for moderate to severe postoperative pain lasting 12 hours or longer: after listing

Proposed economic evaluation

The applicant's clinical claim is superiority versus single injection nerve blocks based on the duration of analgesia the continuous block can provide in comparison with a single injection block (maximum 12 hours). *PASC noted the applicant confirmed the proposed claim is of non-inferior safety compared to single injection nerve block*. A cost-utility analysis would be the appropriate type of economic evaluation (see Table 14, highlighted section).

Table 14 Classification of comparative effectiveness and safety of the proposed intervention, compared with its main comparator, and guide to the suitable type of economic evaluation

Comparative safety	Comparative effectiveness			
	Inferior	**Uncertain[a]**	**Noninferior[b]**	**Superior**
Inferior	Health forgone: need other supportive factors	Health forgone possible: need other supportive factors	Health forgone: need other supportive factors	? Likely CUA
Uncertain[a]	Health forgone possible: need other supportive factors	?	?	? Likely CEA/CUA
Noninferior[b]	Health forgone: need other supportive factors	?	CMA	CEA/CUA
Superior	? Likely CUA	? Likely CEA/CUA	CEA/CUA	CEA/CUA

CEA=cost-effectiveness analysis; CMA=cost-minimisation analysis; CUA=cost-utility analysis
? = reflect uncertainties and any identified health trade-offs in the economic evaluation, as a minimum in a cost-consequences analysis
[a] 'Uncertainty' covers concepts such as inadequate minimisation of important sources of bias, lack of statistical significance in an underpowered trial, detecting clinically unimportant therapeutic differences, inconsistent results across trials, and trade-offs within the comparative effectiveness and/or the comparative safety considerations
[b] An adequate assessment of 'noninferiority' is the preferred basis for demonstrating equivalence

The superiority claim does not form the basis of a higher fee for the requested item. The higher complexity for this item if listed (five basic units) was previously supported by ESC in Application 1308 and does not need to be established via a superiority claim. Nevertheless, demonstration of superiority (instead of non-inferiority) compared with the single injection nerve block item could address MSAC's request to show higher value nerve blocks.

Application 1308 presented three exemplar nerves (one for each type of nerve block) and based the claims and evaluation around those examples. This application will be more focused, as follows:

- it only seeks funding for continuous nerve block;
- the item is proposed for all peripheral nerves; and
- there is now a single main comparator listed on the MBS, which also covers all peripheral nerves.

The evidence search can encompass continuous nerve block for analgesia of any nerve (per examples in Table 8). Comparative evidence of continuous block versus a secondary comparator (systemic opioids or epidural) could be included as supportive if the evidence for the main comparator is limited. This could be a decision based on the results of the literature search made during the Assessment Report compilation.

The applicant claims the proposed intervention is less costly than a single injection nerve block based on savings to the hospital system while also noting that the catheter kits are more expensive than the kits for the single injection nerve block. None of these will be savings to Medicare or the Commonwealth. Savings to the hospital system will either be savings to State and Territory health budgets (for private patients in public hospitals), to private hospitals, or to private hospital patients themselves. Note that PBS medicines

cannot be funded by the Commonwealth for hospital in-patients, thus reduction in opioid or other analgesic use would still represent a saving to the States and Territories. In States and Territories where PBS medicines can be dispensed on discharge, reduced opioid or other analgesic dispensing may lead to a saving to the Commonwealth in the event that continuous nerve block is listed.

Proposal for public funding

This application is relevant to private patients only, either in public hospitals (where the services would most likely be bulk-billed to Medicare), or in private hospitals (where the patient pays the costs, absorbing any gap, and the fee is rebated by Medicare less the 25% co-payment).

Furthermore, for private patients in public hospitals, an anaesthetist may only claim a benefit for an RVG item if they are working in that public hospital as part of their private practice, and not as an employee of the public hospital (intern or registrar, per MBS Schedule general explanatory note GN.12.30).

PASC noted it is not clear what the current funding arrangements are for patients currently receiving continuous nerve blocks. This remains an issue for clarification in the Assessment Report.

Type of item change, complexity and fee

Place in the Schedule

The relevant section of the Schedule and the group of MBS nerve block items where the new item is proposed to be listed, that is Group T10 of the RVG, is presented in Table 2, in 'Purpose of application'.

The applicant states the proposed item will always be provided with anaesthesia and will be co-claimed with other eligible items, consistent with rules for other RVG nerve block items.

Type of item change

This proposed use will require a new item. The MSAC consideration of Application 1308 and the report from the MBS Review's Anaesthesia Clinical Committee determined that a continuous nerve block should have a higher complexity, and a different item, than single injection nerve block.

Draft item and descriptor wording

A draft item descriptor is presented in Table 15, based on wording of existing Group T10 / RVG items *Nerve or Plexus Blocks for Post Operative Pain*, and adapted from the applicant's proposed wording.

Table 15 Proposed item descriptor

Category 3 – THERAPEUTIC PROCEDURES GroupT10 - Relative Value Guide For Anaesthesia - Medicare Benefits Are Only Payable For Anaesthesia Performed In Association With An Eligible Service Subgroup19 - Therapeutic And Diagnostic Services
MBS item XXXX Perioperative introduction of a plexus or nerve block to a peripheral nerve, using an *in situ* catheter in association with anaesthesia and surgery, for post operative pain management (5 basic units). (See para TN.10.17 of explanatory notes to this Category)
Fee: $104.75 Benefit: 75% = $78.60 85% = $89.05

75% benefit is payable for treatment of hospital in-patients; 85% to all other services

The wording in the existing single injection nerve block item 'proximal to a lower leg or forearm' has been omitted from the proposed descriptor wording, which arose out of the MBS Review's Anaesthesia Clinical Committee report, intended for limb surgery only. Use of continuous nerve blocks will not be limited to nerves supplying the limbs. Although 'proximal' captures more than just those nerves, the applicant has indicated the reference could be confusing. Instead, the wording above refers to "a peripheral nerve". In theory this could lead to attempts to administer a continuous nerve block "distal to the lower leg and forearm", but the applicant advises the nerves in these areas are too small to accommodate a catheter.

PASC discussed the options for wording of the item descriptor. As noted in 'Intervention Target nerves', the applicant confirmed the proposed item is intended for peripheral nerves for limb surgery and trunk surgery but these nerves should be "proximal to the lower leg or forearm".

It is understood the proposed item will be claimed once per nerve block per surgery, noting that more than one claim may be made if bilateral or multiple continuous nerve blocks are required.

PASC suggested that an explanatory note could be considered, specifying that ultrasound is not eligible to be claimed with this item

Item complexity

For RVG items, the number of basic units determines the MBS fee. Item 22041 is two basic units.

For Application 1308, ESC suggested that a continuous nerve block could be five basic units according to the Group T10 Relative Value Guide for Anaesthesia principles.

The MBS Review's Anaesthesia Clinical Committee suggested instead that a continuous nerve block could be four basic units, although it was considering continuous block for limb surgery only. For reference, the RVG item for an initial neuraxial block with or without a catheter (MBS item 22031) is assigned a complexity of five units.

Item fee

RVG item fees are set using basic units as a measure of complexity; no premium can be included (to reflect a superiority claim, for example). For the current Financial Year, one basic unit for an RVG item is$20.95. The fee proposed by the applicant ($104.75) corresponds to five basic units, as described above.

PASC noted the fee should cover the cost of aftercare.

Out of pocket costs

The applicant notes the actual charge for the service will be approximately $303.56 and acknowledges there may be an out-of-pocket cost for the patient. This claim will need to be explored in the Assessment Report.

The applicant has made a case that the availability of a continuous nerve block with a disposable pain pump means some patients can be discharged earlier or treated as ambulatory. The patient is then discharged on the same day as surgery (or earlier than usual for in-patients). The out-of-pocket cost for the continuous nerve block could be off-set by the reduced or no cost of in-patient stay.

Summary of public consultation input

Consultation feedback was received from one specialist organisation, Sunshine Coast Health and Hospital Services (SCHHS), and six individuals. All of the individuals identified as specialist medical practitioners. The consultation feedback received was all supportive of public funding for continuous nerve blockade using a catheter technique.

Clinical need and public health significance

The main benefits of public funding received in the consultation feedback included superior, ongoing and consistent analgesia for patients, reduced opioid use and equity of access to the benefits of the intervention. Benefits also included avoiding motor and excessive blockade compared to regional analgesia, enhanced recovery and early mobilisation of patients, and reduced length of stay in hospital. Feedback was also received that noted benefits in reducing chronic pain and phantom pain development and reduced PTSD from trauma.

The main disadvantages of public funding received in the consultation feedback included the requirement for additional training of staff and changes to service delivery in hospitals unfamiliar with the service, potential for severe, uncontrolled pain should the system fail, and increased risk of adverse events including haematoma at insertion site and intravascular infusion of local anaesthetic.

Indication(s) for the proposed medical service and clinical claim

The majority of consultation feedback ranged from agreeing to strongly agreeing with the proposed population, comparator and clinical claim. Only one individual selected agree and disagree with regards to the proposed population, comparator and clinical claim. The accompanying comments included that opioids do not deliver a pain free experience unlike well conducted regional analgesia and discharge times are not a good indicator of success as there is more to postoperative care than pain relief.

One individual stated that any continuous nerve block (including for example distal forearm placement) should be included and that the service should be generic to allow for long bone fractures, frozen joints and chronic pain conditions. Several respondents supported the use of continuous nerve blockade using a catheter technique for non-operative management of rib fractures, noting that this can be complex, time consuming and more costly than other patient groups within the population. One respondent suggested a higher service fee for this class of catheter technique.

Cost information for the proposed medical service

The majority of consultation feedback ranged from agree to strongly agree with the proposed service descriptor and fee. One individual selected agree and disagree for the proposed service fee stating that follow up visits need to be included in funding.

Additional comments

The difference in techniques regarding continuous versus top up in catheters was brought up. Notably that there may be different follow up requirements for patients depending on the technique used, for example home based nurse visits versus electronic follow up by the same staff.

Next steps

The applicant confirmed their intention for the application to proceed as a DCAR.

Applicant comment on the ratified PICO Confirmation

The clinical management algorithms above are accurate depictions of post operative analgesia for major surgery. Noting that a continuous nerve block via catheter is typically used for up to 72 hours. Use may extend beyond 72 hours where clinically appropriate.

We would like to clarify that the figure of $303.56 is an estimated maximum charge for the service. This figure incorporates the cost of catheters, which are currently covered by the hospital. We would like to note this figure is not indicative of the actual charge for the service to the patient, and that an out-of-pocket expense for this service is not likely to be charged to the patient.

The ASA will provide further input on the proposed fees for the service. Any charge for the service will be in line with the MBS fee and Private Health Insurers rebate schedules.

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Appendix

Background – previous MSAC considerations

Application 1308 – Local anaesthetic nerve blockade

A previous application for peripheral nerve blocks, from the same applicant, was considered at the April 2017 MSAC meeting (1308 Local anaesthetic nerve blockade for post-surgical analgesia). That application requested three new items for regional nerve block; major, minor and continuous. It was proposed that the new items would replace three MBS items (22040, 22045 and 22050 – subsequently deleted; see Table 16) that were specific to nerve block of the femoral and sciatic nerves (for hip, knee, ankle or foot surgery) and the brachial plexus (for shoulder surgery).

Table 16 Deleted MBS items: Intraoperative Blocks for Postoperative Pain

MBS#	Basic units	Administration	Purpose	Explanatory Notes
22040	2	Regional or Field Nerve Block *[single injection item]*	In addition to the general anaesthesia for the related procedure For postoperative pain via the femoral OR sciatic nerves, in conjunction with hip, knee, ankle or foot surgery	TN.10.17; TN.10.21
22045	3	Regional or Field Nerve Block *[single injection item]*	In addition to the general anaesthesia for the related procedure For postoperative pain via the femoral AND sciatic nerves, in conjunction with hip, knee, ankle or foot surgery	TN.10.17; TN.10.21
22050	2	Regional or Field Nerve Block *[single injection item]*	In addition to the general anaesthesia for the related procedure For postoperative pain via the brachial plexus in conjunction with shoulder surgery	TN.10.17; TN.10.21

Source: Medicare Benefits Schedule Book, 1 July 2019.

For reference, Application 1308 considered blocks of the following major nerves: paravertebral, lumbar plexus, extrapleural, intercostal, coeliac plexus, cervical plexus, retrobulbar, peribulbar, sub-tenons and adductor canal. Not all of these are relevant to the current application (for example, nerve blocks of the eye). Minor nerve blocks considered in Application 1308 included transversus abdominis plane, rectus sheath, fascia iliaca compartment, axillary plexus and others. Perioperative nerve blocks (without catheter insertion) have since been covered by listing of MBS item 22041 (see below).

The ESC suggested that five basic units would be reasonable for a continuous nerve block item.

MSAC did not support the requested listing of nerve blockade for post-surgical analgesia, noting *"evidence for the comparative safety and effectiveness of nerve blocks against placebo or no block was greater than that for comparators such as epidural or intrathecal blocks"*. This appears to be the basis for MSAC's recommendation that in any resubmission, "no block" should be the nominated comparator. *MBS item 22041 has subsequently been listed (see below). This item represents an appropriate comparator for the current application and is the basis of the applicant's clinical claim.*

Report of the Anaesthesia Clinical Committee – MBS Review

Subsequent to Application 1308, the MBS Review's Anaesthesia Clinical Committee made further recommendations regarding regional or field nerve blocks in its 2017 report[3]. The outcome of that process

[3] www.health.gov.au/resources/collections/mbs-review-final-taskforce-reports-findings-and-recommendations

resulted in the listing of item 22041 (though the Committee had recommended listing for use both with and without a catheter).

Several points noted in the 1308 assessment are relevant to this application:

- The Committee's consideration was specific to limb surgery only, reflected in the descriptor for item 22041.
- The report recommended a combined item for plexus or nerve blocks in the lower leg or forearm with/without a catheter.
- Nerve blocks for postoperative pain management following limb surgery would be covered by two items, one with a catheter (4 units) and one without a catheter (2 units).
- A maximum one service to be claimed per patient (per episode).
- Additional time required for complex blocks should be compensated by co-claiming the appropriate anaesthesia time item.
- An item was recommended for follow-up visits by a practitioner following limb surgery to provide plexus or major nerve catheter top-up.

The following changes were made to the MBS on 1 November 2019:

- The three nerve block items identified for amendment (22040, 22045, 22050) were deleted.
- A new item 22041 for single injection nerve block was listed, combining the uses of the deleted items, and expanding the nerves to which the item could be applied.

Further changes were made on 1 March 2022:

- The descriptors for these two Group T7 maintenance items (18222, 18225) with the addition of the words 'continuous' and 'or injection by catheter'.

The possibility to administer nerve blocks with a catheter, although recommended, was not included in the descriptor for MBS item 22041. During implementation of the MBS Review recommendations, it was determined that a continuous block would be a new service as the existing items only covered single injection nerve blocks. This would require a new submission to MSAC.

Application 1183 – Ultrasound imaging in the practice of anaesthesia

Best practice for administration of nerve blocks is to use ultrasound guidance for insertion. Previously, MBS item 55054 had been used to claim this ultrasound use. However, in 2012 the business rules for this item were amended to remove anaesthetists as eligible providers because the cost-effectiveness of this use had not been established. An application for ultrasound imaging in the practice of anaesthesia for patients requiring a central line catheter for venous access or percutaneous neural blockade (Application 1183) was considered by MSAC in November 2014 but was not supported. MSAC noted the use of ultrasound imaging was already best practice in anaesthesia and likely to continue as such, regardless of MBS funding status. Ultrasound guidance for injection or catheter insertion for anaesthesia is therefore not funded on the MBS. This applies to all the nerve block items in Table 3 as well as the item proposed in the current application. Note that ultrasound under item 55054 can still be claimed for administration of a nerve block for Group T7 items.